This report is based on research conducted by the University of Ottawa Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-02-0021). The findings and conclusions in this document are those of the author(s), who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

Evidence Report/Technology Assessment
Number 171

Diagnosis and Treatment of Erectile Dysfunction

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-02-0021

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AHRQ Publication No. 08(09)-E016
May 2009

Suggested Citation:
Tsertsvadze A, Yazdi F, Fink HA, MacDonald R, Wilt TJ, Soares-Weiser K, Bella AJ, Deforge D, Garritty C, Ansari M, Sampson M, Daniel R, Moher D. Diagnosis and Treatment of Erectile Dysfunction. Evidence Report/Technology Assessment No.171 (Prepared by the University of Ottawa Evidence-based Practice Centre (UO-EPC) under Contract No. 290-02-0021). AHRQ Publication No. 08(09)-E016, Rockville, MD: Agency for Healthcare Research and Quality. May 2009.

No investigators have any affiliations or financial involvement (e.g. employment, consultancies, honoraria, stock options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in this report.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The American College of Physicians requested and provided funding for this report. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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Acknowledgments

The authors would like to thank numerous individuals for their support of the present project. Investigators thank Nathalie Lapierre, Gloria Baker, and Dorothey Ann Curran for their assistance with screening articles and helping with data abstraction; David Mackie and Mary Ocampo for helping with the evidence tables and appendices; and Tanya Horsley and Kasey Parker, both of whom helped to coordinate the process. Investigators would also like to thank Anne Marie Todkill, who assisted in the editing of the report.

Structured Abstract

Objectives: To systematically review the evidence on efficacy and harms of pharmaceutical treatments used in the management of male erectile dysfunction (ED); to explore the clinical utility of routine hormonal blood tests (e.g. testosterone, prolactin) for identifying and treating hormonal disorders and thereby affecting therapeutic outcomes for ED.

Data Sources: MEDLINE®, EMBASE, PsycINFO®, SCOPUS™, and Cochrane CENTRAL were searched up to June 2007. Reference lists of relevant studies were also searched.

Review Methods: English language primary studies reporting effects of pharmaceutical treatments used to treat men with ED were eligible for inclusion. The records were screened for relevance, abstracted, and assessed for quality by two reviewers independently. The evidence was summarized qualitatively and the results of randomized controlled trials (RCTs) were pooled using meta-analyses. Subgroup and sensitivity analyses were also conducted.

Results: The evidence needed to ascertain the clinical utility of routine hormonal blood tests was limited in terms of the amount and interpretability. Studies were heterogenous with wide variations in the prevalence of hypogonadism or hyperprolactinemia in patients with ED. Overall phosphodiesterase type 5 (PDE–5) inhibitors were superior to placebo in treating patients with ED with clinically important and statistically significant between-group differences. Adverse events however, were more frequent in PDE–5 inhibitor-treated patients. Few trials demonstrated dose-response trends in the degree of efficacy or frequency of adverse events associated with PDE–5 inhibitors. The clinical benefits conferred by use of PDE–5 inhibitors relative to placebo were observed in patients with wide spectrum of comorbidities irrespective of the origin, duration, or severity of ED. In head-to-head trials evaluating PDE–5 inhibitors, more patients preferred tadalafil to sildenafil or vardenafil. Patients treated with intracavernosal or subcutaneous injections experienced pain and priapism. The evidence for topical, intra-urethral, and hormonal treatments for male ED was insufficient and inconclusive.

Conclusions: Evidence comparing cause-specific therapies (i.e. targeting underlying causes of ED) to symptomatic treatments (e.g. PDE–5 inhibitors, injections, hormonal treatments) for management of ED is lacking. Moreover, long-term effects of ED treatments have not been adequately explored in RCTs. Studies using comparable study populations, diagnostic criteria, and types of tests for hormonal disorders are needed to clarify the clinical utility of routine hormonal blood tests in ED patients. There is also a need for trials comparing PDE–5 inhibitors to other symptomatic treatments for ED (e.g. hormonal treatments, injections, topical applications). This review outlined current gaps in knowledge that need to be addressed in future research.

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Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/erectiledys/erecdys.pdf

Executive Summary

Introduction

Erectile dysfunction (ED) is a complex condition involving psychosocial and biological factors. It is defined as the persistent inability to achieve or maintain penile erection sufficient for satisfactory sexual performance. ED is a common disorder of male sexual function, affecting all age groups with a considerable impact on quality of life.

Oral phosphodiesterase type 5 (PDE–5) inhibitors are the first-line treatment options offered to patients with ED. This systematic review of the recent evidence on clinical benefits and harms associated with different pharmaceutical treatments used in the management of male ED is to clarify uncertainties in the field, as well as to identify existing knowledge gaps and directions for future research.

The University of Ottawa Evidence-based Practice Center (UO–EPC) reviewed and synthesized the published literature on the pharmaceutical treatment of male ED. This review addressed the following key questions (KQ):

KQ 1: *What is the clinical utility of routine blood tests—testosterone, prolactin, luteinizing hormone (LH), follicle stimulating hormone (FSH)—in identifying and affecting therapeutic outcomes for treatable causes of ED?*

KQ 2: *What are the benefits of pharmaceutical treatments for patients with ED? How do patient-specific characteristics (e.g. specific symptoms, age, comorbid conditions) affect prognosis and treatment success for ED patients? Does likelihood of treatment success vary by underlying cause of ED?*

KQ 3: *What are the harms of pharmaceutical treatments for ED? What is the evidence on specific harms such as nonarteritic ischemic optic neuropathy (NAION) and penile fibrosis of pharmaceutical treatments for ED?*

Methods

Literature Search

A comprehensive search was conducted in MEDLINE® (1966–2006), Cochrane CENTRAL (2006–2007), EMBASE (1980–2007), PsycINFO® (1985–2007), and SCOPUS™ (2006). The search was limited to English language reports published in 1990 or later. MEDLINE® (1966–2007) and EMBASE (1980–2007) were searched for reports of visual problems associated with the use of sildenafil, and MEDLINE® (1950–2007) and EMBASE (1980–2007) were searched for reports regarding fibrosis associated with penile injections.

Study Selection

English-language primary studies examining pharmaceutical treatments of ED were eligible for inclusion. Reviews, editorials, commentaries and letters were excluded for all questions except Q3. The reasons for exclusion were noted in the QUOROM flow diagram. Only randomized controlled trials (RCTs) were eligible for evidence on efficacy, whereas non-randomized controlled trials and observational studies were included to examine harms

associated with ED treatments. Two independent reviewers performed full-text screening; discrepancies were resolved by consensus.

Data Extraction and Assessment of Study and Reporting Quality

Two reviewers independently abstracted relevant information from included studies using a data abstraction form. One reviewer completed the primary extraction, which was then verified by a second reviewer. Abstracted data included study, population, and treatment characteristics (type, mode, dose, route of administration); efficacy outcomes such as absolute mean endpoint/change (from baseline) in scores for the International Index of Erectile Function (IIEF) "Erectile Function (EF) domain," Sexual Encounter Profile (SEP) Q–2/3, and the proportion of patients with improved erection measured with Global Assessment Question 1 (GAQ–1)(see Appendix H). We abstracted information on any and most frequently encountered specific adverse events, withdrawals due to adverse events, and serious adverse events. Additionally, for Q1, prevalence rates of hypogonadism and hyperprolactinemia in ED populations were ascertained and abstracted. The Jadad scale and Schulz questionnaire were used to assess the study and reporting quality and the adequacy of allocation concealment in RCTs.

Synthesis of the Evidence

The outcomes for each study were summarized qualitatively. The information pertaining to sample size and demographics, setting, funding source, treatment (dose and duration), comparator characteristics, study quality, and confounders was recorded and summarized in the text and summary tables. The decision to statistically pool results of individual studies was based on clinical and methodological judgement. If relevant numerical data (e.g. arm-specific mean endpoint/change in score, standard deviation, and standard error) were not reported adequately, we attempted to calculate the needed parameters. For dichotomous and continuous effect measures, pooled estimates of relative risk (RR) and weighted mean differences (WMD) with corresponding 95 percent confidence intervals (95 percent CI) were generated using the DerSimonian and Laird random effects model. The degree of statistical heterogeneity was evaluated using a chi-square test and the I^2 statistic.

A series of subgroup analyses was also performed to explore the consistency of the results. Publication bias was assessed by means of funnel plots.

Results

KQ 1: What is the clinical utility of routine blood tests (testosterone, prolactin, LH, FSH) in identifying and affecting therapeutic outcomes for treatable causes of ED?

The prevalence of hypogonadism varied widely across the studies (12.5 to 25.32 percent). This variation reflected differences in diagnostic criteria for hypogonadism, testosterone measurement methods (e.g. serum total, bioavailable or free levels) and concurrent conditions present across the studies. The prevalence of hypogonadism was higher in men $\geq$ 50 years versus men < 50 years of age. The results of several studies indicated that ED patients with decreased libido, testicular damage/abnormality, arterial disease, obesity, hyperlipidemia, diabetes, or hypothalamic abnormalities were more likely to have hypogonadism than those presenting without these factors.

The prevalence of hyperprolactinemia varied from 1.42 to 14.3 percent. One Egyptian study in elderly and obese men reported a prevalence of 32 percent. In one of the 9 studies reporting abnormal levels of LH/FSH, about 44 percent of the hypogonadal men had low LH/FSH levels (<13 IU/mL). The prevalence of high LH/FSH levels across three studies varied from 1.03 to 5.79 percent.

KQ 2: What are the benefits of pharmaceutical treatments for patients with ED?

How do patient-specific characteristics (e.g. specific symptoms, comorbid conditions) affect prognosis/treatment success for ED patients?

Does likelihood of treatment success vary by underlying cause of ED?

In total, 126 RCTs evaluating clinical benefits and harms of oral PDE–5 inhibitors (i.e., sildenafil, tadalafil, and vardenafil) in ED patients were included in the review. Patients receiving PDE–5 inhibitors (regardless of dose/dosing regimen) experienced statistically significant and clinically relevant improvements in erectile functioning (mean total IIEF–"EF domain" and IIEF–Q3/Q4 scores, mean SEP–Q2/Q3 scores, improved erection measured by GAQ–Q1) and satisfaction (mean total IIEF-"Intercourse Satisfaction" and "Overall Satisfaction" domains, Erectile Dysfunction Index of Treatment Satisfaction scores) compared with those receiving placebo. The meta-analyses indicated that the use of sildenafil was associated with statistically significant improvements in penile penetration (IIEF-Q3 mean difference: 1.46, 95 percent CI: 1.26–1.65) and improved erection (RR = 2.61, 95 percent CI: 2.34–2.91) compared with placebo. The clinical benefit associated with the use of PDE–5 inhibitors relative to placebo was also observed in clinically distinct subgroups of patients (e.g. diabetes, depression, prostate cancer).

Patients with mild or moderate ED at baseline (IIEF score 11–25) achieved higher mean IIEF–"EF domain" or IIEF–Q3/Q4 scores compared with those with severe ED. The mean scores for IIEF and SEP, improvement in erection, and mean duration of penile rigidity (>60 percent) tended to increase with higher doses of sildenafil (25 mg versus 50 mg versus 100 mg) and vardenafil (5 mg versus 10 mg versus 20 mg).

Results from four head-to-head trials comparing sildenafil, vardenafil, and tadalafil for improvements in erectile function were inconclusive. The between-arm differences in the mean IIEF-EF scores were either statistically non-significant or significant but of small magnitude. In all 4 trials, higher proportion of patients preferred tadalafil to sildenafil or vardenafil. The mean time (in hours) between dosing and sexual attempt was longer for tadalafil compared with sildenafil (5.6 versus 2.7, $p < 0.001$) and a greater proportion of tadalafil-treated men had one or more successful intercourse attempt 12 or more hours post-dose versus sildenafil-treated men (55 versus 29 percent, $p < 0.001$).

The administration of intracavernosal injections (ICI) of alprostadil improved erections more often than no treatment, placebo, papaverine, or phentolamine alone, and at least as often as trimix (prostaglandin E_1 plus papaverine plus phentolamine). In three trials, the use of intraurethral suppositories containing alprostadil was shown to be more effective than placebo.

There were 18 RCTs evaluating the efficacy of hormonal treatment with testosterone (in oral, injection, gel, patch, and cream forms) predominantly in hypogonadal patients with or without

ED as a main complaint. In only one of four small trials, the intramuscular injection of testosterone improved erectile function compared with placebo. Gel testosterone (50 mg and 100 mg doses) was found to have increased sexual intercourse frequency compared with placebo or patch testosterone.

Two RCTs compared testosterone treatment (alone or combined) with PDE–5 inhibitors in hypogonadal patients with ED that was refractory to prior sildenafil therapy (this was also relevant to Question 1). In both trials, patients treated with the combination of testosterone (either patch 5 mg/d or gel 1 percent) and 100 mg sildenafil had statistically significantly greater IIEF scores compared with those treated with sildenafil alone (endpoint: 21.8 versus 14.4, $p < 0.05$ and mean change: 4.4 versus 2.1, $p = 0.029$).

KQ 3. What are the harms of pharmaceutical treatments for patients with ED?

What is the evidence on specific harms such as nonarteritic ischemic optic neuropathy (NAION) and penile fibrosis related to pharmaceutical treatments in patients with ED?

All-cause adverse events were more frequent in patients treated with PDE–5 inhibitors compared with those treated with placebo. In particular, meta-analyses demonstrated that patients receiving sildenafil (any dose) were at higher risk of any adverse (RR = 1.51, 95 percent CI: 1.32–1.72). The 12-week use of 20 mg tadalafil was also associated with an increased risk of any adverse events (RR = 1.61, 95 percent CI: 1.37–1.89). The most common adverse events in PDE–5 inhibitor-treated patients were headache, flushing, dyspepsia, and rhinitis. The use of both sildenafil and vardenafil was associated with an increased risk of headache, dyspepsia, or flushing compared with placebo. Patients treated with sildenafil had an increased risk of visual disturbances (RR = 3.66, 95 percent CI: 2.27–5.92).

Serious adverse events were not statistically different between PDE–5 inhibitor and placebo groups. For example, patients treated with vardenafil experienced a statistically non-significant 34 percent increase in risk of serious adverse events (RR = 1.34, 95 percent CI: 0.76–2.36). Although the rate of withdrawals due to adverse events was slightly increased in patients receiving vardenafil versus those on placebo, the pooled RR estimate did not reach the level of statistical significance (RR = 1.29, 95 percent CI: 0.78–2.13).

The incidence of adverse events increased with the dose of PDE–5 inhibitors. Meta-analyses demonstrated a statistically significant increase in the risk of any adverse events between patients receiving 20 mg versus 10 mg of either tadalafil (RR = 1.21, 95 percent CI: 1.05–1.38) or vardenafil (RR = 1.15, 95 percent CI: 1.06–1.25). The pooled RR estimates for specific events in sildenafil treated patients were: flushing (50 mg versus 25 mg; RR = 1.65, 95 percent CI: 1.13-2.42), headache (100 mg versus 50 mg; RR = 1.31, 95 percent CI: 0.93-1.84), and visual disturbances (100 mg versus 50 mg; RR = 4.18, 95 percent CI: 0.44-39.54). The differences in the incidence of any adverse events between treatment and placebo groups did not vary significantly among four head-to-head trials with patients treated with sildenafil, tadalafil, or vardenafil.

Penile pain or priapism was more frequent in patients treated with alprostadil injections compared with those who received placebo. Patients who received a testosterone patch had a higher rate of skin reactions at the application site compared with those who received the placebo. One trial reported prostate cancer in two patients treated with a testosterone patch. The use of gel testosterone did not show a dose-related increase in adverse events.

To ascertain the incidence of NAION in subjects using PDE-5 inhibitors, this review identified 19 case reports and one large retrospective cohort study of U.S. veterans aged 50 years or older. In almost all case reports, the minimum dose of sildenafil was 50 mg. The risk of NAION in veterans prescribed PDE-5 inhibitors for 2 years was not increased compared with those who were not prescribed PDE-5 inhibitors (RR = 1.02, 95 percent CI: 0.92–1.12). The long-term data on fibrosis amongst penile injection users (e.g. PGE_1, papaverine, and/or phentolamine) was obtained from 13 reports of non-randomized controlled trials and 7 retrospective cohort studies. In these studies, the proportion of patients with fibrosis amongst those receiving PGE_1 injections for at least one year, ranged from 4.4 to 23.3 percent. Clinical diversity (i.e., populations, intervention dose/duration/frequency, injection type, duration of followup), scarce data, confounding, and lack of appropriate comparator precluded a meaningful between-group comparison of the incidence of fibrosis.

Discussion and Future Research

The utility of routine endocrinological blood tests to identify treatable causes of ED and to improve therapeutic outcomes was unclear due to study heterogeneity. Prevalence of endocrinopathies, patient characteristics, diagnostic criteria, age distribution, laboratory methods (cut-off values, total, free, bioavailable hormonal levels), and/or study methodology varied widely. Factors such as obesity, decreased libido, testicular damage/abnormality, arterial disease, and/or insulin resistance may be predictive of hypogonadism in patients with ED. Studies to measure the prevalence of endocrinopathies and RCTs comparing the efficacy of testosterone relative to PDE–5 inhibitors would further clarify the clinical utility and cost-effectiveness of routine blood tests. The standardization of blood tests would facilitate this process. Furthermore, determination of subgroups (or risk factors) of ED patients with increased risk of hypogonadism is warranted. Additionally, clinicians would need to direct their efforts towards correctly identifying and treating underlying causes of ED, including hormonal disorders.

The efficacy of PDE–5 inhibitors was evaluated using clinically relevant and validated outcome measures. These measures are based on patient responses, and therefore are subjective in nature. Patients preferred tadalafil over sildenafil or vardenafil in four head-to-head trials in part due to the longer duration of the action of tadalafil compared with the other two agents. The evidence regarding the incidence of serious adverse events is not conclusive for several reasons, including poor reporting practices and the use of different definitions of serious adverse events. Some reports indicated only the most frequently encountered or treatment-related adverse events, the ascertainment of which may be prone to subjective judgment. In open label trials, patients or investigators may have over- or underreported the incidence of adverse events because of their knowledge of the assigned treatment. Moreover disease-specific complications in patients with comorbidities or disorders known to cause ED could have been overlooked. The exclusion criteria reported for many PDE-5 inhibitor trials mean that results may not be readily applicable to patients diagnosed with major chronic disorders (e.g. cancer, CVD, diabetes, psychiatric disorders, or hepatic or renal diseases) or those who had undergone surgery (e.g. prostatectomy).

The comparative evidence for the efficacy and harms associated with subcutaneous injections, sublingual, topical treatments, or intra-urethral suppositories was limited and inconsistent. One common limitation of the trials evaluating these therapies was that clinically relevant efficacy outcomes were not reported. Differences in patient inclusion criteria (e.g. not all trials were comprised exclusively of ED patients), methods of evaluation, interventions (e.g.

different formulations/modes of application), or outcome definitions could explain some of the discrepancies in results across the studies evaluating the efficacy of testosterone.

Future efforts are needed to improve the quality of reporting of primary studies. In the presence of comorbidities or causes underlying ED, the comparison of cause-specific therapies (i.e. targeting underlying causes of ED) to symptomatic treatments (e.g. PDE–5 inhibitors, injections, hormonal treatments) in terms of efficacy and safety profiles is warranted. New, well-designed trials are warranted to examine long-term clinically relevant treatment outcomes (6 months or longer) in both broadly defined and clinically homogeneous subgroups of ED patients. There is also a need for head-to-head trials to compare various PDE–5 inhibitors with one another as well as trials comparing PDE–5 inhibitors with other symptomatic treatments for ED (e.g. oral, injected, and topical treatments).

Viewed in perspective, this report represents a striking example of a situation that reviewers of medical effectiveness research encounter often: a field of information in which one corner is intensively cultivated and other areas lie fallow. Erectile dysfunction can be treated at present by two main classes of drugs, phosphodiesterase type-5 inhibitors and/or androgens. This review finds a dearth of credible evaluations of androgens as treatment for ED – clarifying neither short-term effectiveness nor long-term outcomes (positive or negative). In light of the growing popularity of androgen supplementation for a variety of indications in aging men, and in the context of complicated and controversial findings of the far more extensive studies of hormone replacement therapy in women, this gap in our research base is especially noteworthy. For PDE-5 inhibitors, in contrast, an impressive amount of clinical trial evidence is available, demonstrating that these drugs do have a real effect. The impetus for much of this research arose from the desire to get PDE-5 inhibitors approved by the FDA. For instance, nearly three-quarters of the PDE-5 inhibitor trials in this review were funded by pharmaceutical companies.

Even for the PDE-5 inhibitors, important aspects remain inadequately explored. The effects observed in the controlled trials mostly denote differences of small magnitude in self-reported subjective judgments of function on a standardized questionnaire (e.g., the difference between “a few times” and “sometimes,” or between “sometimes” and “most times”). Because of the randomization and the large number of subjects, the evidence is convincing that there is some therapeutic effect; the extent to which these “real” effects are great enough to be clinically meaningful is not as clear, and that is a separate question which this review does not address. Moreover, although short-term side-effects of the PDE-5 inhibitors have been investigated (as the FDA requires), very few studies have tried to investigate long-term side-effects or long-term outcomes - such as persistence or attenuation of effectiveness with continued use.

In summary, while research pertaining to short-term effects of the PGE-5 inhibitors is abundant, comparable studies on androgens and information on long-term treatment outcomes for either class are sparse. The skewed concentration of research on the effectiveness of treatments for ED reflects the short-term focus of the new-drug approval process. The value of information might be enhanced by new sources of financial support for research and/or a change in regulatory requirements that would encourage broader comparisons and a longer time horizon.

Conclusions

The evidence comparing cause-specific therapies with symptomatic treatments (e.g. PDE–5 inhibitors, injections, and hormonal treatments) for management of ED is lacking. Due to the complexity of causative and comorbid factors, more studies are needed to clarify the best treatment management options for various subgroups of patients with ED (e.g. endocrinopathies,

concurrent clinical conditions). There is also a need for trials comparing PDE–5 inhibitors with other treatments for ED (e.g. oral, injected and topical). Long-term effects of ED treatments in RCTs have not been adequately explored. To clarify and determine the clinical utility of routine hormonal blood tests in ED patients, studies are needed in representative populations, with comparable diagnostic criteria and types of tests for hormonal disorders.

Evidence Report

Chapter 1. Introduction

Objectives of the Systematic Review

The purpose of this evidence report was to review systematically the literature on the diagnosis and pharmaceutical treatments of erectile dysfunction (ED) and to address the following objectives put forth by the Agency for Healthcare Research and Quality (AHRQ) and the American College of Physicians (ACP).

The primary objectives of this evidence report were:

KQ 1. To determine the clinical utility of routine blood tests - testosterone, prolactin, luteinizing hormone (LH), follicle stimulating hormone (FSH) - in identifying and affecting therapeutic outcomes for treatable causes of ED.

KQ 2. To determine the benefits of pharmaceutical treatments for patients with ED.

KQ 3. To determine the harms of pharmaceutical treatments for patients with ED.

The secondary objectives of this evidence report were:

KQ 2a. To explore how patient-specific characteristics (e.g. specific symptoms, age, comorbid conditions) may affect prognosis and treatment success for ED patients.

KQ 2b. To determine if the likelihood of treatment success varies by underlying cause of ED.

KQ 3a. To identify specific harms, such as nonarteritic ischemic optic neuropathy (NAION) and penile fibrosis of pharmaceutical treatments in patients with ED.

The findings of this report are intended to assist the AHRQ and the ACP in identifying areas for future research and in the development of practical information for healthcare providers and consumers.

Background

Definition of Erectile Dysfunction

Erectile dysfunction (ED) is defined as the persistent inability to achieve or maintain penile erection sufficient for satisfactory sexual performance.[1] The 1992 National Institutes of Health (NIH) Consensus Development Conference recommended the use of *erectile dysfunction* as the preferred term to *impotence*, the former being more precise.[1] There is no universal consensus or agreed criteria as to how consistent the problem (i.e., inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance) has to be and for what duration it should last to fulfill this definition. A period of persistence over 3 months has been suggested as a reasonable clinical guideline.[1,2]

Physiology of Erection

Penile erection is a complex process involving interactions between neural, psychological, vascular, and hormonal factors. The pathway of normal sexual function in males consists of four stages: sexual desire (i.e., libido), erection, ejaculation (i.e., orgasm), and detumescence (penile flaccidity).[3] The erection cycle is initiated by sexual stimulation. Erection subsides at ejaculation or cessation of sexual stimulation and the subsequent flaccidity state is maintained until the next sexual stimulation or nocturnal erection occurs. Thus, both the erection and the flaccidity states of the penis exist in two phases, initiation and maintenance. Pathways responsible for penile

flaccidity are no less important than pro-erectile mechanisms, and may play critical roles in certain types of erectile dysfunction (ED).[4] Additionally, hormones function not only at the libido level, but help maintain anatomical and physiological integrity of penile cavernosal structures; testosterone deficiency interferes not only with normal function, but can also diminish response to ED treatment.[5]

The mechanism of erection involves responses to external sensory stimuli through parasympathetic activity, which leads to release of nitric oxide (NO) from nonadrenergic-noncholinergic (NANC) cavernous (penile) nerve endings and the endothelium of the penis. The initial phase of smooth muscle relaxation results in reduced peripheral resistance of cavernosal arterioles and thereby allows blood to flow into the penis under the driving force of systemic blood pressure.[4] Once blood rushes into the sinusoids of the corpora cavernosa, shear stress can also release NO from endothelium to augment smooth muscle relaxation and erection. In addition, oxygen tension and substances secreted by endothelium lining the sinusoidal spaces, (i.e. prostaglandins, endothelins, and angiotensin) may also be involved in penile erection and detumescence.[6,7]

The somatic sensory nerves originate at receptors in the penis to transmit pain, temperature, touch, and vibratory sensations, and the brain modulates the spinal pathways of erection via the medial preoptic area and paraventricular nucleus of the hypothalamus, periaqueductal gray of the midbrain, and the nucleus paragigantocellularis of the medulla.[3] During sexual stimulation, NO released from the penile cavernosal nerve endings and endothelium, diffuses into the trabecular and arterial smooth muscle cells to activate guanylyl cyclase, thereby catalyzing the formation of second messenger cyclic guanosine monophasphate (cGMP). The cGMP in turn activates protein kinase G, phosphorylating potassium and calcium channels; the end result is hyperpolarization, reduced intracytosolic calcium, and dissociation of the myosin head from acting as smooth muscle relaxes. Cyclic adenosine monophosphate (cAMP) is another second messenger involved in smooth muscle relaxation and is activated by cAMP-signaling molecules including adenosine, calcitonin gene-related peptides, and prostaglandins.[4]

On the other hand, norepinephrine, phenylephrine, and endothelin appear to activate phospholipase C, leading to the formation of inositol triphosphate and diacylglycerol. The net result is increased cytoplasmic calcium and subsequent smooth-muscle contraction. Detumescence occurs following degradation of cGMP and cAMP to GMP and AMP, respectively, by specific phosphodiesterases. Sympathetic discharge occurs if sexual stimulation results in ejaculation.[8,9] Activated Rho-kinase phosphorylates, inhibits the regulatory subunit of smooth muscle myosin phosphatase, preventing dephosphorylation of myofilaments and maintaining contractile tone.[10] In the flaccid state, these smooth muscles are tonically contracted due to intrinsic smooth-muscle tone, adrenergic discharge, and other signaling molecules such as endothelin.[4]

Diagnosis of Erectile Dysfunction

The diagnosis of ED involves a clinical evaluation including medical/physical examination as well as documentation of sexual and psychosocial history.[11,12] Erectile dysfunction is one of many symptoms of sexual disorders including premature ejaculation, increased latency time associated with age, psycho-sexual relationship problems, and loss of libido. During diagnosis of ED, it is important that other sexual dysfunctions (e.g. loss of libido) be recognized and taken into account.[13,14] A few validated instruments are used in diagnosing ED, grading its severity,

and assessing treatment satisfaction. Some examples of such instruments are the International Index of Erectile Function (IIEF),[15] the modified 5-item version of IIEF (IIEF–5),[16] and the Erectile Dysfunction Index of Treatment Satisfaction (EDITS).[17] The IIEF is a self-administered 15-item questionnaire consisting of five distinct domains: erectile function (total score range 1–30), orgasmic function (total score range 0–10), sexual desire (total score range 2–10), intercourse satisfaction (total score range 0–15), and overall satisfaction (total score range 2–10).[18]

Recommendations based on biochemical investigation may consist of hormonal screening to detect hypogonadism or other underlying common diseases such as hyperprolactinemia, diabetes and dyslipidemia.[19,20] Other methods that may be used are urine analysis, blood count, lipid levels, or prostate-specific antigen (PSA) concentration.[1] There are also specialized evaluation techniques such as duplex ultrasonography, penile tumescence studies, RigiScan, test injections, audio-visual stimulation and penile brachial index measurement.[21]

Epidemiology of Erectile Dysfunction

ED is a common disorder of male sexual function that affects all age groups and has a profound impact on quality of life.[2] Given the increasing trends in life expectancy across the Western world (i.e., the aging of the general population) and the high prevalence of diabetes and cardiovascular disease, the impact on lifestyle and quality of life imposed by ED in men is projected to be substantial.[1] It was estimated that, in 1995, over 152 million men worldwide experienced ED. For 2025, the prevalence of ED is predicted to be approximately 322 million worldwide.[22] The severity, prevalence and incidence of ED increase with age.[2,22,23] The Massachusetts Male Aging Study[2] surveyed 1,709 men aged 40–70 years between 1987 and 1989, using a self-administered questionnaire that asked participants to rate themselves as not having ED, or having minimal ED, moderate ED, or complete ED. There was a total prevalence of erectile dysfunction of 52 percent when participants with minimal (17.2 percent), moderate (25.2 percent) and complete (9.6 percent) dysfunction were combined.[2] Both the prevalence and severity of erectile dysfunction increased proportionally with age. When adjusted for age, patients with lower level of education, heart disease, hypertension, and diabetes had a higher probability of ED.[2,23] In the same study, a sample of 847 men without ED at baseline (1987–1989) was followed prospectively until 1995–1997.[23] The crude incidence rate of ED in this population was estimated to be about 26 cases per 1,000 man-years (95% CI: 22.5–29.9). The annual age-specific incidence rate of ED increased with each decade of age. For example, the incidence rates (and 95% CIs) for men in two age groups of 50–59 and 60–69 years were 29.8 cases per 1,000 man-years (95% CI: 24.0–37.0) and 46.4 cases per 1,000 man-years (95% CI: 36.9–58.4), respectively.[23] In a Canadian cross-sectional survey of primary care facilities, about 50 percent of 3,921 men aged 40–88 years had ED (IIEF "EF" domain score <21).[24] The presence of cardiovascular diseases or diabetes was associated with an increased risk of having ED after adjustment for age and other confounders.[24]

Classification of Erectile Dysfunction and Related Conditions

Today, ED is considered a disorder with multiple causes. The current evidence suggests that about 80 percent of ED cases are of organic origin.[1] Organic causes of ED may be vascular (e.g. cardiovascular disease, hypertension, lipid disorders, endothelial dysfunction), neurological (e.g. spinal cord injury, Parkinson's disease, multiple sclerosis), iatrogenic (e.g. pelvic surgery,

prostatectomy, antipsychotic agents, antidepressants, beta-blockers, diuretics, antitestosterone hormonal agents), penile injury/anatomic abnormalities (e.g. Peyronie's disease, priapism), tumors (e.g. prostate cancer, colorectal cancer), various conditions (chronic renal or hepatic failure, lower urinary tract symptoms, prostatic hyperplasia), substance use and abuse (e.g. alcohol, tobacco) or endocrine disorders (e.g. diabetes, andropause, hypogonadism, hyperprolactinemia, hypothyroidism). Some of the psychogenic causes of ED may be depression, dysphoria, or anxiety states.[1] The majority of ED patients with organic causes present with vascular diseases and have decreased blood flow to the penis.[2,21,25] In many patients the cause of ED may be a combination of psychological and organic factors.[26]

Treatment of Erectile Dysfunction

Today, unless contraindicated, the first-line therapies offered for the treatment of ED are lifestyle and risk factor modification (e.g. exercise and weight loss)[27] and the use of the oral phosphodiesterase type 5 (PDE–5) inhibitors such as sildenafil, tadalafil, or vardenafil.[13,28] Given that PDE–5 drugs may interact with nitrates with respect to vasodilatory effect, all PDE–5 drugs are contraindicated in patients taking nitrates for cardiac disease. The introduction, availability, and production of PDE–5 inhibitors have revolutionized the management of ED, allowing physicians to treat the condition in the primary care setting.

Although other types of medical treatments (e.g. intracavernosal injections, intraurethral suppositories) for erectile dysfunction have existed for years, their use has been associated with specific adverse events (e.g. local pain, priapism, fibrosis) and low compliance rates resulting from the invasive nature of these therapies. Topical therapies of agents that are approved by FDA for other indications have been explored as alternative options given their less invasive routes of administration (e.g. alprostadil, papaverine, organic nitrates). Other second-line treatment modalities for patients with refractory ED or who cannot tolerate PDE–5 therapy are hormonal treatments, vacuum constriction devices and surgical therapies (e.g. penile prosthesis implants, penile arterial bypass).[14] Psychological counseling (e.g. psychotherapy) and recommended lifestyle modifications (e.g. smoking cessation, low-fat diet, physical activity, weight loss) should be offered to men with ED either alone or in combination with other treatments.

Utilization and Costs Related to Treatment of ED

Estimates from the National Health and Nutrition Examination Survey (NHANES) suggests that the cost of treatment of ED in the U.S. could reach $15 billion if all men sought care.[29] Analyses by the Erectile Dysfunction subgroup for the Urologic Diseases in America Project identified that almost 1.5 percent of privately insured males between the ages of 18 and 64 had at least 1 claim related to ED in 2002; shifting forms of health care were demonstrated, as the use of diagnostic tests for underlying causes of ED markedly decreased and utilization of pharmacological therapy especially with oral PDE-5 inhibitors, increased.[29]
National pharmacy claims data indicated an increased prevalence of sildenafil use from 1.5 percent in 1998 to 2.9 percent in 2002, with its use increasing with age. For example, in 2002, 6 percent of men aged 55 or older had one or more claims for sildenafil.[30] Furthermore, the Department of Veteran Affairs (VA) indicated a nine-fold increase in treatment for ED between 1999 and 2003, with 9.3 percent of men 55-64 years of age reporting filling a prescription for oral agents in 2003.[29] The overall use of pharmacological treatment for ED increased from 17,458/100,000 in 1999 to 56,716/100,000 in 2003.[29] This is reflected by data from the VA

Pharmacy Benefits Management Group, as prescriptions for specific ED drugs increased from 681/100,000 to 6,120/100,000 during this period.[29] According to national sales, in 2005, the pharmaceutical costs of sildenafil, tadalafil, and vardenafil were $1.6 billion, $747 million, and $327 million, respectively.[31-33]

Harms Observed in Clinical Trials

Headache, flushing, rhinitis, and dyspepsia are the most commonly observed adverse events related to treatment with PDE–5 drugs. There also have been concerns regarding the excess incidence of cardiovascular events and visual disturbances occurring in patients receiving PDE–5 drugs; however, the current evidence does not indicate any marked trends for increased rates of these events in ED patients taking PDE–5 drugs compared with those in the general population.[13,34]

Measures of Efficacy in Erectile Dysfunction Therapy

From the patient's perspective, the most important measures for defining successful ED treatment are: "cure, pleasure, partner satisfaction, reproduction, and naturalness."[35] To address the lack of well-defined standardized guidelines for the assessment of clinical outcomes in comparative trials of ED therapies, an International Consensus Advisory Panel was convened in 2002 in Montréal, Canada, where a new conceptual framework for treatment effectiveness was adopted.[36]

According to this framework, treatment effectiveness consists of two dimensions: *treatment response* and *treatment satisfaction.* Treatment response, in turn, consists of an integrated assessment of efficacy (i.e., ability of an agent to promote achievement and maintenance of adequate erection) and tolerability (i.e., side effects). The response was categorized as *complete responder* (e.g. consistent achievement and maintenance of full erection and ability to tolerate side effects), *partial responder (*e.g. ability to achieve full erection but not on a consistent basis over time and/or patients who experienced adequate efficacy but also had bothersome side effects of treatment), or *nonresponder* (e.g. patients who failed to respond in a clinically significant manner to the treatment and/or those who experienced intolerable effects at any dosage). Generally, the treatment efficacy in ED trials is assessed using event-log or diary-based questionnaires such as the IIEF and IIEF–5, the sexual encounter profile (SEP), and global assessment questions (GAQs).[36] These measures are all based on patient responses and therefore are subjective in nature.[18] The other domain of treatment effectiveness—*treatment satisfaction*—is defined as the degree to which the effects of any particular treatment correspond or exceed the expectations of a patient and his partner.[36] This domain was categorized as *complete satisfaction* (e.g. both the patient and his partner were satisfied), *partial satisfaction* (e.g. either the patient or the partner was not satisfied), and *no satisfaction* (neither the patient nor the partner was satisfied). In summary, according to this framework, the overall measure of treatment effectiveness should ideally integrate the information on both treatment response (i.e., efficacy and tolerability) and treatment satisfaction (i.e., self-rated degree of patient-partner satisfaction).

Knowledge Gaps and Uncertainties

Currently there are several knowledge gaps in the management of ED. There is still insufficient information regarding the effectiveness and safety related to the use of different treatment modalities in various clinical subgroups of patients (e.g. diabetes, cardiovascular

disease). Furthermore, there is insufficient data with regard to long-term adverse effects of oral ED medications that have been used by millions of users for over a decade. Comparative data on the efficacy and safety profiles of PDE–5 drugs have not yet been accumulated. Safety and efficacy data from trials with head-to-head comparisons of PDE–5 drugs are needed to establish the relative superiority of one drug over the others.

Some controversy has surrounded the issue of the clinical utility of and indications for routine endocrinological blood tests (e.g. testosterone, prolactin) for all patients presenting with ED.[19,20,37,38] Current American Urological Association Practice Guidelines Committee (AUA PGC) recommend the determination of hormone levels based on initial clinical assessment or failure of initial PDE–5 management; these tests are not mandatory for all patients.[14] This is in contrast to the guidelines of the European Urological Association and the British Society for Sexual Medicine, both of which define endocrinological “screening” as a mandatory component of the initial evaluation of ED.[39] The purpose of this testing is to identify and treat endocrinopathies such as hypogonadism and hyperprolactinemia as underlying causes of ED. In these cases, therapeutic outcomes for hormonal disorders and resultant ED are thought to be optimized.[20,40] The debate regarding the optimal approach still continues. One group of experts recommends basic endocrine screening to measure serum levels of testosterone and prolactin, to guide treatment of the patients with testosterone and its analogs to correct specific endocrinopathies and symptoms of ED,[41-43] as well as to detect pituitary tumors.[38,44] Other experts do not recommend the administration of routine hormone tests to all ED patients because of the high cost of these tests and the low prevalence of endocrinopathies in the ED population.[20,37,45] These authors suggested that the screening tests for serum hormonal levels be restricted to those patients with clinical signs of hypogonadism (e.g. decreased libido, small testes, reduced body hair) as revealed by a physical examination, or to those in whom the initial PDE–5 inhibitor therapy was ineffective.[20,38,45] Authors of one empirical study advocated routine determination of serum testosterone levels for all ED patients older than 50 years and serum prolactin levels for only those with low testosterone levels (<4ng/mL), decreased libido, and/or gynecomastia.[38]. Clearly, a universally accepted guideline of “standard of practice” for endocrinological testing of the ED patient is yet to be defined and established.

Chapter 2. Methods

Key Questions Addressed in This Report

The UO–EPC's evidence report on the diagnosis and treatment of erectile dysfunction (ED) is based on a systematic review of the scientific literature. A technical expert panel was recruited to help refine key questions and provide expertise to the review team during the review process.

The finalized key questions were:

KQ 1. To determine the clinical utility of routine blood tests - testosterone, prolactin, luteinizing hormone (LH), or follicle-stimulating hormone (FSH) - in identifying and treating specific hormonal causes of ED.

KQ 2. To determine the benefits of pharmaceutical treatments for patients with ED.

KQ 3. To determine the harms of pharmaceutical treatments for patients with ED.

The secondary objectives of this evidence report were:

KQ 2–a. To explore how patient-specific characteristics (e.g. specific symptoms/age/comorbid conditions) may affect prognosis and treatment success for ED patients.

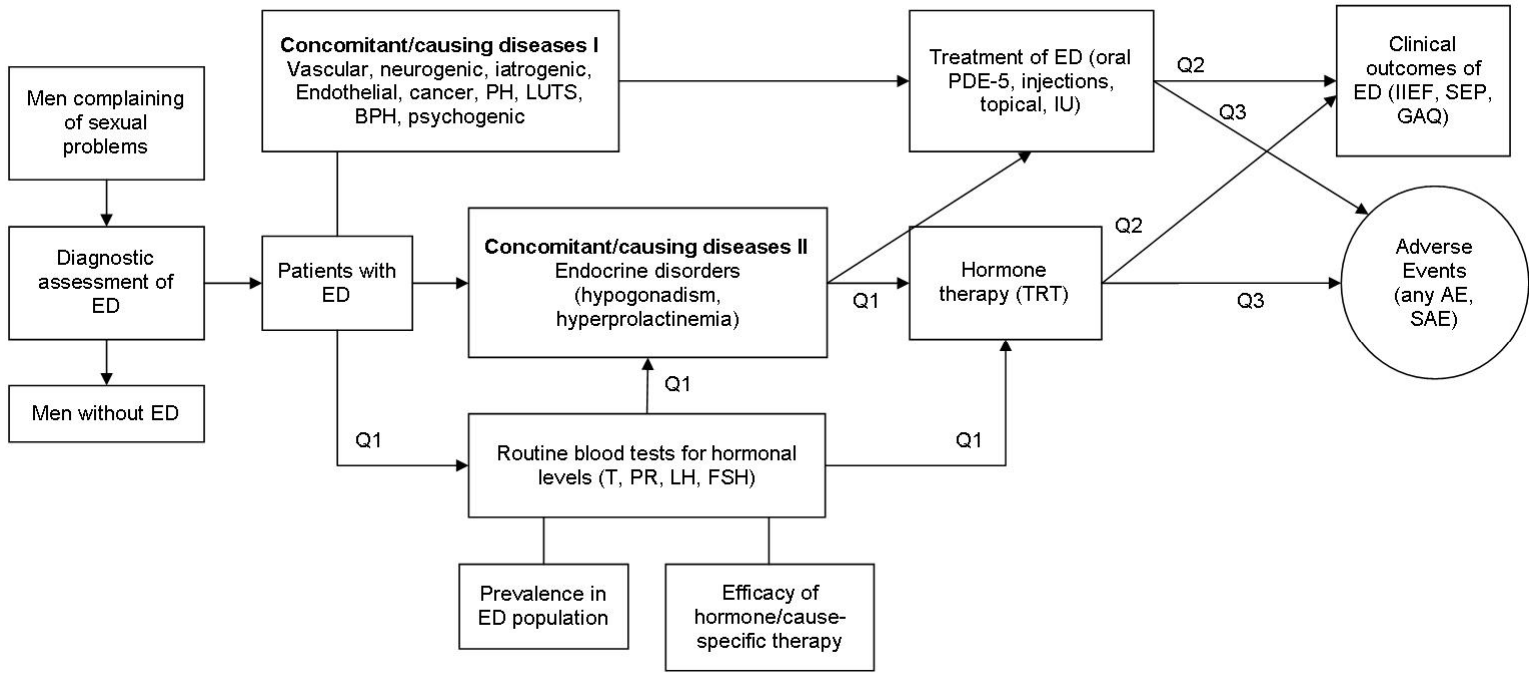
KQ 2–b. To determine if the likelihood of treatment success varies by underlying cause of ED.

KQ 3–a. To identify specific harms—nonarteritic ischemic optic neuropathy (NAION), penile fibrosis—of pharmaceutical treatments in patients with ED.

Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/erectiledys/erecdys.pdf

Analytic Framework

Figure 1. Analytic Framework for the Diagnosis and Treatment of Erectile Dysfunction



Endocrine disorders
Hypogonadism
Hyperprolactinemia
Adrenal glands disease
Diabetes

Vascular disorders
Congestive heart failure
Coronary artery disease
Cerebrovascular disease
Hypertension

Neurogenic
Spinal cord injury
Parkinson's disease
Psychogenic
Depression

Iatrogenic
Prostatectomy
Benign prostatic hyperplasia
Prostate cancer

Search Strategy

A preliminary MEDLINE® (1966–January Week 3 2006) search identified systematic reviews and guidelines in erectile dysfunction published between 1990 and 2006. Searches for diagnostic and efficacy studies were undertaken in the following databases: MEDLINE® (1966–July Week 3 2006, updated to May Week 5 2007); EMBASE (1980–2006 Week 29, updated to 2007 Week 2); Cochrane CENTRAL (1st Quarter 2006 and 2nd Quarter 2007); PsycINFO® (1985–January 2006, updated to June Week 1 2007); AMED (1985–January 2006, updated to June 2007); and Scopus Feb 8 2006. All databases were searched for efficacy; MEDLINE® and EMBASE were searched for diagnostic studies. The searches were limited to English publications from 1990 and later. MEDLINE® (1966–August Week 5 2006, updated to May Week 5 2007) and EMBASE (1980–2007 Week 8, updated to 2007 Week 22) were searched for reports of visual problems and sleep apnea associated with the use of sildenafil. MEDLINE® (1950–September Week 1 2007) and EMBASE (1980–2007 Week 37) were searched for reports regarding fibrosis associated with penile injections. Search strategies are presented in Appendix A.

Study Eligibility Criteria and Selection Process

KQ 1. The clinical utility of routine blood tests—testosterone, prolactin, LH, FSH - in identifying and affecting therapeutic outcomes for treatable causes of ED was examined using reports of measurements of serum testosterone, FSH, LH, prolactin, and/or other hormone levels, (but not gonadotrophin-releasing hormone [GnRH], Inhibin, Activin, or Follistim). It was also examined in reports of the prevalence of reversible hormonal disorders in males with erectile dysfunction. The study selection criteria included the following:

Source: Primary study report published in English

Study design: Any (prevalence studies)

Population: Adults (age ≥ 18 years) diagnosed with ED with or without concurrent endocrinopathy (i.e., hypogonadism, hyperprolactinemia, abnormal levels of LH/FSH)

Intervention (experimental): Hormonal blood tests (i.e., testosterone/prolactin/LH/FSH)

Outcomes: Prevalence of endocrinopathies (i.e., hypogonadism, hyperprolactinemia, abnormal levels of LH/FSH)

KQ 2. Benefits of pharmaceutical treatments (e.g. oral, injections, hormonal, topical, intra-urethral suppositories) in males with ED. To address how patient specific characteristics (e.g. specific symptoms/origin, duration, severity of ED/comorbid conditions) affect prognosis/treatment success for ED patients. Evidence on the following treatment modalities was excluded from this review: Natural health products (e.g. herbals), yohimbine, vacuum constriction devices, and sex or surgical therapies (e.g. penile prosthesis implantation, penile arterial reconstructive surgery). Study selection criteria included the following:

Source: Primary study report published in English

Study design: RCTs (comparative efficacy and harms studies)

Population: Adults (age => 18 years) diagnosed with ED (with or without comorbidities)

Interventions (experimental/control): Oral (PDE–5 inhibitors, sublingual) injections (IC, cream)

Outcomes: Clinically relevant efficacy measures (i.e., scores for the IIEF "EF" domain, IIEF–Q3/Q4, SEP-Q2/Q3, GAQ-Q1, EDITS)

KQ 3. Harms of pharmaceutical treatments (e.g. oral, injections, hormonal, topical, intra-urethral suppositories) in males with ED. Evidence on the following treatment modalities was excluded from this review: Natural health products (e.g. herbals), yohimbine, vacuum constriction devices, and sex or surgical therapies (e.g. penile prosthesis implantation, penile arterial reconstructive surgery). Study selection criteria included the following:

Source: Primary study report published in English

Study design: RCTs (comparative efficacy and harms studies)

Population: Adults (age ≥ 18 years) diagnosed with ED (with or without comorbidities)

Interventions (experimental/control): Oral (PDE–5 inhibitors, sublingual) injections (IC, SC), hormonal (e.g. testosterone), intra-urethral suppositories, CPAP, and/or topical (e.g. patch, cream)

Outcomes: Any adverse events, serious adverse events, withdrawals due to adverse events, and specific adverse events.

KQ 3a. The incidence of specific harms such as Nonarteritic Anterior Ischemic Optic Neuropathy (NAION) and penile fibrosis associated with use of PDE–5 inhibitor and injection therapies, respectively. The review included reports of non-RCTs or observational studies. For identification of data on fibrosis related to use of injection therapies, only studies with at least 6 months of followup were included. Study selection criteria included the following:

Source: Primary study report published in English

Study design: Non-RCTs (experimental or observational case-control and cohort studies, case reports and case-series)

Population: Adults (age ≥ 18 years) diagnosed with ED (with or without comorbidities)

Interventions (experimental/control): Oral (PDE–5 inhibitors), injections (IC, SC)

Outcomes: NAION, penile fibrosis

Systematic and narrative reviews, case reports, editorials, commentaries or letters to the editor were excluded for all questions except Q3–a (specific harms). Studies evaluating interventions such as penile implant devices or natural health products used for the treatment of ED were also excluded.

The results of the literature search were uploaded to the software program TrialStat SRS version 4.0 along with screening questions developed by the review team and any supplemental instructions. A calibration exercise was undertaken to pilot and refine the screening process. One reviewer screened bibliographic records (i.e., title, authors, key words, abstract) using broad screening criteria (Appendix B). All potentially relevant records and those records that did not contain enough information to determine eligibility (e.g. no abstract was available) were retained. The reasons for exclusion are noted in the QUOROM flow diagram (Figure 2). Two reviewers independently performed full-text relevance screening. Disagreements were resolved by consensus. Reasons for exclusion were noted (Appendix E).

Relevant studies were then evaluated to determine study design and were categorized accordingly for inclusion by question. The level of eligible evidence on efficacy was limited to RCTs, since systematic bias is minimized in RCTs compared with all other study designs (e.g. cross-sectional, retrospective cohort).

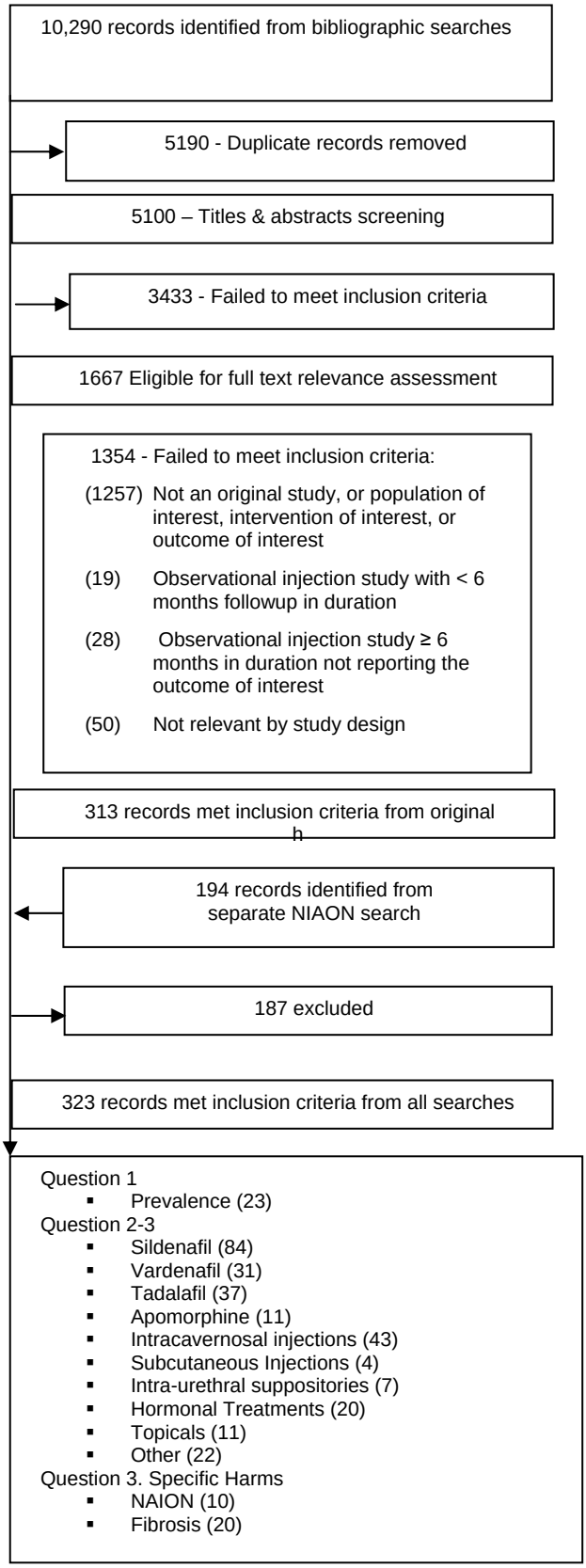
Data Abstraction

Two reviewers independently abstracted relevant information from each included study using a data abstraction form developed a priori for this review (Appendix B). One reviewer completed primary extraction, which was then verified by a second reviewer. Conflicts were discussed and

resolved by consensus. Abstracted data included study characteristics (e.g. design, sample size, country), population characteristics (e.g. age, comorbidities, severity of ED), name/type of treatment (e.g. sildenafil, testosterone), route of administration (e.g. oral, injection, topical), dose, and the duration of treatment. The following clinically relevant and validated efficacy outcomes were abstracted: absolute endpoint/change (from baseline) in scores for the International Index of Erectile Function "Erectile Function" domain (IIEF– EF), per-patient percentage on Sexual Encounter Profile for Q2 and Q3 (SEP–Q2/Q3), and the proportion of patients with improved erection measured with a Global Assessment (or Efficacy) Question (GAQ–Q1 or GEQ–Q1).(Appendix H)

For harms, reviewers abstracted information on any adverse events: i.e., number of patients who developed at least one adverse event; most frequently encountered specific adverse events; withdrawals due to adverse events; and the incidence of serious adverse events. Additionally, for Q1, prevalence estimates of hypogonadism and hyperprolactinemia in ED populations for each included study were abstracted.

Figure 2. Modified QUOROM Flow Chart



Assessment of Study and Reporting Quality

The quality of prevalence studies measuring serum hormonal levels in ED patients was assessed using a subset of QUADAS items.[46] The QUADAS tool consists of 14 items (Appendix B). QUADAS was designed to evaluate the diagnostic accuracy of a test against the reference standard. Since the included studies for this review involved measurements of serum hormone levels, no reference standards were used to assess the diagnostic accuracy of these tests (i.e., levels of testosterone, prolactin, LH and/or FSH). Therefore, the quality assessment of studies was based on a subset of 8 QUADAS items (score range 1–5) that were deemed to be relevant to the present research question.

The Jadad scale was used to assess the methodological and reporting quality of RCTs. (Appendix B). [47] This instrument is designed to assess the reporting of methods used to generate random assignments and double blinding, as well as to determine whether there is a description of dropouts and withdrawals by treatment group (i.e., number and reasons). The scoring ranges from 0 to 5, with higher scores indicating higher quality. An a priori threshold scheme was used for sensitivity analysis: a Jadad total score of $\geq$3 indicated studies of higher quality. In addition, the adequacy of allocation concealment was assessed using an approach proposed by Schulz and colleagues as: adequate, inadequate, or unclear (Appendix B).[48]

Synthesis of Evidence

Qualitative data synthesis. Primary and secondary outcomes were summarized qualitatively for each study. The sample size and demographics, setting, funding source, treatment and comparator characteristics (e.g. type, dose, and duration), study quality, and methods of adjustment for confounders (where applicable) were recorded and summarized in the text, and summary tables.

To determine the clinical utility of routine hormonal blood tests in identifying and affecting therapeutic outcomes for endocrine causes of ED (KQ 1), the reviewers identified relevant studies and synthesized data for two following constructs:

1. The prevalence of hormonal abnormalities (hypogonadism, hyperprolactinemia, abnormal levels of luteinizing and/or follicle-stimulating hormones) in patients with ED
2. The efficacy of hormonal therapies in patients with the above-mentioned hormonal abnormalities for improving clinical symptoms of ED.

The two constructs (i.e., prevalence of hormonal abnormalities and efficacy of available hormonal treatments) jointly determine the clinical utility of routine hormonal blood tests. For example, the administration of routine hormonal blood tests might be justified only if the prevalence of hormonal abnormalities in patients with ED was relatively high (i.e., above a pre-specified threshold) and the available hormonal therapies in affecting symptoms of ED in this subgroup of patients were effective.

Thus, the results for KQ 1 are presented in two sub-sections: 1) the prevalence of hormonal abnormalities in ED patients and 2) the efficacy of hormonal therapy in treating ED in patients with hormonal abnormalities (see also the section for KQ 2-3, Hormonal Treatments, for more detailed description of the studies).

Quantitative synthesis. The decision whether to perform statistical pooling of individual studies was based on clinical and methodological judgment. In the case of outcomes for which meta-analysis was deemed appropriate, we extracted quantitative data (e.g. number of subjects in each group, mean, standard deviation) from reports using a standardized data extraction form

that included intervention characteristics and outcome variables at baseline and followup intervals.

If relevant data (e.g. standard deviations) were not reported adequately, we attempted to calculate the needed parameters. Trials that did not report complete numerical information for relevant efficacy/harms outcomes (i.e., arm-specific mean endpoint or change in score, standard deviation, or standard error, proportion of patients with an outcome at followup) could not be incorporated in the meta-analyses. Trial reports presenting measures of variability (e.g. standard deviation) only graphically (i.e., no numerical data were available) were not pooled. Crossover trials not reporting numerical data from the pre-crossover phase were not included in meta-analyses

We calculated standard deviations from standard errors or 95 percent confidence intervals.

For continuous outcomes (e.g. mean endpoint/change in the total score of IIEF), the absolute difference between treatment-specific means and corresponding standard deviations were ascertained for each individual study. A generic inverse variance method was used to calculate the response outcomes and corresponding 95 percent confidence intervals for the combined treatment groups.

For dichotomous outcomes (e.g. improvement in erection GAQ), studies were grouped by type of treatment and dose to minimize clinical heterogeneity. The intent-to-treat group or number enrolled at the time of study was used for analyses and, when this information was unavailable, we used the number provided in the report. Pooled relative risks with corresponding 95 percent confidence intervals were generated.

The DerSimonian and Laird random-effects model was used to obtain combined estimates across the studies.[49] The degree of statistical heterogeneity was evaluated by using a chi-square test and the I^2 statistic.[50-52] An I^2 of less than 25 percent is consistent with low heterogeneity; 25 to 50 percent with moderate heterogeneity; and over 50 percent with high heterogeneity.[52] When statistically significant heterogeneity was identified, it was explored through subgroup and sensitivity analyses when appropriate. Sources of heterogeneity include reporting and methodological quality (e.g. methods for randomization, adequacy of allocation concealment, blinding, washout period for crossover trials, data analysis) as well as clinical heterogeneity (e.g. study population, dosing of therapeutic agent, duration of followup). Estimates from the heterogeneous groups must be interpreted with caution, especially when small numbers of trials are included.

We also performed a series of subgroup analyses to explore the consistency of the results.

The meta-analyses are presented as forest plots (Figures 3-76). Publication bias was explored through funnel plots (Figures D1-16, Appendix D) by plotting the relative measures of effect (relative risk) versus a measure of precision of the estimate (1/standard error).[51] The visual asymmetry in funnel plots maybe be suggestive of publication bias, although other potential causes for asymmetry exist. The degree of funnel plot asymmetry was measured using the Egger regression test.[53-55]

The statistical analyses in this review were performed using Review Manager 4.2 (The Cochrane Collaboration, Oxford, UK, 2006).

Chapter 3. Results

Question 1. What is the Clinical Utility of Routine Blood Tests (Testosterone/Prolactin/Luteinizing Hormone/Follicle-Stimulating Hormone) in Identifying and Affecting Therapeutic Outcomes for Treatable Causes of Erectile Dysfunction (ED)?

Prevalence of Hormonal Abnormalities in ED Patients

Literature Search

A total of 22 studies (23 publications) were identified as eligible and were included in the review.[20,38,56-76] One study was reported in two publications.[62,76]

Overview of Trials

The prevalence of hypogonadism, hyperprolactinemia, and measurements of serum level LH/FSH were evaluated in 21 [20,38,57-75], 10 [20,38,56,58,60,61,65,67,72,73] and 8 [20,61,63-65,67,69,73] studies, respectively.

The included studies were conducted in North America, Europe (France, Greece, Spain, Sweden, Turkey, and UK), Brazil, Australia, Egypt, Saudi Arabia, and Malaysia.

The characteristics of included studies are presented in Table 1.

Study and Reporting Quality

The quality of the 22 included studies of men with erectile dysfunction who had their serum levels of testosterone, prolactin, luteinizing hormone (LH) and/or follicle-stimulating hormone (FSH) measured was assessed using QUADAS.[46]

The QUADAS scores for each study are presented in Table C-2 (Appendix C).

About 60 percent of the studies provided an adequate description of population characteristics and inclusion/exclusion criteria.

Populations (Studies Reporting on Hypogonadism)

Twenty-one of the included studies measured testosterone serum levels in men with erectile dysfunction as total testosterone (TT) serum levels. [20,38,57-75] Two studies reported free testosterone (FT) serum levels, [59,66] two studies reported calculated free testosterone (cFT) serum levels, [73,74] and one study[73] calculated bioavailable testosterone (BT) serum levels.

Most studies recruited primary care clinic patients. In 10 studies participants were recruited from specialized clinics (urology, andrology, sexual dysfunction, and endocrinology clinics). Only 11 studies reported the use of a validated questionnaire to measure erectile dysfunction. The participants' mean age across studies ranged from 50 to 60 years. Important comorbidities such as hypertension, diabetes mellitus, and ischemic vascular disease were described in only 8 of the 22 studies.

Further details regarding the serum hormonal level measurements (e.g. time the serum was collected, cut-off values for positive/negative test results) are found in Table 1.

Prevalence of Hypogonadism (Total Serum Testosterone Levels)

The studies reporting prevalence rates of hypogonadism in ED patients are described in Table 2. All studies included men with a previous diagnosis of erectile dysfunction. The diagnosis of erectile dysfunction was given by a combination of clinical examination and validated questionnaires: the modified 5-item International Index of Erectile Function (IIEF–5) and Aging Males Symptoms (AMS).

The prevalence of hypogonadism ranged from 1.72 to 47.7 percent. In one study conducted in Japan, hypogonadism was found in 47.7 percent of the patients. Note that all participants in this study had been diagnosed with partial androgen deficiency of the aging male (PADAM) before entry in the study.[68] In one study,[38] which reported a prevalence of 6.6 percent, patients had been receiving androgen therapy. In Zohdy et al. 2007[75] all participants presented with obesity and other signs of metabolic syndrome.

In several studies, patients with ED and hypogonadism, who had been referred to urology clinics, were found more likely to have decreased libido,[20,38,67,72] testicular damage/abnormality,[20,38,70] psychological problems with their partner,[70] arterial disease,[70,72] obesity,[67,75] hyperlipidemia,[62] diabetes,[62,72] or hyperprolactinemia.[72]

In other studies, patients with hypogonadism did not differ (p-value > 0.05) from eugonadal patients either with respect to age,[60,64,67] ED severity,[60,62,67] ED duration,[60,67] the presence of chronic disease,[60] smoking,[60] loss of libido,[64] or premature ejaculation.[67] In contrast, one study[72] demonstrated that age, ED severity, and longer duration of ED were statistically significant predictors of having hypogonadism in patients with ED.

In two primary care clinic based studies,[57,65] hypogonadal patients were more likely to have higher levels of prolactin[65] or hypothalamic abnormalities than those with normal levels of testosterone (21.2 versus 2.9 percent).[57]

Prevalence of Hypogonadism (Free Serum Testosterone Levels)

Two studies reported the prevalence of hypogonadism measured by FT (radioimmunoassay, analog method)[66,74] and two studies reported calculated FT levels based on the TT serum levels (Table 3).[59,73]

The prevalence of hypogonadism using FT serum levels (radioimmunoassay, analog method) across these studies varied from 12.5 to 25.32 percent. The corresponding range for the prevalence of hypogonadism using calculated-free testosterone serum levels was 15.7 to 17.58 percent.

One study,[74] found a statistically significant association between hypogonadism and insulin resistance by showing a higher proportion of patients with insulin resistance amongst hypogonadal versus eugonadal patients (92.3 versus 25.2 percent, p value= 0.02).

Prevalence of Hypogonadism (Bioavailable Serum Testosterone Levels)

Serum Bio-T levels were reported in one study.[73], where the prevalence of hypogonadism was 0.41 percent and the average level of Bio-T was 0.84 ± 0.28 nmol/L. (Table 4).

Populations (Studies Reporting on Hyperprolactinemia)

Ten studies measured prolactin serum levels in men with ED to detect hyperprolactinemia.[20, 38,56,58,60,61,65,67,72,73] Patients were recruited from primary care clinics [56,65,73] or from specialized

clinics (urology, andrology, and endocrinology).[20,38,58,61,67,72] The mean age of participants ranged from 47 to 59 years. Only five studies reported important comorbidities, such as hypertension, diabetes mellitus, and ischemic vascular disease. Further details on these studies are provided in Table 5.

Prevalence of Hyperprolactinemia (Serum Levels of Prolactin)

The information on prevalence of hyperprolactinemia using the total level of serum prolactin was reported in 10 studies (Table 6). Erectile dysfunction was diagnosed using a combination of clinical examination and a validated questionnaire (IIEF–5 was reported in only four of the 10 included studies). Information on the cut-off used to define a positive test result was provided in all studies and ranged from 18 to 20 ng/mL. In these studies, except for one conducted in Egypt,[72] the prevalence of hyperprolactinemia ranged from 1.42 to 14.3 percent.

The prevalence rate of hyperprolactinemia reported in the Egyptian study was 32 percent. [72] The high prevalence observed in this study is not readily explained. Study participants were aging, obese men with ED. Of a total of 877 enrolled patients, 305 completed the study. The mean age was 53.9 (range 26–86) years; 77 percent of the patients were older than 50 years, 86 percent were overweight or obese, and 30 percent were current or former smokers. [72]

In two other studies, the prevalence rates of hyperprolactinemia were compared between men with and without ED. [60,73] These studies used similar cut-off points to define a positive or negative test result (Table 7). The prevalence rate of hyperprolactinemia among men with ED in the two studies ranged from 2.89 to 9.54 percent.

Prevalence of Abnormal Levels of LH/FSH

Information on the prevalence of abnormal levels of LH/FSH in men with ED was provided for eight studies.[20,61,63-65,67,69,73] The studies were divided according to whether they measured secondary hypogonadism (low levels of LH and/or FSH) or primary hypogonadism (high levels of LH and/or FSH). All studies included men with a previous diagnosis of ED. In two studies levels of LH were measured only in patients with low levels of total testosterone.[61,63] The diagnosis of ED was done by a combination of clinical examination and validated questionnaire (IIEF–5 or SAQ; reported in three included studies). The cut-off values used to define a positive/negative test result were provided for two studies only (Tables 8 and 9).

Secondary hypogonadism (low levels of LH and/or FSH). In Bunch et al. 2002, 66 patients with hypogonadism were screened for LH levels. Of these, 44 percent had low levels of LH (<13 IU/mL) and were diagnosed with secondary hypogonadism. Further screening with magnetic resonance imaging (MRI) or computer tomography (CT) imaging led to the identification of hypothalamic-pituitary abnormalities in 10 percent of these men. [63]

El-Sakka 2005[67] assessed the prevalence of endocrine abnormalities in obese men with sexual dysfunction. Low levels of LH and FSH were identified only in 1.7 percent of men (Table 9).

Primary hypogonadism (high levels of LH and/or FSH). In three studies, the proportion of men with ED who had abnormally high levels of LH ranged from 1.03 to 5.79 percent.[20,65,73] There was a prevalence of 21.7 percent in a study in which all men had been previously diagnosed with hypogonadism (i.e., low testosterone levels).[61] Another study[69] investigated possible hypothalamic impotence in 21 ED patients (median age 54 years) with low testosterone and normal levels of LH or FSH by undergoing gonadotropin-releasing hormone (GnRH)

stimulation and a challenge test with clomiphene citrate. Twenty-nine percent of men presented with a reduced LH level and 5 percent with a reduced FSH level.[69]

Prevalence of Hypogonadism and Hyperprolactinemia by Age

We descriptively examined patients' age distribution (mean and range) in individual studies to determine whether age could account for the between-study differences in the reported prevalence rates of hypogonadism and hyperprolactinemia. The results did not reveal any numerical trends between the age distribution and the prevalence rates.

Studies reporting age-stratified prevalence rates of hypogonadism. Buvat et al. 1997[38] reported the prevalence of hypogonadism in patients older than 50 years as being twice as high as that among patients younger than 50 years (9 percent versus 4 percent).[38] In Fahmy et al. 1999[64] the corresponding rates were 24.2 percent versus 14.3 percent, respectively. In another study, the prevalence rate in men older than 50 years was 20.25 percent (all patients were older than 50 years).[73] All three studies indicated higher prevalence of hypogonadism in men aged 50 years or older compared with those under 50 years of age.

Studies reporting age-stratified prevalence rates of hyperprolactinemia or abnormal levels of LH/ FSH. There was no report providing evidence on prevalence of hyperprolactinemia, or on abnormal levels of LH/FSH, by age group among patients with ED.

The Efficacy of Hormonal Therapy in Treating Erectile Dysfunction in Patients with Hormonal Abnormalities

Overview of Trials

Two studies were identified and were judged to be eligible to address the present question. Both trials were randomized[5,77] comparing the efficacy of combined treatment of testosterone (gel or patch) plus sildenafil to that of sildenafil alone in ED patients with low testosterone levels who failed to respond (score of 2–3 on IIEF–Q3/Q4) to prior treatment with sildenafil. More detailed information on trial design, patient population, and efficacy/harms results for these trials are presented in the section for Questions 2-3, Hormonal Treatments. (Evidence Table F-9, Appendix F)

Gel testosterone plus sildenafil versus sildenafil. In this double-blind trial[5] 75 hypogonadal men (mean age: 58 years; total testosterone <400 ng/dL) with ED were randomized to 1 percent gel testosterone plus 100 mg sildenafil versus 100 mg sildenafil for 12 weeks. At the end of the study, the proportions of men with scores of 4-5 on IIEF–Q3/Q4 was statistically nonsignificantly greater in the combination therapy group than in the sildenafil only group (51.4 versus 39.4 percent; RR = 1.30, 95 percent CI 0.77–2.21). Men who received gel testosterone plus sildenafil also had greater mean change from baseline in the IIEF "EF" domain score at week 4 (4.4 versus 2.1, 95 percent CI: 0.3–4.7). One patient withdrew from the combination treatment arm due to an adverse event.

Testosterone patch plus sildenafil versus sildenafil. In this open label trial,77 20 hypogonadal men (mean age:56 years; total testosterone:10-13 nmol/L) with ED were randomized to receive either 5 mg patch testosterone plus 100 mg sildenafil or 100 mg sildenafil plus placebo patch. After one month of treatment, patients in the patch testosterone plus sildenafil group had either numerically or statistically significant improvements for the following outcomes: "EF domain" score (21.8 +/- 2.1 versus 14.2 +/- 0.7, WMD = 7.60, 95 percent CI:

6.23–8.97), number of sexual intercourses (2.8 +/- 0.9 versus 1.5 +/- 0.5, WMD = 1.30, 95 percent CI: 0.66–1.94), intercourse satisfaction (12.1 +/- 1.6 versus 7.7 +/- 1.2, WMD = 4.40, 95 percent CI: 3.16–5.64), and reported improved erections (80 versus 10 percent, RR = 8.00, 95 percent CI: 1.21–52.69).

Questions 2-3. What is the Evidence of the Relative Clinical Benefits and Harms of Pharmaceutical Treatments (e.g. Oral Medications) for Men Diagnosed With Erectile Dysfunction?

Oral Treatments — Phosphodiesterase Type 5 (PDE–5) Inhibitors - Sildenafil

Literature Search

In total, 90 unique trials (reported in 100 publications) reporting relative efficacy and harms related to sildenafil use (mono or combined therapy) met the eligibility criteria and were included in the review.[5,77-175]

Seventeen (reported in 16 publications) of the 90 trials are described in the following sections of the review: Question 1-3,[5,77] Topical,[144] Hormonal,[145,170] Injections, [119,172] Tadalafil,[103,118, 121, 163] and Sublingual (apomorphine).[114,117,120,148,159]

This section reviews the remaining 73 unique trials (reported in 84 publications).[78-102,104-113, 115,116,122-143,146,147,149-158,160-162,164-169,171,173-175]

In 5 publications,[85,86,90,130,152] two separate unique trials were described (a and b). 12 unique trials were reported in two or more publications. The following list shows the reference identifications for these 12 unique trials and their corresponding publications (each row).

The first reference (author, year, citation) denotes primary publications (i.e., those reporting the most relevant and complete data for the trial), which are used throughout the Sildenafil section. (Tables F-1, in Appendices F):

1. Palmer 2000[78] and Palmer 1999[136]
2. Seidman 2001[79] and Rosen 2004[113]
3. Goldstein 1998a,[86] Padma-Nathan 1999,[154] and Barry 1998a[152]
4. Tan 2000[87] and Lim 2002[129]
5. Meuleman 2001[88] and Hartmann 1999[140]
6. Eardley 2002[130] and Eardley 1999[139]
7. Incrocci 2001[131] and Incrocci 2003[92]
8. Cappelleri 2000[135] and Lewis 2001[100]
9. Padma-Nathan 1998,[142] Goldstein 1998b[86] and Young 1999,[141] and Barry b,[152] and Shabsigh 1999b [153]
10. Glina 2001[151], and Glina 2002[127]
11. Perimenis 2007[155], Perimenis 2004[116]
12. Sharma 2006[165], and Salonia 2007[174]

Overview of Trials

Of the 73 trials, 52 (71 percent) used a parallel-arm design,[79-84,86-88,90,91,94-98,101,104,106, 107,109-112,115,122-126,128,133,135,138,142,143,147,151,155-158,160,162,166,167,169,171,173,175,176] while the remaining 21 used a crossover design.[78,85,89,93,99,102,105,108,130-132,134,146,149,150,161,164,165,168]

The trials were conducted in North America,[78,79,81,84,86,90,91,94,102,105,109,122,132,135,142,147,156,158,160,161,166,167,169,171,173,177] Australia,[147,166] South America,[81,83,106,123-126,143,151,166] Africa,[83,110] Europe,[81,85,88,89,93,95,96, 98,99,104,107,108,112,115,128,130,131,133,134,137,138,146,147,150,155,157,167] and Asia.[80,81,81,82,87,97,101,111,149, 162,164-166,168,175]

The trials were published between 1996[85] and 2007.[155-158,160,161,173,175]

Fifty-three trials were supported by Pfizer[78-87,89-91,93-99,107-110,115,122,124-126,128,131,133,135, 137,138,142,143,146,147,151,156,158,160,161,164,166,167,169,171,173,175]. Two Italian trials were supported by Sigma Tau.[104,112] The source of support was not reported for 10 trials.[88,106,111,123,130,134, 149,150,155] Three trials had no source of support,[101,157,162] and five other trials reported other funding sources.[102,105,132,165,168] (Evidence Table F-1, Appendix F)

Populations

Study participants in the included trials were men diagnosed with ED. The total and mean numbers of patients randomized across the 73 trials were 11,064 and 152, respectively. The number of randomized patients across all trials ranged from 12[85,169] to 568.[147]

In these trials the study population inclusion criteria were: adult males aged ≥18 years diagnosed with ED for ≥3 months before study enrolment and in a heterosexual relationship with a sexual partner. The most common reported reasons for the trial exclusion were the presence or history of penile/testicular deformity, cardiovascular disease, stroke, myocardial infarction, use of nitrates, any major hepatic or renal disease, spinal cord injury, retinitis pigmentosa, diabetes, major psychiatric disorder, alcohol/drug abuse or hypotension.

In 31 (42 percent) of the 73 trials the selection of ED patients was restricted to patients with the following conditions: spina bifida,[78] depression,[79,91,115,167] diabetes,[81,93,94,98,101,112] stable coronary artery disease,[84] Parkinson's disease,[99] congestive/chronic heart failure,[102,109] prostatectomy,[104] multiple sclerosis,[107] dialysis,[108,123] obstructive sleep apnea,[155] colorectal cancer,[128] prostate cancer,[131] cardiovascular disease,[133] hypertension,[143,147] benign prostatic hyperplasia (BPH),[160] post-traumatic stress disorder,[164] renal allograft,[165] schizophrenia,[168] lower urinary tract symptoms,[173] and androgen decline.[175] Most patients (≥ 90 percent) included in the 31 trials were diagnosed with ED of organic and/or mixed etiology.[78,79,81,84,91,93,94,98,99,101,102,104,107-109,112,115,123,128,131,133,143,147,155,160,164,165,167,168,173,175] Of the remaining 42 trials,[80,82,83,85-90,95-97,105,106,110,111,122,124-126,130,132,134,135,137,138,142,146,149-151,156-158,161,162, 166,169,171] three[96,106,110] included participants with ED of psychogenic etiology and another three consisted mostly of participants with ED of organic/vasculogenic and mixed etiology.[122,150,157] Participants included in the remaining 36 trials were diagnosed with ED with a broad spectrum of causes (i.e., organic, mixed, and psychogenic). The majority of these trials reported that an organic cause of ED had not been established.

The 73 trials included here enrolled participants aged 18 years or older. In one trial,[78] the participants' age ranged between 19 and 35 years, and in two trials this range was from 35 to 70 years.[130] Two trials included only participants older than 45 years.[160,175]

Interventions

In the 73 reviewed trials, participants were randomly assigned to receive either mono and/or combined therapy of oral sildenafil citrate (as experimental or control intervention) with a dose (at randomization) ranging from 10 mg[85,96] to 100 mg.[101,104,122,130,134,137,146,150,155,158,161,169] Depending on the observed efficacy and tolerability of sildenafil, the daily dose was flexible (upward or downward titrations: 50 mg – 25 mg – 100 mg) in more than half of the included trials.[79-84,87-91,94,95,97-99,107-109,115, 124-126,128,131,133,135,138,142,143,147,150,151,156,157,160,162,164-168,171]

In eight trials, participants were randomized to receive different dosages (e.g. with respect to dose, dose escalation, fixed/on demand, time of administration) of sildenafil monotherapy.[78,85,86, 93,96,137,157,161] Of these, six trials[78,85,86,93,96,137] assessed a dose-response effect of sildenafil given at a fixed dose (dose range 10 mg/d to 100 mg/d). In one trial,[161] participants were randomly assigned to receive 100 mg/d of sildenafil either 1 hour before/during a meal or 30–60 minutes before sexual activity. Participants in another trial were randomly assigned to receive either fixed dosing (50 mg every night) or flexible dosing (50 mg or 100 mg, as needed) of sildenafil.[157]

In nine trials, oral sildenafil was administered in combination with propionyl-L-carnitine (PLC),[112] PLC and acetyl-L-carnitine (ALC),[104] intranasal PT-141,[105] psychotherapy,[106] alfuzosin,[173] dihydro-ergotamine (DHE),[150] atorvastatin,[158,169] quinapril,[158] and cabergoline.[162]

In five trials, patients received either mono (or combined) therapy of sildenafil or monotherapy of another active treatment.[106,124,132,155,173] These therapies were psychotherapy,[106] continuous positive air pressure (CPAP),[155] phentolamine,[124] Ro70–0004 (i.e., α_{1A}-adrenoceptor antagonist),[132] or alfuzosin.[173]

Of the 73 trials, 66 (91 percent) were placebo-controlled (with or without an active treatment arm),[78-91,93-99,101,102,104,105,107-111,115,122,123,125,126,128,130-135,137,138,142,143,146,147,149,151, 156,158,160-162,164-169, 171,175] and the remaining seven trials had no placebo arm.[106,112,124,150,155,157,173]

In most of the trials, the duration of sildenafil treatment was about 12 weeks[79-81,83,84, 87,94,97,98, 102,107,109,115,125,126,131,133,135,137,138,142,151,155,156,158,160,166,169,171,173,175] and ranged from 1–2 weeks[93,168] to 48 weeks.[157]

Outcomes

Harms. The presence or absence of any all-cause adverse events (i.e., the proportion of patients with ≥ 1 adverse event) was reported in 29 trials.[79-83,85-87,90,94,96-98,107-109,115,124-126,132,137, 142,143,147,151,160] The presence or absence of withdrawals due to adverse events was reported in 62 trials.[78-91,94-99,101,104,105,107-109,112,115,122-126,128,130,131,133-135,137,138,142,143,146, 147,149,151,155-157,160,162,165-168, 171,173,175] The absence or presence of serious adverse events was reported in 52 trials.[78,80-85,87-91, 93,95-99,101,105,107-112,123-126,128,131,133-135,138,143,146,147,149,151, 155-157,160,166-168,171,173]

Efficacy. The efficacy outcomes measuring the degree of ED reported in the 73 trials were total mean scores for the 5 IIEF domains: "Erectile Function",[79-84,86-88,90,91,97,98,102, 104,107-109,112,115, 122-126,128,135,137,138,142,143,147,149,155,156,160,161,164-167,169,171,173] "Intercourse Satisfaction",[79,80,82-84,87,88,90, 91,97,104,107-109,115,122-126,137,138,142,143,147,149,155,156,160,162,164-167,171] "Overall Satisfaction",[79,80,82-84,87,88, 90,91,97,104,107-109,115,122-126,137,138,142,143,147,149,155,156,160,164-167,171] "Orgasmic Function",[79,80,82-84,87,88,90,91,97, 104,107-109,115,122-126,137,138,142,143,147,149,155,156, 160,164-167,171] and "Sexual Desire",[79,80,82-84,87,88, 90,91,97,104,107-109,115,122-126,137,138,142,147,149,155, 156,160,164-167,171]

Other commonly reported outcomes were: mean IIEF scores for responses to Q3 and Q4 (penetration and maintenance frequency),[79-84,86-88,90,91,94,97-99,101,107-109,112,115,123-126,131, 133,137,138, 142, 143,147,149-151,162,165,167,173] proportion of successful intercourse attempts,[80-84,87,94,97,98,109, 112,115,124-126,

[131,137,138,142,143,147,151,155,156,161,166,167,171] and proportion of patients with improved erection (GEQ–Q1).[79-90,93-98,107-109,112,115,124-126,128,131,133,137,138,142,143,147,149, 151,156,165,167-169,171]

Several trials reported mean IIEF scores for individual questions (e.g. Q1–Q2 and Q5–Q15)[78,94,101,123,124,126,131,138,143,150,162,165] as well as the mean total IIEF score.[91,106,123,128,155,164,175]

Other reported outcomes were mean severity score of ED (based on the modified 5-item IIEF),[111,123,135,158] time to onset of erections/intercourse attempts (i.e., mean/median number of minutes),[122,130,161] proportion of responders (erection rigidity >60 percent or erection grades 3–4),[130,146] duration of erections (≥60 percent or ≥80 percent rigidity),[93,105,132,146,168] mean number (per week or month) of penile erections (grade 3–4),[85,88,89,93,95,96,138,142,168] peak systolic/end diastolic velocity (PSV/EDV) in cm/s,[104,108,112,157] mean EDITS score,[84,90,109,143,147,156,160,161,167] mean score of responses to Self-Esteem and Relationship questionnaire (SEAR),[156,160,166,171] nocturnal penile tip and base tumescence/rigidity (in mean activity units),[110,134] and endothelial function (brachial artery flow-mediated dilation).[158]

Study and Reporting Quality

The mean of Jadad total score for the 73 trials was 3.3. The Jadad total score for the individual trials ranged from 1[99,124,132,150,178,179] to 5.[81,91,94,95,115,123,128,143,162,168] The method for generating the sequence of randomization was described in only 26 trials,[81,84,89,91,94,95,99,101,104,106,107,109,112,115,123,128,143,155-157,162,164,165,167,168,171] and in four of these[89,99,104,112] the method was determined to be inappropriate.(Table C-1, Appendix C)

Of the 73 trials, 64 (88 percent) were described as double- blind[79-91,93-99,101,102,104,105,107-109,111,112,115,122,123,125,126,128,130,131,133-135,137,138,142,143,146,147,149,151,156,158,160-162,164-169,171,175] and nine trials as open-label.[78,106,110,124,132,150,155,157,180] Of the 64 double-blind trials, 42 (66 percent) reported some description of the blinding methods.[79-83,86-91,94,95,97,98,102,104,107,108,112,115,122,123,125,128, 30,133,134,137,138,142,143,151,158,162,164,168,169,173,175] The blinding methods reported for two trials[102,146] were judged to be inappropriate.

Information on methods for allocation concealment was reported for only 11 trials.[81,91,94,95,101,106,107,112,123,156,165] The methods reported for 10 trials were judged to be adequate,[81,91,94,95,101,106,107,112,123,165] and for one trial inadequate.[156] The methods used to conceal the treatment allocation for the remaining 61 trials could not be ascertained (i.e., these were rated "unclear").

Of the 21 crossover studies, seven (33 percent) reported the use of washout periods,[85,130,132,146,150,165] and one study reported not to have employed a washout period.[89] For the remaining 13 trials, it was not clear whether any washout periods were applied.[78,93,99,102,105,108,130,131,134,149, 161,164,168] The length of washout period for the seven crossover trials was 4 days,[150] 7 days,[85, 130,132,146] and 2 weeks.[165]

Qualitative Synthesis

Sildenafil (mono or combination therapy) versus placebo. In four placebo-controlled trials[158, 161,162,169] the efficacy and safety profiles of sildenafil and placebo were not compared (see sildenafil dose/dosage one versus dose/dosage two and sildenafil mono versus sildenafil in combination sections). Thus, results provided here are based on data obtained from 62 placebo-controlled trials.[78-91,93-99,101,102,104,105,107-111,115,122,123,125,126, 128,130-135,137,138,142,143,146,147,149,151,156,160,164-168,171,175]

Harms. In the majority of the placebo-controlled trials, the proportion of patients with at least one adverse event was greater either numerically or with statistical significance for participants taking sildenafil compared with those taking placebo. For example, in one trial of flexible dose

(titrated to 100 or 25 mg), 51.3 percent and 32.9 percent of patients experienced one or more adverse events in sildenafil and placebo arms, respectively (p values were not reported).[125] In another study, the corresponding proportions were 59.7 percent for the sildenafil treatment group versus 29.6 percent for the placebo arm, respectively (p = 0.079).[126]

The most commonly observed all-cause adverse events across the trials were headache, flushing, and dyspepsia. Other adverse events were myalgia, rhinitis, cardiovascular events, flu-like symptoms, nausea, respiratory events, diarrhea, vomiting, dizziness, chest pain, urinary tract infections, depression, and anxiety. Overall, these events were less frequent for participants taking placebo compared with those taking sildenafil. These effects were usually of a mild to moderate or transient nature not requiring discontinuation of the therapy.

The occurrence of specific adverse events involving visual disturbances, including blurry vision and chromatopsia, were reported in 33 trials.[79-84,86,88,90,91,94,95,97,98,107,109,115, 122,125,126,131,135, 137,138,142,146,147,151,156,164,165,167] The percentage of patients experiencing visual side effects across the trials ranged from 1 percent[88,137,165] to 57 percent[164] for participants taking sildenafil, and from 0 percent[80,87,88,94,95,98,101,107,109,122,125,126,135,138,147,165,167,171] to 61.9 percent[164] for participants taking placebo.

Cardiovascular events were reported in 18 studies.[79,83,84,87-89,94,96,97,101,102,107,109,125,126, 137,143,166] These events were numerically more frequent in participants treated with sildenafil, ranging from 3 percent[94] to 29 percent,[97] compared with the range of 0 percent[101] to 12 percent[97] for placebo-treated participants.

A few studies reported the need for dose reduction as a result of adverse events.[80,84,87,115,151] The reasons for dose reduction were headache,[80,87,151] flushing,[87] chest tightness,[87] nasal stuffiness,[87] and visual disturbance.[80]

Twenty-four trials reported the absence of withdrawals due to adverse events.[78-80,82, 85,98,104, 105,107,110,112,128,131,133,134,138,146,149,156,167,168,171] The rate of WDE (presented as the proportion of patients who withdrew) in sildenafil treatment groups was under 5 percent in 18 trials,[81,83,84,88,90, 91,96,109,115,125,135,137,142,151,156,160,175] and up to 8 to 12.5 percent in four trials.[96,99,101,126] In the majority of these trials, the rate for withdrawals due to adverse events in placebo-treated participants ranged between 2 and 8.5 percent. The specific events leading to withdrawals were headache,[88,101,109,137,142,151] nausea, vomiting, gastrointestinal symptoms,[86,88,137] visual disturbances,[88,165] cardiovascular events,[87,89,99,101,165,166] urinary tract infection,[166] chest pain,[101] and cerebrovascular events.[160] These events were reported for participants treated with sildenafil, with the exception of one case of myocardial infarction[89] and one case of urinary tract infection[166] in placebo-treated participants.

The occurrence/absence of serious adverse events was reported in 51 trials. In 29 trials, no patient experienced any serious adverse event.[78,80,81,85,90,91,98,99,101,105,108,110-112, 124,125,128,131,133,134, 138,146,149,156,157,167,168,173] Thus, the occurrence of serious adverse events was reported in 22 trials (Table 10).[82-84,87-90,93,95-97,107,109,123,126,135,143,147,151,160,166,171] In general, the quality of reporting serious adverse events was poor, and some studies did not provide a full description of events.[82, 95,107,109,126,135,147,151,160,166] In total, 95 participants had at least one serious adverse event while taking sildenafil or placebo, of which 32 were taking sildenafil[83,84,87,88,90,93,97,107,109, 126,135,143,147, 151,160,166] and 36 were taking placebo.[82,84,87,89,97,107,109,123,126,135,143,147,151,160,166,171] For the remaining 27 participants in two trials,[95,96] the treatment group designation was not reported. Cardiovascular events were the most frequent category of serious adverse events. These included myocardial infarctions, which occurred in one participant taking sildenafil,[83] two participants taking placebo,[89,126] and one participant whose group designation was unknown.[96] Severe angina

pectoris occurred in a participant taking 100 mg sildenafil[87] and in another patient taking placebo.[84] Heart failure, atrial fibrillation, and arrhythmia occurred in two participants taking sildenafil.[143] Cerebrovascular events occurred in two participants taking sildenafil,[143,160] one of which was taking 100 mg of sildenafil.[160] Respiratory events included pneumococcal pneumonia in one participant on placebo[143] and pulmonary edema in another participant on sildenafil.[143] Accidental injuries were reported in two participants, one severe vertebral fracture in a participant taking sildenafil,[83] and the other a hand injury in a participant taking placebo.[87]

Six deaths during four trials,[88,123,126,171] and one death during the open-label phase of the study[95] were reported. Four of the eight deaths occurred in placebo groups, one resulting from myocardial infarction.[126] The reasons for the other three deaths were not reported.[123,171] Two deaths occurred in participants treated with sildenafil; one of these resulted from an accident,[123] and the other from cardiac arrest.[88] For more details on serious adverse events in each trial, please refer to Table 10.

Efficacy. In the trials reporting mean scores for IIEF "EF" domain and IIEF–Q3/Q4, the proportions of patients with successful intercourse attempts, and improved erection demonstrated that participants receiving sildenafil (regardless of mono/combination therapy or dosage and duration) experienced a statistically significant greater improvement in erectile function compared with those receiving placebo. These improvements were observed for the mean total "EF domain" scores (38 trials),[79-84,86-88, 90,91,97,98,102,104,107-109,115,122,123,125,126,128, 135,137,142,143,147,149,156,160,164-167,171] mean IIEF Q3–Q4 scores (35 trials),[79-84,86-88,90,91,94,97-99,101,107-109, 115,123,125,126,131,133,137,138,142,143,147,149,151,165,167] the proportion of successful intercourse attempts (25 trials),[80-84,87,94,97,98,101,109,115,125,126,131, 137,138,142,143,147,151,156,166,167,171] and the proportion of patients with improved erection (based on their responses to GEQ–Q1) (all 40 trials).[79-90,93-98,107-109,115,125,126,128,131,133,137, 138,142,143,147,149,151,156,165,167,168,171]

All trials (i.e., those that reported mean scores for the five IIEF domains) except for one,[164] yielded statistically significant higher mean IIEF scores in participants treated with sildenafil compared with placebo-treated participants for two IIEF domains ("Intercourse Satisfaction" and "Overall Satisfaction").[79,80,82-84,87,88,90,91,97,104,107-109,115,122, 123,125,126,137,138,142,143,147,149,156,160,165-167,171] In general, the results for two IIEF domains of "Sexual Desire" and "Orgasmic Function" were less consistent that those for three other domains (i.e., "Erectile Function," "Intercourse Satisfaction," and "Overall Satisfaction").

Specifically, in 17 trials no statistically significant difference was shown in mean IIEF scores for "Sexual Desire" between sildenafil and placebo groups.[84,88,90,91,104,108,115,123,125,138,142,143,149,156, 164,165] In six trials,[109,115,125,143,156,164] the between-group (sildenafil versus placebo) differences for mean scores of "Orgasmic Function" were not statistically significant.

All seven trials[85,88,89,93,95,96,168] that assessed and reported the mean number of grade 3–4 erections per week, yielded a statistically significant increase in the mean number of erections among participants treated with sildenafil (range 1.3[93]–6.5[168]) compared with placebo-treated participants (range 0.6[88,93,95]–3.32[168]). Similarly, two other trials[86,138] showed that participants treaded with sildenafil compared with those on placebo, experienced a significantly greater mean number of erections (grade 3–4) per month. The ranges for the mean numbers of erections were 4.3–6.9 (sildenafil) and 2.4–3.1 (placebo). Five trials[93,105,132,146,168] indicated a statistically significant longer mean duration of erections (≥60 percent rigidity) for participants treated with sildenafil compared with those who received placebo.

In nine trials, mean EDITS scores indicated that participants exhibited a statistically significant higher degree of treatment satisfaction after being treated with sildenafil compared with placebo.[84,90,109,143,147,156,160,167]

The beneficial effect of sildenafil use found in trials of participants with psychogenic ED[96,110] or distinct clinical subgroups (e.g. spina bifida, depression, diabetes, stable coronary artery disease, Parkinson's disease, congestive heart failure, multiple sclerosis, prostate cancer)[78,79,81,84,91,93,94,98,99,101,102,104,107-109,115,123,128,131,133,143,147,160,164,165,167,168,175] were consistent with those of other trials conducted in patients with ED of mixed etiology or those with clinically heterogeneous conditions.

Reports of only four trials provided treatment efficacy subgroup analyses (i.e., stratification of efficacy results) with respect to baseline severity of ED.[81,90,128] The evidence from these trials indicated that participants with mild/moderate ED (IIEF score 11–25) after taking sildenafil tended (statistically nonsignificant trends) to experience a greater degree of improvement in erectile function as measured by mean scores for responses to "EF domain" and Q3–Q4 of the IIEF questionnaire and the proportion of patients with improved erections (i.e., those who responded "yes" to GEQ–Q1) compared with those with severe ED (IIEF ≤10).

Efficacy subgroup analyses with respect to duration of ED (0–3, 3–6, and >6 years) and age (18–49, 50–64, and ≥65 years) were reported in two trials.[94,101] In both trials sildenafil was shown to have improved erectile function (i.e., mean IIEF–Q3/Q4 scores and percentage of patients who responded "yes" to GEQ–Q1) regardless of the participants' age and the duration of ED. The results of analyses provided for these trials did not reveal any treatment effect modification by the above-mentioned factors. In another trial, younger age ($p = 0.034$) and a shorter duration of ED ($p = 0.028$) were found to be predictive of a greater baseline-to-endpoint improvement in erectile function (i.e., mean scores for the IIEF "EF" domain and "Intercourse Satisfaction" domain).[156]

Reports of five trials provided the treatment efficacy stratification analyses by ED origin (i.e., organic, psychogenic, and mixed).[86,88,96,134,142] The improvements in erectile function (mean scores for IIEF "EF" domain and percentage of patients who responded "yes" to GEQ–Q1) were observed regardless of the origin of ED in patients receiving sildenafil compared with those receiving placebo, without identifying the origin of ED as a treatment effect modifier or predictor.

Sildenafil dose/dosing 1 versus sildenafil dose/dosing 2. Six studies assessed the efficacy and harm profiles for different doses (i.e., 10 mg, 25 mg, 50 mg, and 100 mg) of sildenafil monotherapy.[78,85,86,93,96,137] Additionally, two other trials[157,161] examined and compared two different dosage regimens of sildenafil (i.e., fixed versus flexible, different timing of administration).

Harms. In one trial,[137] which reported the incidence of any adverse events, specifically, events in >5 percent of participants in one or more treatment groups, the proportions of participants experiencing at least one adverse event (due to all causes) in either the sildenafil 25 mg, 50 mg, and 100 mg treatment groups were 49, 61, and 72 percent, respectively. The corresponding dose-specific proportions observed in another trial,[86]a were 32, 69, and 86 percent, respectively. Both trials indicated a numerically increasing trend in the incidence of any adverse events observed with the higher dose of sildenafil. In one trial,[96] the proportion of patients with any adverse events (i.e., events in >5 percent of patients) observed in the 25 mg and 50 mg sildenafil groups were numerically higher (59 and 45 percent, respectively) compared with the 10 mg sildenafil group (24 percent). None of these three trials[86,96,137] reported any

statistical test results for the observed between-treatment differences. In two trials,[85,93] the number of participants with treatment-related adverse events did not differ across the 25 mg and 50 mg sildenafil treatment groups. Of the events observed across the trials,[78,85,86, 93,96,137] headache, myalgia, nausea, dyspepsia, and flushing were the most frequently experienced and were mild to moderate or transient in nature.

A total of four serious adverse events were reported in two studies.[93,96] These trials compared 25 mg to 50 mg,[93] and 10 mg to 25 mg and 50 mg of sildenafil.[96] One participant (4.7 percent) in the 25 mg sildenafil group discontinued the treatment because of pneumococcal pneumonia (the authors did not consider this a serious adverse event).[93] There were three other instances of serious adverse events (myocardial infarction, renal cell carcinoma, and epileptic crisis) in one trial.[96] The group designation of the participants experiencing these events were not reported.

Withdrawals due to adverse events were reported in five trials.[85,86,93,96,137] The rate of discontinuation ranged from 0 percent[85] to 3 percent[96] for the 10 mg dose of sildenafil, from 0 percent[137] to 4.7 percent[93,96] for the 25 mg dose, from 0 percent[85]a to 11 percent[96] for the 50 mg dose, and from 2 percent[86]a to 4 percent[137] for the 100 mg dose.

Safety data was not reported for the trial that compared different timing of sildenafil (100 mg) administration in relation to food and sexual activity.[161] In the trial[157] comparing "nightly" (50 mg) and "as needed" (50 mg to 100 mg) sildenafil dosing regimens, the proportion of withdrawals due to adverse events was similar across the two groups (approximately 7 percent). The authors of this trial did not report the incidence of any adverse events. Overall, more participants experienced adverse events (headache, flushing, dyspepsia, and rhinitis) in the "as needed" compared with the "nightly" group. Reportedly, none of the participants in this trial developed a serious adverse event.[157]

Efficacy. All six trials[78,85,86,93,96,137] assessing the efficacy of different doses of sildenafil monotherapy (10 mg, 25 mg, 50 mg, and 100 mg), demonstrated a dose-response trend for sildenafil toward improving erectile function. Although none of these trials provided a formal statistical test for the observed between-arm (sildenafil versus placebo) differences, the degree of improvement tended to increase numerically with a higher dose of sildenafil. For example, the range for the mean IIEF Q–3 and Q–4 scores for three sildenafil dose arms in two trials[86,137] were as follows: 25 mg (Q–3: 3.18–3.20, and Q–4: 2.99–3.10), 50 mg (Q–3: 3.50–3.65, and Q-4: 3.50–3.64), and 100 mg (Q-3: 3.79–4.00 and Q-4: 3.63–3.90). The proportion of participants with an improved erection (based on GEQ–Q1) across four trials[86,93,96,137] ranged from 50 to 79 percent for 25 mg and from 52 to 88 percent for 50 mg sildenafil arms. In two trials,[86,137] the corresponding proportion of participants who received 100 mg sildenafil ranged from 84 to 88 percent. The authors of two trials,[78,86] reported dose-response treatment effects associated with administration of 25 mg,[78,86] 50 mg,[78,86] and 100 mg[86] of sildenafil with respect to mean scores for the IIEF "EF" domain (no numerical data provided; $p < 0.001$)[86] and IIEF–Q1 (25 mg: 3.7, versus 50 mg: 4.5).[78] In two other trials[85,93] the participants' mean duration of penile rigidity (>80 percent and >60 percent, respectively) in minutes at the base and the tip of the penis was shown to increase numerically with higher doses of sildenafil (10 mg versus 25 mg versus 100 mg). In one trial,[85] the mean duration of penile rigidity at the base of the penis for participants receiving 10 mg sildenafil was 3.5 minutes (95 percent CI: 1.6–7.3). The ranges for the mean duration of penile rigidity (>60 percent or >80 percent) in two trials,[85,93] were 5.0 to 8.0 minutes (in participants receiving 25 mg sildenafil) and 10.1 to 11.2 minutes (in participants receiving 50 mg sildenafil). The proportions of participants who achieved grades 3–4 erections in the 25 mg, 50 mg, and 100 mg sildenafil groups were 72, 80, and 85 percent, respectively.[86] The mean

number of erections per week (grades 3–4) was also shown to be numerically greater in two trials.[93,96] For example, the mean number of erections per week in one trial among participants who received 10 mg, 25 mg, and 50 mg sildenafil was 2.8, 3.0, and 3.6, respectively.[96]

In two trials,[157,161] the efficacies of two different dosage regimens of sildenafil were compared. In one trial,[157] participants received either a fixed dose (50 mg every night) or a flexible dose (50 or 100 mg, as needed) of sildenafil for 12 months; in the other trial[161] participants were randomly assigned to receive 100 mg/d of sildenafil either 1 hour before/during a meal or 30–60 minutes before sexual activity. In the first trial,[157] the effect of a fixed dose of sildenafil given every night was maintained to a greater extent compared with that achieved with a flexible dosage of sildenafil. Specifically, the proportion of patients with a normal IIEF score (i.e., mean IIEF "EF" domain score ≥26) at 12 months in the two treatment groups (the "fixed 50 mg nightly" arm versus the "50–100 mg, as needed" arm), was similar (66.7 versus 67.3 percent, respectively); however, the corresponding proportions for the two groups after 1 month of post-treatment followup were 60.4 percent (95 percent CI: 45.3–74.2) versus 8.2 percent (95 percent CI: 2.3–19.6) in favor of nightly dosage group. The 13-month (i.e., one month after the 12-month treatment stopped) end-point mean peak systolic velocity (PSV) values for participants in the "nightly" and "as needed" groups were 37.0 (SD = 10.4) cm/s versus 26.5 (SD = 8.9) cm/s, respectively, favoring the "nightly" group. In the other trial,[161] the time between sildenafil administration and intercourse attempt (0–0.5 to >10 hours) had no statistically significant effect on the mean IIEF "EF" domain score and the proportion of intercourse attempts (based on SEP–Q2; $p = 0.56$), however, a longer period of time between taking sildenafil and intercourse attempt was associated with a statistically significant reduction in successful intercourse attempts (based on SEP–Q3; 92.8 percent at 1.5–2 hours versus 81.6 percent at >10 hours; $p = 0.003$). No statistically significant differences were observed for EDITS scores between the study arms ($p > 0.80$).[161]

Sildenafil monotherapy versus sildenafil in combination. This review included nine trials[104-106,112,150,158,162,169,173] in which the efficacy and harm of mono- versus combination therapy of sildenafil were compared. In these trials, sildenafil was used in combination with PLC and acetyl-L-carnitine (ALC),[104] intranasal PT–141,[105] psychotherapy,[106] propionyl-L-carnitine (PLC),[112] dihydro-ergotamine (DHE),[150] cabergoline,[162] atorvastatin,[158,169] quinapril,[158] and alfuzosin.[173]

Harms. In general, harms were poorly reported in four trials.[106,150,158,169] The incidence of any adverse events were reported in only one[162] of the nine trials.[104-106,112, 150,158,162,169,173] This study reported a higher proportion of participants with one or more adverse events in the combination arm (cabergoline and sildenafil) compared with the sildenafil monotherapy arm (12.2 versus 2.0 percent, $p = 0.001$).[162] In two trials no serious adverse events were reported during the trial period.[112,173] The remaining seven studies did not report serious adverse events.[104-106,150,158, 162,169]

Five studies reported information regarding withdrawals due to adverse events.[104,105,112,162,173] There were no withdrawals due to adverse events in three of these trials in any of the compared treatment groups,[81,105,112] and two trials[162,173] reported higher rates of withdrawals in sildenafil combination therapy than in sildenafil monotherapy. These rates were 5.8 percent with sildenafil/cabergoline therapy compared with 1.0 percent in sildenafil monotherapy,[162] and 14.5 percent with sildenafil/alfuzosin therapy compared with 9.5 percent in sildenafil monotherapy.[173]

Efficacy. In all nine trials, participants who received combination therapies, in comparison with those who received sildenafil alone, were shown to have experienced numerical or statistically significant improvements for mean IIEF (or IIEF–5) scores for the "EF domain" and

individual Q1–Q15 items,[104,106,158,162,169,173] higher frequency of penetration and maintenance of erection (mean scores for IIEF–Q3/Q4),[112,150,162,173] improved mean duration of rigidity of the tip/base of the penis (≥60 percent),[105] and a greater proportion of participants with improved erection (positive responses to GEQ–Q1).[112] However, in three trials[104,158,169] there was no statistically significant difference between the combination therapy and monotherapy groups in mean PSV values[104,158] or the proportion of patients with improved erection (positive responses to GEQ–Q1).[169]

Sildenafil versus other active treatment. This review included five trials in which the efficacy and harms for sildenafil and other active treatment were compared.[106,124,132,155,173] These therapies were psychotherapy,[106] continuous positive air pressure (CPAP),[155] phentolamine, [124] Ro70–0004 (i.e., α1A-adrenoceptor antagonist),[132] and alfuzosin.[173]

Harms. Among these five trials,[106,124,132,155,173] the incidence of any adverse event was reported in only one, in which more participants were found to have experienced one or more adverse event in the 40 mg phentolamine treatment group as compared with the flexible-dose (25 mg to 100 mg) sildenafil treatment group (41.2 versus 33.3 percent).[124] More patients in the phentolamine group than in the sildenafil group experienced respiratory (17.6 versus 8.9 percent) and digestive (12.6 versus 9.8 percent) adverse events. The most frequent adverse events that occurred during the trial were headache and rhinitis.[124] In the phentolamine treatment group, three participants (2.5 percent) experienced serious adverse events, as compared with only one participant (0.8 percent) in the sildenafil treatment group. These events were flushing, chest pain, shortness of breath with tachycardia in one participant, and cerebrovascular event and worsening of existing pterygium in the other two participants. One participant in the sildenafil treatment group experienced a rupture of the Achilles tendon.[124]

The rate of withdrawals due to adverse events was reported in two trials,[124,173] in which it was higher among participants receiving phentolamine[124] or alfuzosin[173] than among those receiving sildenafil alone. The rates of withdrawals due to adverse events in participants treated with sildenafil in two trials were <1.0 percent[124] and 9.5 percent.[173] The corresponding rates for participants treated with phentolamine and alfuzosin were 3.4 percent[124] and 10 percent,[173] respectively.

Efficacy. In two trials[124,155] sildenafil use was associated with a statistically significant increase in the proportion of successful intercourse attempts, the mean IIEF "EF" domain score, and improved erections (GEQ–Q1), in comparison with the use of CPAP[155] and phentolamine.[124] In two other trials,[132,173] administration of sildenafil resulted in only numerical improvement in the mean duration of rigidity at the base/tip of the penis (>60 percent),[132] mean IIEF scores for the "EF domain," as well as the frequency of penetration/maintenance of the erection (mean scores for IIEF–Q3/Q4),[173] in comparison with treatment with Ro70-0004[132] or alfuzosin.[173] In one trial,[106] post-treatment mean IIEF scores were lower among those treated with sildenafil in comparison with those treated with psychotherapy, but the statistical significance was marginal (52.8 versus 62.5, $p = 0.049$).

Quantitative Synthesis - Meta-analysis of Trials

Monotherapy (any dose: 10, 25, 50, 100 mg) versus placebo. In 62 trials the efficacy and harm-related effects of sildenafil compared with placebo in the treatment of ED were

investigated.[78-91,93-99,101,102,104,105,107-111,115,122,123,125,126,128,130-135,137,138,142,143,146,147, 149,151,156,160,164,168, 171,175]

The quantitative analysis was considered separately for two groups of trials (n = 62), as follows:

Trials conducted in clinically heterogeneous groups of participants with ED (with no established specific organic cause) (n = 34)

Trials conducted in clinically homogenous groups of participants with ED (participants diagnosed additionally with specific clinical conditions (2a-2e) (n = 28)

The 34 clinically heterogenous trials were potentially eligible for the meta-analyses (24 parallel-arm and 10 crossover).[80,82,83,85-90,95-97, 105, 110,111,122,125,126,130,132,134,135,137,138,142,146, 149,151,156, 166,171] None of the 10 crossover trials[85,89,105, 130,132, 134,146,149] however, were incorporated in the meta-analyses (pre-crossover phase data were not reported), leaving 24 trials for further consideration.[80,82,83,86-88,90,95-97,110,111,122,125,126,135,137,138,142,151,156,166,171]

Efficacy. Absolute endpoint mean IIEF "EF" domain score. The meta-analysis was based on two trials. [88,126] The pooled estimate of mean difference was 6.39 (95 percent CI: 2.89–9.90), indicating a statistically significant improvement in the mean IIEF "EF" domain score for participants receiving sildenafil (any dose) compared with those receiving placebo (Figure 3).

Absolute endpoint mean IIEF–Q3/Q4 scores. The two meta-analyses yielded statistically significant pooled estimates of mean differences for both IIEF–Q3 (mean difference 1.46, 95 percent CI: 1.26–1.65) and IIEF–Q4 (mean difference 1.52, 95 percent CI: 1.21–1.82). Thus, the use of sildenafil was associated with statistically significant improvements with respect to penetration and erectile maintenance frequency (Figures 4–5).

Proportion of participants with improved erection (GEQ–Q1). This meta-analysis included 17 trials including two trials reported in Young et al. (2002).[80,82,83,86-88,90,95,97,125, 126,137,138,142,151,156] The pooled estimate of relative risk (RR) of 2.61 (95 percent CI: 2.34–2.91) indicated a greater proportion of participants experiencing improved erection (i.e., those who answered "yes" to GEQ–Q1) in the sildenafil than in the placebo treatment groups (Figure 6).

Sensitivity analysis was performed with respect to the duration of sildenafil treatment. The duration of sildenafil treatment in 11 trials lasted 12 weeks.[80,83,87,97,125,126,137,138,142,151,156] The duration of treatment in the remaining trials was 6 weeks,[90] (studies a and b) 8 weeks,[82] 16 weeks,[95] and 26 weeks.[86,88] The meta-analysis restricted to trials with 12-week treatment did not appreciably affect the magnitude of the effect estimate and the degree of I^2 test for heterogeneity, which decreased from 51.9 percent to 50.0 percent.

Harms. 24 trials (including trials with participants with psychogenic ED),[96,110] were considered for the meta-analysis of adverse events.[80,82,83,86-88,90,95-97,110,111,122,125,126,135,137, 138,142, 151,156,166,171] (note that "favors" in forest plots refers to increased frequency of the event for the respective treatment arm, regardless of the desirability of the event).

Proportion of participants with at least one adverse event (all cause). The pooled estimate of RR suggested that participants randomly assigned to receive sildenafil were at a higher risk of developing any all-cause adverse event than those receiving placebo (RR = 1.51, 95 percent CI: 1.32–1.72) (Figure 7).

Proportion of participants with at least one adverse event (treatment-related). This meta-analysis incorporated 11 trials.[80,82,83,87,90,97,125,135,137,156] The meta-analysis yielded a pooled RR of 2.56 (95 percent CI: 2.17–3.03), indicating that participants randomly assigned to receive sildenafil were at a higher risk of developing any treatment-related adverse event than those receiving placebo (Figure 8).

Proportion of participants with headache (all cause). This meta-analysis was based on 16 trials.[80,82,83,86-88,95-97,122,125,126,137,142,151,166] The pooled estimate of RR indicated that participants randomly assigned to receive sildenafil were at a higher risk of having a headache than those receiving placebo (RR = 2.57, 95 percent CI: 2.09–3.18) (Figure 9).

Proportion of participants with flushing (all cause). This meta-analysis is based on 16 trials.[80,82,83,86-88,95-97,122,125,126,137,142,151,166] The meta-analysis yielded a pooled RR of 5.34 (95 percent CI: 3.32–8.58), indicating that participants randomly assigned to receive sildenafil were at a higher risk of having flushing than those receiving placebo (Figure 10).

Proportion of participants with visual disturbances. This meta-analysis is based on 20 trials.[80,82,83,86-88,90,95,97,122,125,126,135,137,138,142,151,156,171] The pooled estimate of RR suggested that participants randomly assigned to receive sildenafil had a statistically significant greater risk of developing visual disturbances than those receiving placebo (RR = 3.66, 95 percent CI: 2.27–5.92) (Figure 11).

Twenty-eight trials of clinically homogenous groups compared the efficacy/safety of sildenafil to that of placebo in patients with distinct, specific clinical conditions.[78,79,81,84,91,93,94,98,99,101,102,104,107-109,115,123,128,131,133,143,147,160,164,165,167,168,175] Of these, 13 trials were single trials per disease and were not considered further for meta-analysis. Thus, 15 trials were deemed as potentially eligible for the meta-analyses. The trials were conducted in participants diagnosed with diabetes,[81,93,94,98,101] depression,[79,91,115,167] congestive chronic heart failure,[102,109] hypertension,[143,147] or who were on dialysis.[108,123]

Four trials with patients with diabetes could be pooled[81,94,98,101] with respect to IIEF–Q3/Q4, GEQ–Q1, and treatment-related adverse events. The meta-analyses were based on trials involving patients with Type I and Type II diabetes combined, as well as trials involving only patients with Type II (Figures 12–17).

Efficacy. Proportion of participants with improved erection, GAQ–Q1, mean IIEF–Q3/4 score. The pooled effect estimates of meta-analyses of diabetic patients were all statistically significant, favoring the use of sildenafil over that of placebo to improve the erection (GEQ–Q1) in both Type I and II (RR = 4.25; 95 percent CI: 2.60- 6.93) as well as only in Type II patients, (RR = 5.33, 95 percent CI: 3.89–7.29). The pooled effect estimates for penile penetration ability (IIEF–Q3) (WMD: 1.03, 95 percent CI: 0.34–1.73) and erectile maintenance frequency (IIEF–Q4) (WMD: 1.15, 95 percent CI: 0.74–1.55) were also statistically significant in favor of sildenafil (Figures 12–15).

Harms. Proportion of participants with at least one treatment related adverse event. In the meta-analysis of combined Type I and Type II diabetes patients, a high degree of heterogeneity was found (I^2 = 72.2 percent) (Figure 16). To explore the source of this heterogeneity, a sensitivity analysis was performed with respect to Type I and Type II diabetes. The meta-analysis based on Type II diabetes patients yielded a lower degree of heterogeneity (I^2 = 24.4 percent), and the pooled effect estimate of the meta-analysis suggested that participants receiving sildenafil had a statistically significant increased risk of having any treatment-related adverse event in comparison with those receiving placebo (RR = 9.08, 95 percent CI: 4.01–20.54) (Figure 17).

Four trials compared sildenafil to placebo in participants with depression.[79,91,115,167] Of these, three trials[91,115,167] involved participants with major depressive disorder (MDD) in remission. In two of these trials,[91,167] participants had ED associated with the use of antidepressants, namely, selective serotonin reuptake inhibitors (SSRIs). In the third trial,[115] about 28 percent of the participants used SSRIs. The three trials[91,115,167] were deemed to be potentially combinable.

Given that the fourth trial[79] looked at ED patients who had depression but were not being treated with antidepressants at the time of their enrollment (this being one of the exclusion criteria), SSRI use could not be considered the cause of the ED, and the trial was therefore not combined with the other three for meta-analysis.[91,115,167]

The results for the following efficacy outcomes (i.e., numerical effect estimates and standard deviations [SDs]) were ascertained from the three trials: percentage of successful intercourse attempts,[115,167] patients with improved erection (GEQ–Q1),[115,167] and mean IIEF–Q3/Q4 score.[91,115] The mean IIEF–Q3/Q4 scores and the corresponding SDs were ascertained graphically from one trial.[115] Separate meta-analyses for these efficacy outcomes are presented (see Figures 16–19). No meta-analysis for adverse events could be performed, due to a lack of sufficient detail for the adverse events definitions provided in the trials. Note that one trial[91] included younger patients (mean: 45, range 18–55 years) compared with the other trial (mean: 53, range 24–75 years).[115]

Efficacy. Percentage of successful intercourse attempts, proportion of patients with improved erection, mean IIEF–Q3/Q4 score.

The pooled effect estimates of meta-analyses based on participants with depression were statistically significant, favoring the use of sildenafil over placebo with respect to: increasing the percentage of successful intercourse attempts (RR = 2.44, 95 percent CI: 1.87–3.18); improving erection, GEQ–Q1 (RR = 2.40, 95 percent CI: 1.87–3.06); improving penile penetration ability, IIEF–Q3 (mean difference 1.26, 95 percent CI: 0.82–1.70); and improving erectile maintenance frequency, as assessed by IIEF–Q4 (mean difference 1.48, 95 percent CI: 0.96–1.99) (Figures 18–21).

Two sildenafil versus placebo trials conducted in participants with chronic congestive heart failure (CHF) were potentially combinable.[102,109] However, no meta-analysis was performed in view of the fact that the only common outcome reported in both trials was the mean IIEF "EF" domain score, for which numerical values of the measures of variability—SD or standard error (SE) could not be ascertained. One of the trials[102] used a crossover design; it reported pre-crossover results graphically, without presenting numeric measures of the variability. In the same trial, no participant had any adverse events; therefore, no meta-analysis for adverse events was performed.

There were two trials that looked at patients with chronic renal failure on peritoneal dialysis. Although they were both eligible for meta-analysis (with respect to the mean IIEF "EF" domain score),[108,123] they could not be pooled in view of a lack of complete numerical data (i.e., a SD or SE) in one of the trials.[108] A meta-analysis for adverse events was also not feasible, since in one of the trials[108] only one event was observed.

Meta-analysis was possible for sildenafil versus placebo trials involving hypertensive patients using multiple antihypertensive drugs (i.e., two or more different classes).[143,147] The meta-analyses were performed for efficacy outcomes (i.e., mean IIEF–Q3/Q4, GEQ–Q1, percentage of successful intercourse attempts) as well as all-cause and treatment-related specific adverse events (headache, flushing, and dyspepsia) (Figures 22–29).

Efficacy. Mean IIEF–Q3/Q4, GEQ–Q1, percentage of successful intercourse attempts.

The mean IIEF–Q3/Q4 scores with respective SDs were ascertained from the reports of both trials, as well as for GEQ–Q1, along with the percentage of successful intercourse attempts (see Figures 20–23). The pooled effect estimates indicate a statistically significant improvement in patients receiving sildenafil in comparison with those receiving placebo with respect to: improving penile penetration ability, IIEF–Q3 (mean difference 1.09, 95 percent CI: 0.59–1.58);

erectile maintenance frequency, IIEF–Q4 (mean difference 1.34, 95 percent CI: 0.75–1.93); erection, as assessed by GEQ–Q1 (RR = 3.07, 95 percent CI: 1.81–5.19); and percentage of successful intercourse attempts (RR = 2.41, 95 percent CI: 1.99–2.92) (Figures 22–25).

A high degree of heterogeneity with respect to the proportion of patients with improved erection (GEQ–Q1) was present across the two trials (I^2 = 83.2 percent) (Figure 24). Although the effect size for the two estimates of the RR was in the same direction, the magnitude of this effect differed between the two trials (2.33[143] versus 3.94[147]). One explanation of this finding could be the disparate rates of improvement on GEQ observed in the placebo arms of these trials (29 percent[143] versus 18 percent[147]). Note that the respective rates in the sildenafil arms were quite similar (73 percent versus 71 percent). The higher rate of improvement on GEQ for the placebo arm in the first trial[143] resulted in the smaller effect size (RR = 2.33). This could be explained by a higher proportion of participants with a mild to moderate form of ED, which may have resulted from the difference between the two trials in with respect to the use of inclusion criteria based on IIEF scores (≤25[143] versus ≤21[147]). Moreover, other contributing factors for the observed differences for the improvement rates between the two placebo arms could have been due to the fewer patients with organic ED (18 percent[143] versus 51 percent[147]) and a shorter mean duration of ED in the first trial (2.2 years[143] versus 4.5 years[147]). The two trials employed similar dosing regimens (from 50 mg to 25 mg or 100 mg) and duration of sildenafil treatment (6–8 weeks).[143,147]

Harms. Incidence of any adverse event: headache, dyspepsia, flushing.

The pooled RR estimates showed a statistically significant increase in risk among participants treated with sildenafil compared with those receiving placebo for all-cause adverse events (RR = 1.72, 95 percent CI: 1.33–2.24) and for the treatment-related specific events such as headaches (RR = 6.32, 95 percent CI: 1.92–20.85), dyspepsia (RR = 8.31, 95 percent CI: 1.54–44.86), and flushing (RR = 7.10, 95 percent CI: 1.58–31.95) (Figures 26–29).

Meta-analysis of trials comparing different doses of sildenafil (dose-response effect).

The dose-response efficacy/harm effect of sildenafil given at a fixed dose (10 mg, 25 mg, 50 mg, and 100 mg) was assessed in six trials.[78,85,86,93,96,137] Of these, two trials were conducted in clinically distinct groups of participants (those with spina bifida[78] and diabetes[93]) and therefore were not included in the meta-analysis. Therefore, the meta-analysis exploring the dose-response effect of sildenafil was based on three trials.[86,96,137]

The following two pair-wise comparisons were made:

1) Sildenafil 25 mg versus sildenafil 50 mg

2) Sildenafil 50 mg versus sildenafil 100 mg

The efficacy and harm outcomes examined in the meta-analysis (i.e., those assessed and reported in sufficient detail in all three trial reports) were the proportions of participants with improved erection (GEQ–Q1) and the proportions of participants who experienced a specific all-cause adverse event (i.e., headache, flushing, or visual disturbances) (Figures 30–37).

Sildenafil 25 mg versus sildenafil 50 mg – Efficacy. Proportion of participants with improved erection (GEQ–Q1). A statistically significant greater proportion of participants in the 50 mg sildenafil treatment group reported improved erection (GEQ–Q1) in comparison with the 25 mg group (RR = 1.19, 95 percent CI: 1.06–1.34) (Figure 30).

Sildenafil 25 mg versus sildenafil 50 mg - Harms. Proportion of participants with headache, flushing, or visual disturbances.

The pooled estimates for the observed between-group (50 mg sildenafil versus 25 mg sildenafil) differences with respect to proportions of participants experiencing all-cause

headaches (RR = 1.02, 95 percent CI: 0.69–1.50) and visual disturbances (RR = 2.87, 95 percent CI: 0.70–11.80) were not statistically significant (Figures 31 and 33). The latter result may have been due to the small sample of the meta-analysis (Figure 31). The incidence of all-cause flushing was significantly greater among participants receiving the higher 50 mg dose of sildenafil (RR = 1.65, 95 percent CI: 1.13–2.42) (Figure 32).

Sildenafil 50 mg versus sildenafil 100 mg – Efficacy. Proportion of patients with improved erection.

The difference in the proportion of participants with improved erection (i.e., those who answered "yes" to GEQ–Q1) between the 50 mg and 100 mg sildenafil treatment groups was not statistically significant (RR = 1.10, 95 percent CI: 1.00–1.20) (Figure 34).

Sildenafil 50 mg versus sildenafil 100 mg - Harms.

Proportion of patients with all-cause headache, flushing, or visual disturbances. There was no statistically significant difference between the 100 mg and 50 mg sildenafil treatment groups in the incidence of all-cause headaches (RR = 1.31, 95 percent CI: 0.93–1.84), flushing (RR = 0.87, 95 percent CI: 0.61–1.23), and visual disturbances (RR = 4.18, 95 percent CI: 0.44– 39.54) (Figures 35–37).

Assessment of Publication Bias

Funnel plots were generated to assess the extent of asymmetry for each meta-analysis. Visual inspection of these plots did not reveal any substantial asymmetry. [53] (Figures D-1-8, Appendix D).

Oral Treatments — Phosphodiesterase Type 5 (PDE–5) Inhibitors – Vardenafil

Literature Search

In total, 22 unique randomized controlled trials (RCTs) (31 publications) met the eligibility criteria and were included in the review.[180-210](see also summary Evidence Table F-2, Appendix F) Seven unique trials were reported in more than one publication. The following list shows the reference identifications for these trials and corresponding publications (each row).

The first reference (author, year, citation) denotes the primary publication (i.e., reporting the most relevant and complete data for the trial), which is used to designate the trial throughout the Vardenafil section.

1. Valiquette 2005[182] and Valiquette 2006[202]
2. Nehra 2005[183] and Brock 2003[187]
3. Carson 2005[184] and Hatzichristou 2005[188]
4. Hatzichristou 2004[191] and Hatzichristou 2005[207]
5. Porst 2001[194] and Porst 2003[185]
6. Goldstein 2005[197] and Fisher 2005[186]
7. Hellstrom 2002,[192] Hellstrom 2003,[208] Hellstrom 2005,[209] and Donatucci 2004[210]

Overview of Trials

The trials were conducted in North America,[181-184,190,190,192,192,197,197-199,199,203] Europe,[184,190,191,193-201,203,204] South America,[182,190,203] and Asia.[180,182,184,189,203,203,205,206]

Of the 22 trials, two were of crossover design[193,195] and the remaining 20 trials used parallel-arm design. All but one (active arm-controlled)[190] were placebo-controlled trials.

The trials were supported by Bayer[181,183,189,190,192-195,197,198,200,201,203,205] Bayer and GlaxoSmithKline,[182,184,191,196,199] and GlaxoSmithKline.[204] Funding sources could not be ascertained for two trials.[180,206]

Populations

The included trials involved participants diagnosed with ED. The total and mean numbers of patients randomly assigned to an intervention or placebo across the 22 trials were 8,621 and 392, respectively, while the number of randomly assigned patients in each trial ranged from 21[193] to 1020.[190]

The inclusion criteria across most of the included trials were: adult males aged ≥18 years, diagnosed with ED for ≥ 6 months in a stable monogamous heterosexual relationship.[180-184,189-195,197-201,203,204] In one trial,[205] the inclusion criteria for the patients' age and duration of ED were slightly different (≥20 and ≥5 years, respectively). In the report of one trial[206] the patient inclusion criteria for age and duration of ED were not clear.

The additional inclusion criteria in seven trials were diagnoses for the following conditions: diabetes types I or II,[181,205] diabetes type I,[204] nerve-sparing retropubic prostatectomy,[183] history of renal transplant,[206] untreated mild major depressive disorder,[199] or arterial hypertension.[196] One trial included ED patients who had not responded to previous sildenafil therapy.[184] In three trials, the included patients were sildenafil-naïve.[180,201,204] In one of these trials,[180] patients had not received any previous treatment for ED.

In most trials, patients had ED with a broad spectrum of causes (i.e., organic, psychogenic, and mixed).[180,182,184,189-195,197,198,200,201,203] The mean age across the 22 trials ranged from 34 years[195] to 60 years.[183,184]

Exclusion criteria were not reported for two trials.[180,200] Patients with the following conditions were excluded from the trials: primary hypoactive sexual desire[181-184,190-193,196-199,201,203-205] penile/genital anatomical deformity,[182,184,189-192,195-199,201,203,204,206] any medical psychiatric or substance abuse disorder affecting the ability to complete the study,[182,184,189,199,201,205] ED resulting from spinal cord injury,[181-184,189-199,201,203-205] cardiovascular conditions (e.g. coronary artery disease, myocardial infarction, electrocardiographic ischemia, life-threatening arrhythmia, stroke, uncontrolled atrial tachyarrhythmia, unstable angina pectoris, uncontrolled atrial fibrillation),[181-184,189-193,195-198,201,203-206] hyper/hypotension (resting),[181-184,189-193,195,196,201,203-206] postural hypotension,[182,183,189,192,196,201,204,205] liver disease,[181,183,189,191,192,196,198,201,204-206] radical prostatectomy,[190-199,201,203-205] bleeding or hematological disorder,[181,183,189,191,192,198,201,203,204,206] retinitis pigmentosa,[181-183,190,192,193,195-199,203-205] poorly controlled diabetes mellitus,[182,183,189-195,198,203] hepatitis B,[189,192,194,195,198,203] hepatitis C,[189,192,194,196,201,204] peptic ulceration,[183,189,192,201,205,206] major psychiatric disorders,[193,195,199] endocrine diseases,[193,195] autonomic neuropathy,[181] or prostate cancer.[183]

The following concomitant medications were not allowed: nitrates or nitric oxide donors,[181-184,189,191-198,201,203-206] cimetidine, erythromycin, ketoconazole or trazodone, current use of digoxin derivatives or digitoxin antiarrhythmics,[189,192,194,196-198,201,204] anticoagulants,[181-183,192,194,196-198,201,204] androgens,[192,196-198,201,203,204] ketoconazole,[194,196,197,204] alpha blockers,[196-198,201] or rifampicin.[189,194]

Patients with abnormal hormone profiles such as low serum total testosterone,[182-184, 189,192,194,201,203] elevated serum creatinine,[184,189,192,196,201,203,204] serum free thyroxine (T4) out of the normal range,[189] or thyroid-stimulating hormone (TSH) below the normal range were also excluded.[189,194]

Also excluded were sildenafil nonresponders[189-194,198,199,203] and patients who had discontinued previous sildenafil treatment because of side effects.[181,183,189-191,198]

Interventions

The patients in all 22 included trials were randomly assigned to receive monotherapy of oral vardenafil at either a fixed or a flexible dose. In 12 trials,[180-183,189,190,192-195,198,205] vardenafil was administered at a fixed dose ranging from 5 mg/d[189,192,194] to 40 mg/d,[193] whereas in the remaining 10 trials a flexible dose with upward and downward titration was used, depending on the observed response in terms of efficacy and tolerability (i.e., 10 mg/d, 5 mg/d, 20 mg/d).[184,191,196,197,199-201,203,204,206]

The patients were randomly assigned to receive placebo in all but one trial,[190] in which two doses (10 mg/d and 20 mg/d) of vardenafil were compared. In one trial the study medication (i.e., vardenafil) was coadministered with visual sexual stimulation.[195]

In 10 trials patients were randomly assigned to receive two or more different fixed doses of vardenafil in each arm: 10 mg/d versus 20 mg/d,[181,183,190,195,198,205] 5 mg/d versus 10 mg/d versus 20 mg/d,[189,192,194] and 20 mg versus 40 mg.[193]

In the majority of included trials, the duration of treatment with vardenafil was about 12 weeks.[181-184,189,194,211] The treatment duration across the trials ranged from 4 weeks[198,206] to 24 months.[190]

Patients were instructed to take the study medication one hour before their sexual activity[182-184,189-192,194,196,204-206] or as needed[181,198] for maximum of one dose per day. In one trial patients were instructed to take the dose 8 hours before sexual activity for up to one dose a day.[203] Five trials did not report the dosage instructions clearly.[180,197,199-201]

Outcomes

Harms. The presence or absence of any adverse events was reported in eight trials.[182-184,189,191,193,200,203] The presence or absence of serious adverse events was reported in 18 trials.[181-184,190-198,200,201,203-205] The presence or absence of withdrawals due to adverse events was reported in 19 trials.[181-184,189-199,201,203-205]

Efficacy. The most commonly reported outcomes that measured the degree of ED were: the mean IIEF scores for the "Erectile Function" domain (endpoint or mean change from baseline);[181-184,189-192,194,196-201,203-206] the mean endpoint score/mean score changes on questions two and three of the Sexual Encounter Profile (SEP–Q2: "*Were you able to insert your penis into your partner's vagina?*" and SEP–Q3: "*Did your erection last long enough for you to have successful intercourse?*")[181-184,190-192,196-201,203-205] and a Global Assessment Question (GAQ–Q1: "*Has the treatment you are taking improved your erection?*").[181-184,189-192,196,199-201,203]

Other commonly reported outcomes were total mean scores for the following IIEF domains: "Intercourse Satisfaction,"[183,194,198,204] "Overall Satisfaction,"[183,194,198,204] "Orgasmic Function,"[183,194,204] "Sexual Desire,"[194,204] and the mean scores for individual IIEF questions Q3/Q4 (i.e., penetration and maintenance frequency).[183,189,194,200,205]

Other less frequently reported outcomes were measured using the following instruments: Center for Epidemiologic Studies Depression Scale (CES-D),[183,190,199] the quality of life (QoL) Fugl-Meyer assessment,[189,190,194] the Rosenberg Self-Esteem Scale,[199,200] tip and base rigidity activity unit (RAU) and tumescence activity units (TAU),[193,195] the duration of erection with rigidity of >60 percent (or >80 percent),[193,195] patient's diary of satisfaction with erection/ejaculation,[191] ED severity,[206] endothelial function of cavernous and brachial arteries (flow mediated dilation: FMD),[180] and sexual quality of life domain from the modified Sexual Life Quality Questionnaire (mSLQQ).[197]

Study and Reporting Quality

The mean total Jadad score for the 22 trials was 3.3 (Appendix C, Table C-1). The Jadad total score for the individual trials ranged from one[206] to five.[191,197] The methods for generating the sequence of random assignment were described for four studies[183,191,192,197] and were judged to be appropriate. All trials except for one[206] were described as double-blind. For all trials except for one[189] the methods for treatment allocation concealment were judged to be "unclear." The method of allocation concealment reported in the above-mentioned trial was deemed to be appropriate.[189] Both crossover trials[193,195] employed a washout period of five days.

Qualitative Synthesis

Vardenafil (any dose, fixed dose, flexible dose) versus placebo. This section presents results derived from 21 placebo-controlled trials that compared the efficacy and harms profile of vardenafil (any dose) to that of placebo.[180-184,189,191-201,203-206] One trial[190] that explored a dose-response effect of vardenafil, without using a placebo arm, is reviewed in a later section (vardenafil dose 1 versus vardenafil dose 2).

Harms. Of the 21 trials, harms-related data were reported in all but one.[180] Therefore, this section describes harms reported in 20 trials.[181-184,189,191-201,203-206]

Any all-cause adverse events. This outcome was reported in eight trials, where it was shown that the incidence of any adverse events (number of patients with one or more adverse event),[182-184,189,191,193,200,203] was higher (either numerically or with statistical significance) in vardenafil groups (regardless of vardenafil dose or dose regimen) than in placebo groups. The proportions of patients with one or more adverse event in vardenafil groups across the trials ranged from about 27 percent (10 mg dose)[182] to 74 percent (20 mg dose).[189] The corresponding proportion for the placebo groups ranged from about 17 percent[200] to 52 percent.[189]

Specific adverse events. In general, vardenafil was described as well tolerated. Most adverse events were reported as mild or moderate in nature and followed a profile similar to that seen in other medications of the PDE–5 class (e.g. sildenafil, tadalafil). Most commonly, patients in the vardenafil arms experienced headache, flushing, rhinitis, and dyspepsia.

Withdrawals due to adverse events. Two[200,206] of the 20 trials[181-184,189,191-201,203-206] did not report the proportion of withdrawals due to adverse events. Overall, the rate of withdrawals due to adverse events (i.e., the proportion of patients) in vardenafil and placebo-treated groups of patients were numerically similar. The withdrawal rate in vardenafil groups across the 18 trials[181-184,189,191-199,201,203-205] ranged from 0 percent[193,195,198] to 5 percent.[192] The corresponding rate for the placebo-treated patients ranged from 0 percent[193,195,203] to 6 percent.[189] Some of the reported specific events leading to the withdrawals were myocardial infarction, proctalgia, aortic bifurcation graft,[212] abnormal liver enzyme levels,[182,192] myalgia, flushing,[181,182] nausea,[192] headache,[181,191,192] kidney calculus,[192] abnormal vision, and rhinitis.[181]

Serious adverse events. The absence or occurrence of serious adverse events could not be ascertained for three trials.[189,199,206] The specific serious adverse events observed across the trials in patients after random assignment to vardenafil therapy were: skin ulcer,[198] reflux disease,[198] unstable angina,[197] myocardial infarction,[198,201] syncope and encephalitis[198] aortic bifurcation,[201] facial palsy, and appendicitis.[182] Serious adverse events that occurred in 10 trials were not specified.[181,183,184,191,192,194,196,203-205] In three trials[193,195,200] reportedly no serious adverse events occurred. In general, judging from the results of these trials, there were no obvious numerical or statistical differences in the occurrence of serious adverse events between patients randomly assigned to receive vardenafil and those assigned to placebo.

Vardenafil (fixed dose: 5 mg, 10 mg, 20 mg, 40 mg) versus placebo. In 11 trials vardenafil was administered at a fixed dose (5 mg, 10 mg, 20 mg, and/or 40 mg).[180-183,189,192-195,198,205]

The results of all trials demonstrated statistically significant improvements for patients who received vardenafil (5 mg, 10 mg or 20 mg) compared with those treated with placebo after 12 weeks of treatment (or longer followup) with respect to the mean IIEF scores for the "EF domain,"[181-183,189,192,194,198,205] IIEF–Q3/Q4,[189,194] SEP–Q2/Q3,[181,182,192,198,205] GAQ–Q1,[181,182,189,192,194] and the mean IIEF scores for the domains of "Intercourse Satisfaction," "Overall Satisfaction," "Sexual Desire," and "Orgasmic Function."[183,194]

Results obtained from two trials[193,195] showed a statistically significant increase in the mean duration (in minutes) of penile tip/base rigidity (>60 percent) in patients randomly assigned to receive vardenafil at a dose of 10 mg,[195] 20 mg,[193,195] or 40 mg,[193] as compared with those randomly assigned to receive placebo.

In one trial,[180] patients treated with vardenafil (20 mg), in comparison with those treated with placebo, experienced a statistically significant improvement in endothelial function measured by the degree of brachial artery flow-mediated dilation (13.0 percent versus 10.7 percent).

The beneficial effects of vardenafil use relative to that of placebo observed in trials of homogeneous clinical groups such as diabetes,[181,205] nerve-sparing retropubic prostatectomy,[183] and no previous ED treatment[180] were consistent with those of other trials conducted in participants with ED and a wide spectrum of diseases.[182,189,192-195,198]

Treatment efficacy subgroup analyses (i.e., stratified efficacy results) were reported for five trials with respect to the origin of ED,[180,194] baseline severity of ED,[182,192,194] age groups,[194] and previous sildenafil use.[194,198] The results of these analyses indicated numerically greater improvements associated with milder forms of ED,[192,194] no previous use of sildenafil (i.e., sildenafil-naïve patients),[198] and arteriogenic ED (versus organic nonarterial or psychogenic ED).[180] In one of these trials,[194] the degree of improvement in IIEF "EF" domain scores was not modified by age, previous sildenafil use or the origin of ED (organic, mixed, or psychogenic).

Vardenafil (flexible dose: 5 mg- 10 mg- 20 mg) versus placebo. Ten trials administered vardenafil with a flexible daily dose (5 mg, 10 mg, 20 mg).[184,191,196,197,199-201,203,204,206] The results of all trials demonstrated statistically significant improvements for patients receiving a flexible dose of vardenafil compared with those treated with placebo after 12 weeks of treatment (or longer followup) with respect to the mean IIEF scores for "EF domain,"[184,191,197,199-201,203, 204, 206] IIEF–Q3/Q4,[200,206] SEP–Q2/Q3,[184,191,196,197,199-201,203,204] and GAQ–Q1.[184,191,196,199-201,203] Statistically significant improvements in vardenafil-treated patients, relative to those on placebo, were also observed with respect to mean scores for the following IIEF domains: "Intercourse Satisfaction," "Overall Satisfaction," "Orgasmic Function"[199,200] and/or "Sexual Desire."[199,204]

In four trials,[184,201,203,204] at followup after 12 weeks of treatment, a statistically significant greater proportion of patients with an IIEF "EF" domain score ≥26 was found in groups treated with vardenafil compared with those who received placebo.

The relative beneficial effects of vardenafil use with respect to the above-mentioned outcomes observed in trials of homogeneous clinical groups, such as patients with diabetes,[204] renal transplant,[206] untreated mild major depressive disorder,[199] or arterial hypertension,[196] as well as sildenafil nonresponders[184] and sildenafil- naïve patients[201,204] were consistent with those of other trials conducted in participants with ED and a wide spectrum of diseases.[191,197,200,203]

Treatment efficacy subgroup analysis (i.e., stratified efficacy results) was reported for only one trial[191] with respect to dose-sequence, in which patients who received a stable dose of 10 mg vardenafil over 12 weeks experienced greater improvements on the mean scores for IIEF "EF domain," SEP–Q2/Q3, and the proportion for GAQ–Q1 compared with those who gradually increased their vardenafil dose to 20 mg over the followup of 8 weeks.

Vardenafil dose 1 versus vardenafil dose 2. There were 10 trials with two or more dose-specific arms of vardenafil.[181,183,189,190,192-195,198,205] None of the trials were designed to compare flexible and fixed dosage regimens of vardenafil.

Harms. Any all-cause adverse events.

In seven[183,189,190,192,193,195,205] of the 10 dose-response studies,[181,183,189,190,192-195,198,205] the incidence of any adverse events was shown to be numerically dose-dependent, increasing with a

higher dose. In one multicenter North American study, for example, after 26 weeks of treatment with 5 mg, 10 mg, or 20 mg of vardenafil or placebo 19, 33, 42 and 7 percent of patients, respectively, experienced at least one adverse event.[192] In a trial of similar design of 12 weeks' duration, these proportions were 57, 63, 74, and 52 percent, respectively.[189] The similar trend was observed in a trial that compared 20 mg and 40 mg doses of vardenafil (47.6 versus 60.9 percent, respectively).[193] Statistical test results for these differences were not reported.

Specific adverse events. The most frequently observed adverse events in the 10 trials were headache, flushing, dyspepsia, or rhinitis. In one trial,[190] eight and 13 patients developed visual disturbance(s) in the 10 mg and 20 mg groups, respectively. In another trial,[189] two patients (one patient in each 5 mg and 20 mg groups) were observed to have visual disturbances (sensory, abnormal vision, and brightening).

Withdrawals due to adverse events. In three trials,[193,195,198] none of the patients treated with vardenafil withdrew because of adverse events. For the remaining seven trials,[181,183,189,190,192,194,205] the rate of withdrawals was numerically similar between treatment arms using 10 mg versus 20 mg of vardenafil.[181,183,189,190,192,194,205]

Serious adverse events. There was no apparent numerical or statistically significant difference in the occurrence of serious adverse events across the treatment arms of various doses of vardenafil. For example, one trial reported 4, 1, and 1.4 percent of patients with at least one serious adverse event in 5 mg, 10 mg, and 20 mg vardenafil groups, respectively.[194] In another study, the corresponding proportions of patients with at least one serious adverse event were 5, 3, and 4 percent.[192] Four deaths were reported during one trial;[190] one death resulted from suicide (10 mg group), while the other three (in the 20 mg group) occurred after myocardial infarction, coronary angioplasty, and ischemic cardiomyopathy. None of the deaths was attributed to the effects of vardenafil.

Efficacy. In three trials,[189,192,194] at 12 weeks after randomization, a dose-related effect of vardenafil with respect to the mean IIEF "EF" domain score was observed. Specifically, patients in either 10 mg or 20 mg vardenafil groups had statistically significant higher mean IIEF "EF" domain scores compared with those in the 5 mg vardenafil groups. Although for five trials[189,190,192,194,198] the differences in the mean IIEF "EF" domain scores observed between the 10 mg and 20 mg were not statistically significant, patients receiving 20 mg of vardenafil had numerically greater scores than those receiving 10 mg vardenafil.

In two trials,[181,205] patients treated with 20 mg had statistically significantly higher mean IIEF "EF" domain scores compared with those treated with 10 mg vardenafil: 19.0 versus 17.1[181] and 22.9 versus 21.8.[205] In another trial,[183] the mean IIEF "EF" domain score was similar for patients receiving 10 mg and 20 mg of vardenafil (7.7 versus 7.2, respectively).

After 12 weeks of treatment, there was a numerical increase (a statistically nonsignificant improvement) in the mean scores of IIEF–Q3/Q4[189,194] and SEP–Q2/Q3[181,190,192] across the three doses of vardenafil (5 mg versus 10 mg versus 20 mg), the highest being observed in the 20 mg group. For the mean SEP–Q2/Q3, one trial[205] demonstrated a statistically significant difference between the two doses of vardenafil (10 mg and 20 mg) in favor of the 20 mg dose.

In one trial,[194] the proportion of participants with improved erections (i.e., who answered "yes" to GAQ–Q1) was shown to be statistically significantly greater in the 20 mg versus 5 mg (80 versus 66 percent, $p < 0.01$). Results from two other trials[189,192] demonstrated trends of a numerical increase in the rate of improved erections across 5 mg, 10 mg, and 20 mg doses of vardenafil. The highest proportion of patients with improved erections was observed in the 20 mg groups (range 80.7–86.4 percent).[189,192] In another trial,[181] the proportion of participants with

improved erections was higher in participants who received 20 mg compared with those who received 10 mg of vardenafil (72 versus 57 percent, $p < 0.03$).

In one trial,[193] the difference in the mean change of the duration of penile rigidity (>60 percent) between the 20 mg and 40 mg doses of vardenafil was not statistically significant (42.9 versus 49.3).

Quantitative Synthesis - Meta-Analysis of Trials

Series of meta-analyses were performed using efficacy and harms data obtained from the reports of 21 trials[180-184,189,191-201,203-206] that were conducted in:

1) Clinically heterogenous groups of patients
2) Clinically homogenous groups of patients

Clinically heterogenous groups of patients - vardenafil (any dose: 5 mg, 10 mg, 20 mg, 40 mg) versus placebo. The analyses presented in this section did not include 10 trials for the following reasons: distinct clinical groups of patients (e.g. those with diabetes, prostatectomy, renal transplant, depression, hypertension);[181,183,196,199,204-206] crossover design in which no pre-crossover data were reported);[193,195] and lack of measurement or reporting of relevant clinical outcomes.[180,195] Thus, there remained 11 trials that were potentially eligible for meta-analysis.[182,184,189,191,192, 194,197,198,200,201,203]

Efficacy. Mean IIEF "EF" domain score.

This meta-analysis incorporated three trials[182,194,200] in which the pooled estimate of mean difference at 12 weeks after randomization was 7.35 (95 percent CI: 6.43–8.27), indicating a statistically significant improvement in the mean IIEF "EF" domain score in participants on vardenafil (any dose) compared with those on placebo. (Figure 38)

Mean per-patient proportion of successful intercourse attempts (SEP–Q2). This meta-analysis was based on two trials of flexible vardenafil dose.[184,200] The estimated mean difference between vardenafil- and placebo-treated participants after 12 weeks of treatment was statistically significant in favor of vardenafil (WMD = 27.59, 95 percent CI: 17.06–38.11). One of the trials[184] was restricted to patients who were nonresponders to previous treatment with sildenafil. This difference between the populations of the two trials might have led to the high degree of statistical heterogeneity that was found ($I^2 = 61$ percent) (Figure 39).

Mean per-patient proportion of successful intercourse attempts (SEP–Q3). This meta-analysis was based on two trials[184,200] and yielded a statistically significant pooled estimate of mean difference for erectile maintenance (SEP–Q3) (WMD = 33.19, 95 percent CI: 26.04–40.33), indicating that the treatment with vardenafil was associated with greater improvements in erectile maintenance frequency compared with placebo. (Figure 40)

Proportion of patients with improved erection (GAQ–Q1). Two separate meta-analyses were performed (Figures 41–42). The first incorporated results of 9 trials (Figure 41).[182,184,189,191,192, 194,200,201,203] There was a statistically significantly higher rate of improvement at week 12 in erection among participants who received vardenafil compared with those who received placebo (RR = 2.50, 95 percent CI: 2.19–2.86). The trial that included only participants who did not respond to sildenafil[184] had an outlying value of larger effect estimate size (RR = 4.1), leading to a high degree of statistical heterogeneity across the trials ($I^2 = 51.5$). The second meta-analysis, which did not incorporate the trial of sildenafil nonresponders[184] (see Figure 42), yielded a substantially lower degree of heterogeneity ($I^2 = 3.7$) and a pooled RR of 2.38 (95 percent CI: 2.16–2.61). The vardenafil effect size may have been modified by the previous response to

sildenafil; specifically, this effect might be greater in sildenafil nonresponders compared with responders or participants naïve to sildenafil or other PDE–5 treatments.

Proportion of patients with IIEF–EF ≥ 26. This outcome was reported for three trials.[184,201,203] The pooled estimate of relative risk in the meta-analysis based on the results of these three trials indicated that a higher proportion of participants reached at least 26 on the IIEF score in the vardenafil group compared with the placebo group (RR = 4.05, 95 percent CI: 2.74–6.01) (Figure 43).

Harms.

Proportion of patients with any adverse events (all-cause). The result of this meta-analysis, based on six trials,[182,184,189,191,200,203] showed a statistically significantly higher incidence of adverse events from any cause among participants who received vardenafil compared with those who received placebo (RR = 1.61, 95 percent CI: 1.40–1.87) (Figure 44). (Note: "favors" in forest plots refers to increased frequency of the event for the respective treatment arm, regardless of desirability of the event)

Patients who withdrew due to adverse events. This meta-analysis incorporated data from 10 trials.[182,184,189,191,192,194,197,198,201,203] Although the pooled effect estimate of RR indicated a 29 percent increase in the rate of withdrawal due to adverse events for patients treated with vardenafil relative to those treated with placebo, the observed difference in rates between the two treatment groups was not statistically significant (RR = 1.29, 95 percent CI: 0.78–2.13) (Figure 45).

Patients with serious adverse events (all-cause). This meta-analysis incorporated 9 trials.[182,184,191,192,197,198,200,201,203] Although the pooled effect estimate of RR indicated a 34 percent increase in the risk of experiencing at least one serious adverse event among patients treated with vardenafil relative to those treated with placebo, the observed difference in the rates between the two treatment groups was not statistically significant (RR = 1.34, 95 percent CI: 0.76–2.36) (Figure 46).

Patients with headache (all-cause). This meta-analysis incorporated the results of nine trials.[182,191,192,194,197,198,200,203,213] According to the pooled estimate, the use of vardenafil was associated with a significantly increased risk of headache relative to the use of placebo (RR = 4.10, 95 percent CI: 2.56–6.57) (Figure 47).

Proportion of patients with flushing (all-cause). This meta-analysis included nine trials.[182, 191,192,194,197,198,200,201,203] Patients treated with vardenafil patients were at a statistically significant increased risk of flushing compared with patients treated with placebo (RR = 10.22, 95 percent CI: 5.26–19.87). The magnitude of the pooled RR may have been an overestimate of the true RR because low counts observed in the placebo arms which would cause some instability and inflation of individual estimates of RR (Figure 48).

Proportion of patients with dyspepsia (all-cause). This meta-analysis included six trials,[182,191, 192,194,197,198] the outcome of dyspepsia was not ascertainable for five trials.[184,189,200,201,203] Patients who received vardenafil were at a statistically significantly higher risk of dyspepsia compared with those who received placebo (RR = 6.58, 95 percent CI: 2.61–16.60) (Figure 49).

Clinically homogenous groups of patients. Seven trials included ED patients who additionally presented with diabetes Types I and II,[181,204,205] nerve-sparing retropubic prostatectomy,[183] renal transplantation,[206] untreated mild major depression,[199] or arterial hypertension.[196] Only three trials[181,204,205] including diabetic patients were potentially suitable for meta-analysis.

Efficacy. Meta-analyses for efficacy outcomes in diabetes patients were not performed in view of missing qualitative or quantitative information (i.e., the outcome was not reported at all or no numerical data were given on measures of variability).

Harms.

Patients with serious adverse events (all-cause). This meta-analysis included results from three trials.[181,204,205] There was a statistically nonsignificant finding of a 40 percent increased risk of a serious adverse event in patients who received vardenafil versus those who received placebo (RR = 1.40, 95 percent CI: 0.59–3.29) (Figure 50).

Patients who withdrew due to adverse events. This meta-analysis included results from three trials of patients with diabetes.[181,204,205] The difference in the withdrawal rates resulting from adverse events between these patients in vardenafil and placebo groups was not statistically significant (RR = 1.80, 95 percent CI: 0.66–4.91) (Figure 51).

Dose-response effect of vardenafil (20 mg versus 10 mg). There were 10 trials with two or more dose-specific arms of vardenafil.[181,183,189,190,192-195,198,205] The analysis in this section excluded trials of distinct clinical groups of patients[181,183,205] and crossover trials.[193,195] Therefore, five potentially eligible trials remained for the analyses.[189,190,192,194,198] Meta-analysis could be performed with respect to only one efficacy outcome, the IIEF "EF" domain endpoint score. For other efficacy outcomes (IIEF–Q3/Q4, SEP–Q2/Q3) quantitative data necessary for meta-analysis were missing.[189,190,192,198]

Efficacy.

Mean IIEF "EF" domain score. This meta-analysis incorporated two trials.[190,194] The estimate of pooled mean difference for the IIEF "EF" domain score observed between the two groups of patients at weeks 12–104 was not statistically significant (WMD = 0.92, 95 percent CI: -0.03 to 1.87) (Figure 52).

Proportion of patients with improved erection (GAQ–Q1). This meta-analysis incorporated results of four trials.[189,190,192,194] The proportion of patients with improved erection at week 12 was similar in the 20 mg and 10 mg vardenafil treatment groups (RR = 1.03, 95 percent CI: 0.99–1.08) (Figure 53).

Harms.

Proportion of patients with any adverse events (all cause). The result of this meta-analysis, incorporating two trials,[189,190] indicated a marginally statistically significant increase in risk for any adverse event for patients treated with 20 mg vardenafil compared with those treated with 10 mg vardenafil (RR = 1.15, 95 percent CI: 1.06–1.25) (Figure 54).

Proportion of patients with serious adverse events (all cause). This meta-analysis was based on results of three trials.[190,192,198] The occurrence of serious adverse events could not be ascertained for two trials.[189,194] The pooled estimate of relative risk indicated that the risk of developing any serious adverse event did not differ between the groups of patients receiving 20 mg and 10 mg doses of vardenafil (RR = 1.02, 95 percent CI: 0.37–2.82) (Figure 55).

Patients who withdrew due to adverse events. This meta-analysis included five trials.[189,190,192,194,198] The difference in withdrawal rates resulting from adverse events observed

between patients treated with 20 mg and 10 mg doses of vardenafil was not statistically significant (RR = 1.60, 95 percent CI: 0.85–3.00) (Figure 56).

Patients with headache, flushing, or dyspepsia (all cause). Three meta-analyses, each incorporating results from three trials,[192,194,198] were performed separately for the incidence of headache, flushing, and dyspepsia (Figures 57–59). The occurrence of these events could not be ascertained for two trials.[189,190]

Although the pooled effect estimates indicated an increased risk ranging from 25 percent (RR = 1.25, 95 percent CI: 0.87–1.79) to 56 percent (RR = 1.56, 95 percent CI: 0.83–2.91) for the occurrence of any of these events in patients treated with 20 mg vardenafil versus 10 mg vardenafil, none of these estimates reached statistical significance.

Assessment of Publication Bias

Funnel plots were generated and examined to graphically assess the extent of asymmetry (i.e., possible publication bias) present in each meta-analysis. Visual inspection of these plots did not reveal any substantial asymmetry.[53] (Figures D-9-11, Appendix D)

Oral Treatments — Phosphodiesterase Type 5 (PDE–5) Inhibitors – Tadalafil

Literature Search

In total, 30 RCTs (in 37 publications) met the eligibility criteria and were included in the review.[103,118,121,163,214-247]

One additional trial,[231] which employed the combination of topical testosterone and tadalafil is described in the section on hormonal treatments.

Results of four unique trials were presented in multiple publications. The following list shows the reference identifications for these trials and corresponding publications (each row).

The first reference (author, year, citation) denotes primary publications (i.e., those reporting the most relevant and complete data for the trial), which are used throughout the Tadalafil section. (Table F-3, Appendix F)

1. Eardley 2005[103] and Dean 2006[241]
2. Mirone 2005,[214] Moncada 2005,[244] Costa 2006,[245] Wespes 2007,[246] Buvat 2006[247]
3. McMahon 2005[216] and McMahon 2006 [242]
4. Carson 2005[217]and Carson 2005[243]

Overview of Trials

The trials were conducted in the US,[118,121,215,217,222,224,225,230,233,235] Canada,[221,222,227] Europe/UK,[103,118,121,163,214,218-220,222,223,225,226,232,234,239] East and Southeast Asia,[229,236,237,240] Japan,[238] and Australia.[216,228,242] The trials were published between 2002[226] and 2007[232,233,235] inclusively. The authors of all trials but three[163,218,219] stated that the trials were funded by Lilly ICOS LLC. Of the two Italian trials,[218,219] one was funded by Pfizer;[218] the other[219] did not report the funding source.

Of the 30 trials, 22 were parallel-arm[215-227,229,230,233-238,240] and eight were[103,118,121,163,214,228,232,239] crossover trials. Of the 22 parallel-arm trials, 13 had two arms[216-220,222-225,233,234,236,240] and nine trials had three or more arms.[215,221,226,227,229,230,235,237,238] Of the 30 trials, 23 were placebo controlled[215-227,229,230,233-240] and seven were active-arm (e.g. sildenafil, tadalafil, vardenafil) controlled trials.[103,118,121,163,214,228,232] Further information on trial characteristics is provided in Table F-3 (Appendix F).

Populations

The included trials involved men diagnosed with ED. The total and mean numbers of patients randomly assigned to study interventions or placebo across the 30 trials were 10,718 and 358, respectively. The number of patients randomly assigned across the trials ranged from 20[232] to 4,262.[214]

The inclusion criteria in all trials except five [218,222,226,233,239] were: adult males aged ≥18 years, diagnosed with ED for ≥3 months, and in a stable monogamous heterosexual relationship. The inclusion criteria in two studies[222,226] were restricted to patients who either additionally had diabetes (Type I or II)[226] or who had undergone bilateral nerve-sparing retropubic prostatectomy 1–4 years before their enrolment into the trial.[222] In one trial,[218] the study population consisted of mostly older men, aged 59–71 years, who had two or more risk factors for coronary artery disease (CAD) (e.g. total cholesterol level >5.20 mmol/L, diabetes Type II, hypertension >135/85 mmHg, tobacco smoking, family history). Only 50 percent of these patients had ED. In

two other trials[233,239] the patient populations comprised those with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH)[233] and patients with ED undergoing three-dimensional conformal external-beam radiotherapy (3DCRT) for prostatic carcinoma.[239] In the former trial,[233] only 65 percent (183,281) of the patients had ED. In one trial,[163] only PDE–5 naïve patients were enrolled.

The exclusion criteria in the majority of included trials were pelvic surgery,[103,118,121,215,216,219-223,225,229,233,235-240] penile/testicular deformity,[103,215,216,219,221-225, 227,228,230,234-236,238] unstable angina/myocardial infarction,[103,118,121,163,215-218,220-222,224,225,227-229,232-240] prostatectomy,[103,216,217,220,221,223-225,227-230,233-238,240] HIV-positivity/AIDS,[103,118, 121,221-223,227,229,230,235-238,240] use of nitrates,[103,118,121,163,214,215,217,219,220,222,227,229,230,232-235,237-240] any major hepatic/renal disease,[103,216,219-224,227,228,233,234,236-238,240] previous ineffective treatment with sildenafil,[216,217,221,223, 224,227,229,230,234,235,238] stroke,[103,118,121,214,215,217,219,224,225,228,233-235,238,239] endocrine disease,[103,118,216,221,223,230,234-236, 238] retinitis pigmentosa,[103,118,121,163,228] or a history of cancer.[214,215,219,227,229,230,233,239,240] Other exclusion criteria were cancer chemotherapy[232-235,237-240] premature ejaculation,[234-236,238] spinal cord injury[215,219,233-235,239] uncontrolled hypertension,[103,217,233,235,236,238] use of alpha-blockers/androgens,[163,238] and diabetes.[216,221-223,233,234,236] One trial additionally excluded patients with prostate-specific antigen levels >10 ng/mL.[233] None of the trials failed to report exclusion criteria.

The mean age of the study participants across the included trials ranged from 46[219] to 69[239] years. The patients' race was not reported in eight trials.[217-219,223,228,229,232,239] Three trials included Southeast Asian,[236,237,240] one trial Japanese,[238] and one trial Turkish and Egyptian patients.[234] The approximate proportion of Caucasians in the remaining 17 trials ranged from 73 percent[224] to 100 percent.[163,220] The duration of ED of patients was not reported in four trials.[218,219,221,222] In 24 of the remaining 26 trials,[103,118,121,214-217,220,223-230, 232-238,240] eligible patients had to have been diagnosed with ED for at least 3 months before their enrolment into the trial. In two trials, patients had been diagnosed with ED for at least 6[163] and 12 months[239] before trial enrolment. In 22 trials, the majority of patients (≥70 percent) had been diagnosed with ED for at least 1 year before trial entry.[103,118,121,214-217,220,223-227,229,230,234-240]

The most commonly reported comorbidities among study participants were diabetes,[103,118,163,214-217,220,221,223,224,226-230,232,234-238,240] hypertension,[103,118,163,214-217,220,223, 224,226-230,232,234-240] coronary artery disease (CAD),[103,118,163,214,215,217,221,224,228,229,235] hyperlipidemia,[163,214,216,217,223,224,226,227,229,230,232,234,235,237,238,240] BPH,[223,224,233,234,236-238,240] and depression.[103,118,214,224,230,235] The presence or absence of comorbidities could not be ascertained for six trials.[121,218,219,222,225,233] In three trials,[103,215,239] the proportion of ED patients with diabetes was below 10 percent; in five trials,[216,220, 223,235,237] this proportion ranged from 11 percent[220] to 14 percent;[235] in four trials[118,214,224,240] it ranged from 17 percent[118,224] to 18 percent;[214,244-247] and in 10 trials[217,221,227-230,232,234,236,238] the proportion ranged from 20 percent[217,227,232] to 31 percent.[236] In two trials[234,240] the proportion of ED patients with hypertension ranged from 14 percent[240] to 17 percent.[234] In other 12 trials[103,118, 214,218,220,227-229,232,237-239] this proportion ranged from 20 percent [232] to 29 percent,[228] and in eight trials[215-217,223,224,230,235,236] from 30 percent [216,236] to 43 percent.[235] The remaining eight trials[121,163, 219,221,222,225,226,233] failed to report the proportion of hypertensive patients. The proportion of ED patients with CAD in six trials[103,118,214,215,224,229,241] was below 10 percent, and in three trials[217, 228,235] it ranged around 10–11 percent. The proportion of patients with CAD could not be ascertained from the remaining 21 trials.

The approximate proportion of smokers was ascertained for 17 trials,[103,118,121,214,215,217-221,225,227-229,232,234,238] and ranged from 15-16 percent [215,217] to 37–40 percent.[229,238] The authors of 13 trials[163,216,222-224,226,230,233,235-237,239,240] did not report the proportion of smokers.

The majority of the trials included patients with ED of all three etiologic groups (i.e., organic, psychogenic, and mixed.[103,118,121,163,214-217,219,220,223-225,227-229,232,234-238,240] In eight trials[118,215-217,227,229,234,235] the proportion of patients with ED of psychogenic origin was below 10 percent, whereas in 13 other trials[103,121,214,219,220,223-225,228,236-238,240] this proportion ranged from about 10 percent [224] to 29 percent.[238]

The approximate proportion of patients with severe ED (IIEF "EF" domain score: 1–10) across 24 trials[103,118,121,214-217,219-225,227-230,234-238,240] ranged from 18–23 percent [223,228,240] to 50–52 percent.[217,222] In 14 trials,[103,214-216,219-221,224,225,227,230,235,237,238] the approximate proportion of patients with severe ED ranged from 30–32 percent [103,237,241] to 40–42 percent.[220,224,235] In seven trials,[118,121,223,228,229,234,236] this proportion was from 20 to 30 percent. The proportion of patients by ED severity groups was not reported in six trials.[163,218,226,232,233,239]

Interventions

Patients across the 30 trials that were reviewed received oral tadalafil monotherapy in either experimental or active control arms. In most of the trials, tadalafil was given in 10 mg[215,221,226-230,237,238] and 20 mg doses.[118,121,163,214-220,222-230,232,234,236-240] One trial[221] included three additional randomized arms in which patients received 2 mg, 5 mg or 25 mg of tadalafil. In another trial,[238] one additional arm of randomly assigned patients received 5 mg of tadalafil. In one placebo-controlled trial,[235] patients were randomly assigned to receive either 2.5 mg or 5 mg of tadalafil. Dose escalations were used in two trials: 10–20 mg[103] and 5–20 mg.[233]

In three trials,[214,228,232] 20 mg tadalafil on demand was compared with 20 mg three times per week,[214] 20 mg on alternate days,[232] or 10 mg daily.[228] In addition to these three trials,[214,228,232] a fixed dose of tadalafil was used in nine others.[118,121,163,217-220,225,235] "On demand" (i.e., "as needed") dosing of tadalafil was used in 17 trials.[103,215,216,221-224,226,229, 230,234,236-240]

The duration of tadalafil treatment across the trials ranged from about 4–6 weeks[214,215,218,230,232,233,239] to 24–26 weeks.[216] In half of the trials, tadalafil was administered for about 12 weeks.[103,118,217,219,220,222-224,226-229,234,236-238]

Tadalafil was compared with placebo,[215-227,229,230,233-240], sildenafil[103,118,121,163], tadalafil (control dose/dosing regimen),[214,215,221,226-230,232,235,237,238], and vardenafil.[163]

Outcomes

In total, all 30 trials reported some information on the absence and/or occurrence of either total or serious adverse events. In four trials, the incidence of any adverse events was not reported.[121,217,221,224,232] Authors of 14 trials failed to report the absence or occurrence of serious adverse events.[118,121,163,216,218,219,221,225-227,229,230,232,237] The number of patients who withdrew as a result of adverse events was reported in all but two trials.[221,232]

Efficacy. The efficacy outcomes measured in the 30 included trials varied to some degree. The most commonly measured and reported outcomes across the trials were the mean or median endpoint score/mean score change on IIEF domains and/or individual questions,[103,163,214,216,217,219,220,222-224,226-229,233,234,236-240,242,243] the mean endpoint/ mean change in the per-patient proportion of "yes" answers to the Sexual Encounter Profile questions 2 and 3 (i.e., SEP–2/3, "*Were you able to insert your penis into your partner's vagina?*" and "*Did your erection last long enough for you to have successful intercourse?*"),[103,214-217,219,220,222-230,234,236-240,243] and the proportion of

patients who answered "yes" to the Global Assessment Question 1 or 2 (i.e. GAQ–Q1: "*Has the treatment you have been taking improved your erections?*" and GAQ–Q2: "*If yes, has the treatment improved your ability to engage in sexual activity?*").[216,217,220,222-224,226-229,234, 236-240] Of the 16 trials that reported outcomes based on GAQs, nine trials[216,217,224,226-229, 237,238] evaluated the proportion of patients who answered "yes" to GAQ–Q1 only, whereas the remaining seven trials[220,222,223,234,236,239,240] evaluated this parameter for both GAQ–Q1 and GAQ–Q2.

Eight trials additionally evaluated the efficacy (i.e., the mean per-patient percentage of successful intercourse attempts based on "yes" responses to SEP Q3) for different time-periods after dosing of tadalafil.[216,217,219,220,224,225,227,230]

The authors of one trial,[221] derived logistic regression models based on the patient data obtained from a randomized placebo-controlled trial. These dose-response models assessed the relationship between the dose of tadalafil (2, 5, 10, or 25 mg) and the probability of getting an outcome (SEP questions 2 and 3 and/or on IIEF questions 3 and 4). The models included such covariates as baseline severity of ED and IIEF–EF domain score.

In five trials,[103,163,217,222,223,241,243] treatment satisfaction was measured using the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire.

The patients' treatment preference (e.g. percentage of patients who preferred the use of tadalafil to that of sildenafil) was evaluated and reported in six trials, all of which were of a crossover design in which the patients received both tadalafil and sildenafil[103,118,121, 163,241] or alternating dosing regimens of tadalafil (i.e., on demand versus fixed).[214,228,244-247]

Endothelial function using percentage change (compared with baseline) in the mean flow mediated dilation (FMD) of brachial and cavernous arteries was measured in two trials.[218,232]

Study Quality and Reporting

The mean Jadad total score for the 30 included trials was 3.2. The individual Jadad total score for 30 trials ranged from 1[163] to 5.[216,222,225] All 30 trials but six[103,163,214, 219,228, 232] were double-blind. Three trials could not have been double blinded because patients received either on-demand or fixed dosing regimens of tadalafil.[214,228,232] Of the 24 double-blind trials, only nine trials[118,216,218,221,222,224,225,227,239] reported some description of the blinding method(s) used. Only three trials[219,238,239] reported some information on the allocation concealment, which was deemed to be adequate. The adequacy of allocation concealment for the remaining 27 trials could not be ascertained (i.e., was unclear).

Of the eight crossover trials,[103,118,121,163,214,228,232,239] only one [239] failed to report whether a washout period had been applied between the treatment periods. The length of washout period for the seven remaining crossover trials ranged from 4 days[118] to 14 days.[121,228,232]

Qualitative Synthesis

Tadalafil (any dose: fixed or flexible) versus placebo.

Harms. The occurrence of total and serious adverse events across the 23 placebo-controlled trials was reported poorly.[215-227,229,230,233-240]

In the majority of these trials, the frequency of any adverse events (i.e., the proportion of patients with at least one adverse event) was greater either numerically or with statistical significance in the tadalafil arms than in the placebo arms.[215,220,222,223,225-227,229, 230,236-240]

For example, in one trial, the proportion of patients who experienced at least one adverse event in the tadalafil and placebo arms were 51.7 versus 26.5 percent, respectively ($p < 0.001$).[222] In another trial,[225] the corresponding numbers were 40 (22.5 percent) versus two (1.3 percent) (p

value was not reported). Even though the proportion of patients in one trial[226] was numerically greater in the tadalafil arms (39.7–44.4 percent) than in the placebo arm (31.0 percent), this difference was not statistically significant (p = 0.247). Most common adverse events reported across all trials were headache, back pain, dyspepsia, dizziness, nasal congestion, flushing, and myalgia. In general, the occurrence of these events tended to be numerically more frequent in tadalafil arms than in placebo arms. Moreover, a statistically significant higher incidence of these events was reported across several trials in tadalafil versus placebo arms.[215,220,222,223,225,226,239] The majority of the trials reported that tadalafil was well tolerated and that patients had had adverse events mostly of mild or moderate severity.

Eleven of the 23 trials did not report whether there had been any occurrence of serious adverse events.[216,218,219,221,225-227,229,230,237,239]

In the remaining 12 trials,[215,217,220,222-224,233-236,238,240] the incidence of serious adverse events (i.e., the proportion of patients with at least one serious adverse event) was reported to have been about 5.0 percent[222] or less, or 0,[238], and to have been similar in tadalafil and placebo arms.[215,217, 220,222-224,233,235,240] In one trial,[217,243] three patients who received tadalafil developed carotid artery bruit, esophageal spasm, and brain neoplasm (one case of each event).[217] Other specific serious adverse events that were reported were single cases of pulmonary embolism and subarachnoid hemorrhage,[223] two cases of chest pain requiring hospital admission,[224] and one case of worsening CAD.[236] In one trial,[235] five patients experienced at least one of the following serious adverse events in the tadalafil arm: acute myocardial infarction (AMI), benign lung neoplasm, back pain, road traffic accident, and pancreatitis. Two trials[215,234] reported one death each which had occurred due to AMI[215] and cardiac arrest.[234] Of the 12 trials that reported any occurrence of serious adverse events, three trials[215,220,222] did not specify what these events were.

The proportion of patients who withdrew due to adverse events across trials was five–six percent[217,222,224] or less and similar across the tadalafil and placebo arms.[215-220,222-227, 229,230,233-240]

Efficacy. In general, the results of the 23 placebo-controlled trials showed that patients who received tadalafil (10 or 20 mg) experienced greater improvement in erectile functioning (e.g. outcomes based on responses to IIEF, SEP, and GAQ) compared with those who received placebo. The observed between- or within-arm differences in the mean endpoint scores/mean score changes for the IIEF "EF" domain[216,217,219,220,222-224,226, 227,229,234,236-240] and for the per-patient proportion of "yes" answers to the SEP questions 2–3, were statistically significant (p value < 0.05).[215-217,219,220,222-227,229,230,234,236-240] Similarly, the proportion of patients who answered "yes" to the GAQ–Q1/2 was statistically significantly greater in tadalafil than in placebo arms.[216,217,220,222-224,226,227,229, 234,236-240]

For example, the mean within-arm IIEF "EF" domain absolute score change observed in tadalafil arms (10 or 20 mg dose) across trials[216,217,219,220,222-224,226,227,229,234,236-240] ranged from 5.2[222] to 12.0,[219] whereas the corresponding treatment response observed in placebo arms ranged from –1.6[216,242] to 2.9.[219] The mean change in the proportion who responded "yes" to SEP Q3 (i.e., per-patient percentage of successful intercourse attempts) in tadalafil arms (10 or 20 mg dose) ranged from 23.0 percent[222] to 56.5 percent.[220,237] The corresponding mean treatment response change in placebo arms ranged from 0.9 percent[216] to 18.3 percent.[237] The proportion of patients who responded "yes" to GAQ–Q1 in tadalafil arms (10 or 20 mg) across trials[216,217,220, 222-224,226,227,229,234,236-240] ranged from 62.0 percent[222] to 92.3 percent.[229] For placebo arms this proportion across the same trials ranged from 12.8 percent[216] to 54.5 percent.[229]

In a parallel-arm trial of patients with LUTS (65 percent ED patients),[233] 138 patients (n = 99 ED patients) received the dose-escalated tadalafil (5 mg for 6 weeks and the 5–20 mg dose-

escalation for another 6 weeks) and, compared with those receiving placebo, had a statistically significant greater mean change in the IIEF "EF" domain score at 6 and 12 weeks of treatment (12 weeks: 7.7 versus 1.4, $p < 0.001$). Furthermore, results of two trials[235,238] indicated that patients receiving even lower doses of tadalafil (2.5 mg and 5 mg) compared with those in the placebo group had greater statistically significant improvements in erectile functioning with respect to the mean score changes in the IIEF "EF" domain (19.1–20.8 versus 14.6, $p < 0.001$) and the per-patient proportion of "yes" answer to SEP Q2–3 (for Q2: 65.3–70.7 versus 51.1, $p < 0.001$ and for Q3: 50.0–57.0 versus 31.3, $p < 0.001$).[235] Compared with the placebo group, in both tadalafil dose-groups there was a significantly greater proportion of patients who answered "yes" to GAQ1–2 (5 mg: 70.7–72.8 percent, versus 2.5 mg: 58.5–62.8 percent, versus placebo: 23.9–26.1 percent).[235]

Furthermore, patients who received tadalafil compared with those who received placebo had statistically significant greater improvements in erectile function as measured by the mean IIEF score change from baseline to endpoint for the IIEF "Intercourse Satisfaction" and "Overall Satisfaction" domains.[216,217,223,224,226,227,229,234-240,243]

In several trials, there was a statistically significant greater mean per-patient percentage of successful intercourse attempts measured at different intervals after dosing in tadalafil arms compared with placebo arms.[217,219,220,224,225,230]

The mean overall EDITS score in patients who received tadalafil showed a statistically significant improvement compared with that in patients who received placebo.[217,222,223] The mean overall EDITS score values in tadalafil arms across the trials were 66.8,[217,243] 58.0,[222] and 77.[223] The corresponding values for placebo arms in these trials were 35.6, 34.0, and 46.0, respectively. In one of these trials,[223] patients treated with tadalafil had a median EDITS score of 84,(95 percent CI: 80–86) as opposed to those treated with placebo, who had a median EDITS score of 41 (95 percent CI: 32–59). The difference between the two median scores was statistically significant ($p <0.001$).

The mean change measured on individual IIEF Q3–4 scores (Q3, penetration ability; Q4, maintenance ability) was reported in 8 trials (out of the 23 placebo-controlled trials),[217,220,226,234-237,240] all of which showed highly statistically significant improvements for patients treated with tadalafil patients compared with those treated with placebo ($p < 0.001$).

The authors of one trial[218] showed that after a 4-week therapy, patients treated with tadalafil experienced greater improvements in endothelial function as measured by brachial artery flow-mediated dilation (FMD) than patients treated with placebo. For example, in the tadalafil arm, the mean change in FMD from baseline to the end point was statistically significant (9.3 versus 4.2 percent, $p < 0.01$), whereas in the placebo arm the mean FMD did not change (4.1 versus 4.3, $p >0.05$).

Four studies examined the efficacy according to severity of ED.[216,235,237,238] The number of patients achieving normal scores in IIEF–EF were higher in mild ED compared with moderate or severe ED.[216,235,237,238] Similarly higher end scores of IIEF–EF were achieved in patients with mild compared with moderate or severe ED.[216,235,237,238] (Table 11)

Tadalafil (20 mg) versus tadalafil (10 mg) versus tadalafil (5 mg). The effects of both tadalafil doses 20 mg and 10 mg were evaluated in eight trials.[215,226-230,237,238] In one of these trials,[238] there was an additional randomized arm in which patients received 5 mg tadalafil. Another trial[221] evaluated dose-response models for different doses of tadalafil (e.g. 5, 10, 25 mg).

Harms. The incidence of most reported adverse events (e.g. myalgia, nausea, back pain, diarrhea, headache, dizziness, dyspepsia, nasal congestion, facial flushing, infection, flu syndrome) across the eight trials was numerically comparable in patients receiving 20 mg versus 10 mg of tadalafil. In three trials,[228,230,238] the incidence of headache was slightly higher in patients receiving 20 mg tadalafil as compared with those receiving 10 mg (or 5 mg) of tadalafil. For example, in the first trial,[228] the proportions of patients with headache in 20 mg and 10 mg tadalafil arms were 17.1 and 8.1 percent, respectively, with a statistically significant between-arm difference ($p < 0.001$).

In the same trial the incidence of serious adverse events (i.e., two cases of myocardial infarction) was numerically similar in the 20 mg and 10 mg tadalafil groups (two patients in each arm). In the second trial,[230] numerically more patients who received 20 mg tadalafil had headache compared with those who received a 10 mg dose (8.0 versus 4.1 percent). In one trial,[227] compared with those who received 10 mg of tadalafil, patients receiving a 20 mg dose experienced numerically higher rates of dyspepsia (22.0 versus 9.7 percent), vasodilation (6.0 versus 3.9 percent), and accidental injury (5.0 versus 1.0 percent). The incidence of back pain was numerically slightly higher in patients receiving 20 mg versus those receiving 10 mg of tadalafil in one trial (4.0 versus 0.8 percent, respectively).[237] In another trial,[215] one patient died from an AMI after being randomly assigned to receive 20 mg tadalafil. Of the eight trials comparing the efficacy/safety profiles of 20 mg and 10 mg tadalafil, the absence or presence of serious adverse events could not be ascertained for six trials.[221,226,227,229,230,237]

Efficacy. In five trials,[226,227,229,237,238] the degree of improvement in the mean change for IIEF "EF" domain and per-patient proportion of "yes" to SEP Q2–Q3 from baseline was numerically similar between 20 mg, 10 mg, and 5 mg tadalafil arms. The proportions of patients with improved erection (i.e., those who answered "yes" to GAQ) were also similar between the 10 mg and 20 mg tadalafil dose arms.[226,227,229,237,238] In one trial,[215] the magnitude of improvement with respect to the mean change in per-patient proportion of "yes" responses to SEP–Q3 from baseline was numerically greater in the 20 mg than the 10 mg tadalafil arm 24 hours post-dose (46.3 versus 25.5 percent). Similarly, in another trial,[230] the cumulative proportion of patients with at least one successful intercourse attempt ("yes" to SEP–Q3) attempt 30 minutes post-dose was numerically improved in patients who received 20 mg relative to those who received 10 mg of tadalafil (34.0 versus 25.0 percent). In the same trial, patients on 20 mg tadalafil had a faster erectogenic response (starting 16 minutes post-dose) than those on 10 mg of tadalafil (starting 26 minutes post-dose).[230]

The results of one trial[228] were slightly inconsistent with those of others.[215,226,227,229, 230] More specifically, patients on 10 mg (daily) of tadalafil experienced greater improvement in erectile function (based on responses to SEP–Q3, IIEF, GAQ–Q1) compared with those receiving 20 mg (on demand) of tadalafil. For example, there was a statistically significant higher mean per-patient proportion of successful intercourse attempts (i.e., based on "yes" answers to SEP–Q3) among patients receiving 10 mg tadalafil compared with those receiving 20 mg tadalafil (80 versus 67 percent, $p < 0.05$). Similarly, the proportion of patients who answered "yes" to GAQ Q1 was higher in the 10 mg arm compared with the 20 mg arm of tadalafil (88.0 versus 73

percent, p <0.05). Furthermore, patients in the 10 mg tadalafil arm had a higher mean IIEF "EF" domain score than those in the 20 mg tadalafil arm (26.4 percent versus 23.3 percent, p <0.05).

In one study,[221] authors who employed logistic regression models based on patient data obtained from a randomized placebo-controlled trial, showed a statistically significant dose-dependent effect of tadalafil on the patients' outcomes as defined by responses to SEP–Q2/3 and the IIEF "EF" domain questions; more specifically, the magnitude of response increased between the 10 mg and 25 mg doses of tadalafil. Furthermore, the baseline ED severity was an important covariate in these models, indicating that patients with severe ED at baseline experienced greater incremental improvement in erectile function compared with those with moderate or mild ED at baseline.

Tadalafil (20 mg; on-demand therapy) versus tadalafil (20 mg; scheduled therapy). Two trials[214,232] compared the efficacy/safety of two dosing regimens of 20 mg tadalafil (on demand therapy versus scheduled therapy).

Harms. In the first trial,[214] the rate of any adverse events (percentage of patients with at least one adverse event) did not differ between groups who were given tadalafil either on demand or 3 times per week (21.7 versus 25.3 percent, respectively). The most frequent events in both tadalafil arms were headache (7.5 percent), dyspepsia (6.5 percent), back pain (2.7 percent), flushing (2.6 percent), and myalgia (2.5 percent). The proportion of patients who withdrew from the on-demand and the 3 times per week dosing regimens were 4.0 percent and 5.1 percent, respectively. No deaths or serious adverse events occurred during the trial. In the second trial,[232] the most frequent adverse events were dyspepsia, headache, back pain and myalgia, observed in two of the 20 patients.

Efficacy. One crossover trial[214] evaluated the relative effects of alternative dosing regimens of tadalafil (on demand versus 3 times per week) on the outcomes of ED (e.g. patient preference, mean change in IIEF "EF" domain scores and the per-patient proportion of successful intercourse attempts. The 3861 patients' responses to the treatment preference question (TPQ) showed that the on-demand regimen was preferred more frequently than the 3 times per week scheduled regimen, regardless of the sequence of the treatment regimens (57.8 versus 42.2 percent, p < 0.001). The on-demand and the scheduled 3 times per week dosing regimens were shown to be similarly efficacious with respect to the mean IIEF "EF" domain scores (24.6 versus 24.8, respectively). Similarly, the mean per-patient proportion of successful intercourse attempts ("yes" to SEP–Q3) did not differ between the on-demand and scheduled 3 times per week tadalafil groups(72.6 versus 74.4 percent).

The other trial evaluated whether 20 mg tadalafil dosing regimens (on demand versus scheduled on alternate days) differed in improving endothelium-dependent vasodilation of cavernous arteries (e.g. peak systolic velocity and flow-mediated dilation) and in producing morning erections in men diagnosed with ED as ascertained by one of the items of the SIEDY questionnaire (question: "*In the last four weeks, did it ever occur that you wake up with an erection?*").[232] After 4 weeks of therapy, the mean increase in flow-mediated dilation (FMD) from baseline in patients treated with scheduled dosing regimen on alternate days was statistically significant (1.2 versus 8.3 percent, p < 0.05), whereas the corresponding parameter for patients treated with the on-demand therapy schedule did not change (3.3 versus 2.1 percent, p ≥ 0.05). The improvement in FMD observed in patients who had received scheduled therapy was maintained 2 weeks after the discontinuation of the therapy. There was also a statistically significant improvement in regard to morning erections observed in patients treated with the

scheduled dosing regimen (90 percent of the patients; p <0.0001), but not in those treated with the on-demand dosing regimen.

Tadalafil versus sildenafil versus vardenafil. Four crossover trials compared efficacy/safety of tadalafil (20 mg) and sildenafil (25-100 mg, 50 mg, or 100 mg) in treating patients with ED.[103,118,121,163] One of these[163] additionally evaluated the efficacy/safety profile of vardenafil (20 mg).

Harms. In general, in these trials, all three therapies were well tolerated and had similar safety profiles. There were no statistically significant differences in the incidence of any adverse events between tadalafil- and sildenafil-treated groups of patients. In the tadalafil arms the proportion of patients with at least one adverse event across the four trials ranged from 27.7 percent[163] to 34.9 percent.[103] The corresponding proportion in the sildenafil arms ranged from 23.8 percent[121] to 34.1 percent.[103] In the vardenafil group, about 26.6 percent patients had at least one adverse event.[163] Most common events in the three therapy groups were: headache (7.8–12.2 percent), dyspepsia (3.0–6.4 percent), flushing (2.5–7.4 percent), back pain (1.8–4.8 percent), and nasal congestion (1.1–4.7 percent).

In one trial,[103] the incidence of serious adverse events did not differ between the tadalafil (5 patients had prostate cancer, purpura, pulmonary edema, gastric cancer) and sildenafil groups (4 patients had cardiac biopsy, chest pain, perianal abscess). Three remaining trials[118,121,163] did not report the occurrence or absence of serious adverse events.

The total number of withdrawals due to adverse events across the four trials ranged from two[121] to 12 patients.[103,163] The proportion of patients who withdrew from tadalafil groups ranged from one[121] to seven.[103,241] The respective proportion of patients who withdrew from the sildenafil arms ranged from one[121] to five.[103,163] Two patients withdrew due to adverse events in the vardenafil group.[163]

Efficacy. In one trial,[103] the IIEF mean changes from baseline to endpoint were greater in the tadalafil than in the sildenafil arm for the domains of “Orgasmic Function” (difference between the mean changes: 0.28, 95 percent CI: 0.02–0.53) and “Sexual Desire” (difference between the mean changes: 0.19, 95 percent CI: 0.02–0.35).

In general, results of the four trials[103,118,121,163] regarding the measures of erectile function (i.e., mean IIEF-“EF domain” scores) were not consistent.

For example, in one trial the difference between the mean changes for IIEF “EF” domain scores did not reach statistical significance (0.51, 95 percent CI: -0.07 to 1.09).[103] In another trial,[163] there was a statistically significant higher median (percentile range 10–90) IIEF score in the tadalafil group in comparison with the vardenafil group: 30 (25–30) versus 28 (23.1–30.0), p = 0.00022. In the same trial, the differences in the mean IIEF score between the sildenafil/tadalafil and sildenafil/vardenafil groups were not statistically significant.[163]

In one trial,[118] the proportion of men who had at least one successful intercourse attempt 12 or more hours post-dose was greater among patients receiving 20 mg tadalafil than in patients receiving 50 mg sildenafil (55.0 versus 29.0 percent, p <0.001). In another trial,[103] the mean change in per-patient proportion of successful intercourse attempts (“yes” to SEP Q3) was slightly greater in patients receiving tadalafil compared with those receiving sildenafil (difference between the mean changes: 5.2 percent, 95 percent CI: 1.8–8.6). The mean time (in hours) between dosing and sexual attempt was found to be longer for tadalafil than for sildenafil (5.6 versus 2.7, p < 0.001).[118,121]

In the four trials, the proportion of patients preferring tadalafil (range 52.2 to 73.0 percent) was statistically significantly greater than the proportion of patients preferring sildenafil (27.0–

33.7 percent) or vardenafil (20.0 percent). In one trial,[118] 73 percent of the patients preferred tadalafil and 27 percent preferred sildenafil ($p < 0.001$). Similarly, the results from the two other trials[121,163] also indicated that more patients preferred tadalafil (66.3 and 52.2 percent, respectively) compared with those preferring sildenafil (33.7 and 27.7 percent, respectively) or vardenafil (20 percent). In one trial,[163] the reason for 25 percent of men preferring tadalafil to sildenafil was that they could have intercourse again the next day post-dose.

Quantitative Synthesis - Meta-analysis of Trials

A series of meta-analyses was conducted to address the safety and efficacy of tadalafil.[103,118,121,163,214-230,232-240] Of the 30 eligible trials, five were excluded as potentially ineligible given the following distinct clinical features of the patients studied: patients with increased cardiovascular risk of whom 50 percent were patients with ED,[218] patients with radical prostatectomy,[222] diabetic patients,[226] patients with benign prostatic hypertrophy (BPH),[233] and patients with radical prostatic carcinoma.[239] In addition, two more trials were excluded because relevant numerical data needed for meta-analysis was lacking[221] and an inappropriate dose of tadalafil was used (2.5 mg and 5 mg).[235]

Of the remaining 23 trials,[103,118,121,163,214-217,219,220,223-225,227-230,232,234,236-238,240] 16 were placebo-controlled,[215-217,219,220,223-225,227,229,230,234,236-238,240] and seven were active-treatment trials.[103,118,121,163,214,228,232] All 16 placebo-controlled randomized trials had parallel-group design and compared the efficacy and safety of tadalafil (10 mg or 20 mg or both) to placebo.

Tadalafil (any dose: 20 mg or 10 mg) versus placebo.

Efficacy.

Absolute mean change from baseline in IIEF–EF score. This meta-analysis included eight trials.[216,217,220,223,224,227,229,234] The estimate of the pooled mean difference was 8.10 (95 percent CI: 6.98–9.22), favoring the use of tadalafil (any dose: 10 mg or 20 mg) compared with placebo in increasing the mean IIEF "EF" domain total score relative to baseline (Figure 60).

Mean per-patient percentage absolute change (from baseline) in SEP–Q2. This meta-analysis included seven trials.[216,217,220,224,227,229,234] The estimate of the pooled mean difference was 29.34 (95 percent CI: 25.06–33.62), favoring the use of tadalafil (any dose: 10 mg or 20 mg) compared with placebo in increasing the mean per-patient percentage of SEP–Q2 relative to baseline (Figure 61).

Proportion of patients with improved erection (GAQ-Q1). This meta-analysis included eight trials.[220,223,227,234,236-238,240] The pooled estimate of the relative proportion of patients (i.e., RR) with improved erection (i.e., those answered "yes" to GAQ–Q1) was 2.40 (95 percent CI: 2.03–2.83), indicating a statistically significantly higher rate of improvement for patients who received any dose of tadalafil (20 mg or 10 mg) relative to the placebo-treated patients (Figure 62).

Tadalafil (20 mg) versus placebo.

Efficacy.

Absolute mean change from baseline in IIEF–EF score. This meta-analysis included eight trials.[216,217,220,223,224,227,229,234] The estimate of the pooled mean difference was 8.21 (95 percent CI: 7.10–9.32), favoring the use of tadalafil (20 mg) compared with placebo in increasing the mean IIEF "EF" domain total score relative to baseline (Figure 63).

Mean per-patient percentage absolute change (from baseline) on SEP–Q2. This meta-analysis included 7 trials.[216,217,220,224,227,229,234] The estimate of the pooled mean difference was 29.60 (95 percent CI: 25.15–34.04), favoring the use of tadalafil (20 mg) versus placebo in increasing the mean per-patient percentage of SEP–Q2 relative to baseline. (Figure 64).

Proportion of patients with improved erection (GAQ–Q1). This meta-analysis included eight trials.[220,223,227,234,236-238,240] The pooled estimate of the relative proportion of patients with improved erection (i.e., those who answered "yes" to GAQ–Q1) was 2.43 (95 percent CI: 2.06–2.87), indicating a statistically significantly higher rate of improvement for patients who received tadalafil (20 mg) relative to the placebo-treated patients (Figure 65).

Harms.

Proportion of patients with any adverse event (all- cause). This meta-analysis included five trials[215,227,229,238,240] and yielded a RR of 1.95 (95 percent CI: 1.40–2.71) with a statistically significant heterogeneity across trials ($Chi^2_{df=4}$ = 15.60, p = 0.004; I^2 = 74.4 percent) (Figure 66).

We explored potential sources of this heterogeneity by examining other trial characteristics (e.g. populations, severity of ED, duration of ED, length of followup). Figure 67 presents the results based on 4 trials[227,229,238,240] with a 12-week followup that yielded similar effect estimates (RR range 1.45–2.08), whereas one trial[215] whose length of follow up was 6 weeks yielded a more inflated estimate of RR (i.e., RR = 4). After excluding this trial, the pooled estimate of RR was 1.61 (95 percent CI 1.37–1.89), indicating a statistically significantly greater rate of any adverse events in patients who received tadalafil (20 mg) relative to placebo-treated patients. There was no significant heterogeneity between the trials ($Chi^2_{df=3}$ = 2.88, p = 0.41; I^2 = 0 percent) (Figure 67). (Note that "favors" in forest plots refers to increased frequency of the event for the respective treatment arm, regardless of the desirability of the event).

Tadalafil (20 mg) versus tadalafil (10 mg).

Efficacy.

Mean change from baseline in IIEF–EF score. Two trials[227,229] compared 10 mg and 20 mg doses of tadalafil and also reported mean change in IIEF "EF" domain total score. The pooled estimate of these trials indicated that the mean increase in IIEF "EF" domain total score was not statistically different between the two dose-arms (mean difference 0.60, 95 percent CI:-0.92 to 2.11) (Figure 68)

Mean per-patient percentage absolute change (from baseline) on SEP–Q2. Two trials[227,229] compared 10 mg and 20 mg of tadalafil and also reported the mean per-patient percentage of SEP–Q2. The meta-analysis of these trials indicated that the mean increase in per-patient percentage of SEP–Q2 was not statistically different between the two dose-arms (mean difference 0.32, 95 percent CI: 7.53–8.18) (Figure 69).

Proportion of patients with improved erection (GAQ–Q1). Four trials[227,229,237,238] compared 10 mg and 20 mg of tadalafil and also reported the proportion of patients with improved erections as measured by GAQ–Q1. The meta-analysis incorporated three of these trials[227,237,238] and indicated that the difference observed between the rates of improvement in erection for patients who received 10 mg and 20 mg of tadalafil was not statistically significant (RR = 1.07, 95 percent CI: 0.99–1.16) (Figure 70).

Harms.

Proportion of patients with any adverse events (all- cause). This meta-analysis included six trials,[215,227,229,230,237,238] which compared 10 mg and 20 mg doses of tadalafil and also reported the proportion of patients who developed at least one adverse event. The pooled summary estimate of RR indicated a statistically significant higher incidence of adverse events in patients treated with 20 mg tadalafil compared with those treated with 10 mg tadalafil (RR = 1.21, 95 percent CI: 1.05–1.38). There was no statistically significant heterogeneity across the trials ($Chi^2_{df=5}$ = 6.60, p = 0.25; I^2 = 24.3 percent) (Figure 71).

Tadalafil (10 mg) versus placebo.

Efficacy. No meta-analysis was performed.

Harms.

Proportion of patients with any adverse events (all-cause). This meta-analysis included four trials,[215,227,229,238] which compared 10 mg of tadalafil to placebo and also reported the proportion of patients who experienced at least one adverse event. The pooled summary estimate of RR indicated a statistically significant higher incidence of adverse events in patients treated with 10 mg tadalafil as compared with those treated with placebo (RR = 1.53, 95 percent CI: 1.11–2.11). The test of heterogeneity was statistically significant (Chi2df=3 = 8.99, p = 0.03; I2 = 66.6 percent) (Figure 72).

After excluding a trial with a 6 week followup,[215] the pooled estimate of RR for the remaining three trials with 12 weeks of followup[227,229,238] was RR = 1.31 (95 percent CI: 1.10–1.57). The result indicated a statistically significant higher incidence of adverse events in patients treated with 10 mg tadalafil compared with those treated with placebo. There was no statistically significant heterogeneity present across the trials (Chi2df=2 = 0.01, p = 0.99; I2 = 0 percent) (Figure 73).

Tadalafil versus sildenafil. No meta-analysis of the four crossover trials[103,118,121,163] that compared tadalafil with sildenafil was performed because the sildenafil dose/dosage varied,[103,118,121,163] and there was a lack of relevant efficacy outcome data such as the mean absolute change in IIEF "EF" domain total score,[118,121,163] per-patient percentage of successful attempts on SEP–Q2,[118,121,163] and the proportion of patients with improved erection on GAQ–Q1).[118,121,163]

Assessment of Publication Bias

Funnel plots were used to assess the extent of asymmetry (i.e., possible publication bias) present in each meta-analysis. Visual inspection of these plots did not reveal any substantial asymmetry.[53] (Funnel plots, Appendix G.)

Sublingual Treatments - Apomorphine

Literature Search

In total, 12 unique randomized controlled trials (RCTs) (11 publications) met the eligibility criteria and were included in the review.[114,117,120,148,159,248-253] One report[252] described two distinct trials (a and b).

Overview of Trials

The trials were published between 2000[253] and 2007[159] inclusively, and were conducted in the US,[251-253] Europe,[114,120,148,159,248-250] the United Kingdom,[117] and Mexico.[251] The trials were supported by funds from Abbot Laboratories,[248,250,252] Takeda,[248,252] Pfizer UK,[117,159] and Zonagen Inc.[251] Funding sources were not reported for four trials.[114,120,148,249] The duration of followup of eight trials[114,117,120,248,249,252,253] ranged from 4 weeks[249,252] to 8 weeks.[117,148,159,248,253] The duration of followup for two trials could not be ascertained.[250,251] Of the 12 trials, four were parallel-group[248-250,253] and eight were crossover studies.[114,117,120,148,159,251,252] Of the four parallel-group RCTs, three were two-armed[248-250] and one was a four-armed trial.[253] Further information on trial characteristics is provided in (Table F-4, Appendix F).

Populations

The included trials involved men diagnosed with erectile dysfunction (ED). The total and mean (range) numbers of patients randomly assigned to trial arms were 1975 and 179 (12–569), respectively. The inclusion criteria across the trials were adult men (age ≥ 18 years) diagnosed with ED in a stable heterosexual relationship of at least 6 months of duration. The inclusion criteria in two studies [114,120] were restricted either to patients with arteriogenic[120] or nonarteriogenic ED.[114] In one trial,[249] the inclusion criteria were restricted to patients with ED and a history of diabetes (type I or II) who had been naïve to any ED-related treatment. The enrolled patients in one trial[159] had to be naïve to ED drug therapy and had to have an IIEF–5 score ≤ 21.

The exclusion criteria in the majority of the included trials were spinal cord injury[114,120,248,253] and penile/testicular deformity.[114,120,148,159,248,249,251-254] Other frequently reported exclusion criteria were uncontrolled hypertension,[114,148,251-253] diabetes,[148,248,252,253] endocrine disease,[114,248,251-253] any major hepatic/renal disease,[117,148,251] prostatectomy,[148,248,251,253] peptic ulcers,[159] HIV-positivity/AIDS,[248,252,253] the use of nitrates, [114,117,120,148,159,251] a history of cancer,[248,252,253] and serious cardiovascular diseases (e.g. angina pectoris).[148,159] Only one trial failed to report exclusion criteria.[250]

The mean age of the study participants across the included trials ranged from 35[250] to 59 years.[120] The race of the study participants was reported in six trials.[117,159,248,252,253] The proportion of Caucasians across these trials ranged from 85 percent[252] to 99 percent.[248] The duration of ED was at least 3 months at study entry in all trials. The longest mean duration of ED (3.5–4.2 years) was reported in the trial by Porst et al 2007.[159] Most commonly reported comorbidities among the study participants were diabetes,[114,120,148,159,248,252,253] hypertension,[114,120,148,159,248,249,252,253] ischemic heart disease,[114,249] and coronary artery disease.[120,159,248,252,253] The presence or absence of comorbidities could not be ascertained from three trials.[117,250,251] The underlying cause of ED (i.e., etiology) in the patients was specified in three trials to be nonarteriogenic (all patients),[114] arteriogenic (all patients),[120] and various causes (patients with

organic, psychogenic or mixed origin ED).[159] In four trials,[114,120,249,250] the proportion of smokers ranged from 35 percent[249] to 95 percent.[114,120] In the remaining trials this proportion could not be ascertained.[117,148,159,248,251-253]

In seven trials[117,159,248,249,252,253] the authors provided baseline arm-specific distributions of the patients' sociodemographic and clinical characteristics (e.g. age, race, duration/severity of ED, comorbidities) and explicitly stated that the distribution of these characteristics between the randomized arms was generally similar. The authors of the remaining five trials[114,120,148,250,251] did not report this information.

Interventions

Patients in all reviewed 12 trials[114,117,120,148,159,248-253] received apomorphine sublingually with a dose ranging from 2 mg[159,248] to 6 mg.[251,253] In all trials except one,[251] patients received apomorphine monotherapy. In this one trial,[251] two groups of patients received the combination of apomorphine either with phentolamine (40 mg) or with phentolamine (40 mg) plus papaverine (150 mg). One trial did not report the dose of apomorphine.[117]

In six trials[148,249-252] apomorphine was given only at a fixed dose. A flexible-dose-only regimen was used in other five trials.[114,117,120,158,248] In one trial,[253] patients were randomly assigned to receive either a fixed (5 mg or 6 mg) or flexible dose (2 mg–6 mg) of apomorphine.

The duration of apomorphine treatment across the trials ranged from 4 weeks[249,252] to 8 weeks.[117,148,159,248,253] Patients in the control arms received placebo in five trials,[248-250,252,253] sildenafil (50-100 mg/d) in six trials,[114,117,120,148,159,251] and apomorphine (control dose) in two trials.[252]b[253]. An additional comparison group of patients in one trial[251] received a combination of phentolamine (40 mg) and papaverine (150 mg).

Outcomes

Harms. All trials but one[114] reported some information on the absence and/or occurrence of adverse events: any adverse events,[117,159,248,250,251] serious adverse events (including death),[117,159,248,250,251] withdrawals due to adverse events,[117,120,159,248,249,253] and frequently reported (≥5 percent) specific adverse events.[120,148,159,248-253]

Efficacy. The efficacy outcomes measured in the 11 trials varied to some degree. The most commonly measured and reported outcome across the trials was the percentage of successful intercourse attempts.[114,117,120,148,159,248,252,253] In four trials, the percentage of attempts resulting in erections firm enough for intercourse was also measured [148,252,253]. Similarly, in one trial,[251] the proportions of successful vaginal penetration and vaginal intercourse leading to orgasm were estimated. The above-mentioned outcomes were calculated based on the patients' and/or their partners' responses to pre-specified questions provided in home-use diaries.

In five trials, the mean IIEF score (domains of "erectile function," "orgasmic function," "sexual desire," "intercourse satisfaction," "overall satisfaction") was used to assess the relative efficacy of apomorphine.[117,148,159,249,253] For example, in one trial[117] the primary endpoint was the mean difference in IIEF score for the "erectile function" domain, whereas secondary endpoints were mean difference IIEF scores for other domains (e.g. "orgasmic function," "sexual desire," "intercourse satisfaction," and "overall satisfaction"). In another trial,[253] the authors provided differences between treatment-arm specific mean IIEF scores for the "erectile function," "intercourse satisfaction," and "overall satisfaction" domains as secondary efficacy endpoints. In this trial,[249] primary efficacy endpoint was a response rate defined as the proportion of patients who answered "yes" to a Global Efficacy Question (GEQ) (i.e., "*Has the treatment you have*

been taking over the past two or four weeks improved your erections?") combined with an improvement of ≥ 5 points in the "erectile function" domain of the IIEF.

Global Assessment Questions (GAQs) were evaluated and reported in three trials,[117,159,251] as a secondary response endpoint. In one trial[117] the endpoint was defined as the proportion of patients who answered "yes" to two GAQ questions, and in the other trial[251] the corresponding endpoint was treated as a continuous variable whereby responses to one GAQ were given on an ordinal scale (1 = very satisfied, 5 = very dissatisfied).

The treatment preference/satisfaction was measured and reported in three trials.[117,120,251] In one trial the treatment satisfaction was measured as a proportion of patients satisfied with one drug only, alternative drug only, both drugs, or none of the drugs.[120] In two trials,[117,159] the treatment-arm specific differences in IIEF "Overall Satisfaction" domain and the Erectile Dysfunction Index of Treatment Satisfaction (EDITS) questionnaire-based mean scores were used to evaluate the patient's satisfaction with treatment regimens. In their trial, Lammers et al.,[251] employed the Visual Analogue Scale (VAS; range 0–100) to assess patients' treatment satisfaction. The endpoint was the post-treatment mean VAS satisfaction score calculated for patients in each treatment arm.

The authors of one trial[251] measured and reported the mean Sexual Encounter Profile (SEP) questionnaire-based overall score.

Penile rigidity was reported in two trials.[250,251] In one trial,[251] it was measured on VAS as the mean VAS rigidity (range 0–100), and in the other trial,[250] it was measured using a RigiScan and expressed as the percentage rigidity (i.e., percent of linear displacement of the loops due to the constant force). A post-treatment rigidity of at least 40 percent was considered a positive treatment response.

Study Quality and Reporting

The mean (range) of Jadad's total score for the 12 included trials was 2.36 (1^{114} – 5^{249}). Six of the 12 trials were reported to be double-blind.[248,249,251-253] Of these, only two trials[249,253] provided some description of blinding method(s) used. Only one trial reported some information on the adequacy of allocation concealment.[249] The adequacy of allocation concealment for the 11 remaining trials was unclear.

Of the eight crossover trials,[114,117,120,148,159,251,252] only one [251] failed to report whether a washout period was applied between the treatment periods. The length of the washout period for six trials[114,117,120,159,252] ranged from 24–96 hours[252] to 2 weeks,[117,159] and for one trial this duration was 4 weeks.[148]

Qualitative Synthesis

Apomorphine versus placebo. In total, there were five placebo-controlled trials.[248-250,252,253]

Harms. The occurrence of any adverse events across the trials was reported poorly. In one trial,[248] the rate of any adverse events was numerically slightly higher in patients receiving apomorphine than in those receiving placebo (37.8 versus 24.5 percent, respectively). Another trial[250] reported only two patients who had experienced headaches after receiving placebo. Only one trial[248] explicitly stated that none of the patients died during the trial. In two trials,[248,250] the rate of serious adverse events did not differ between patients receiving apomorphine and placebo. In the first trial,[248] four patients had one or more serious adverse events. Specifically, of the two patients in the apomorphine arms (2–3 mg), one had chest infection/severe cough/cough syncope and the other one had moderate unstable angina pectoris. In the placebo arm, two

patients had angina pectoris. In the second trial,[250] no serious adverse events had occurred. The other three trials did not report whether or not patients had experienced any serious adverse events.[249, 252,253] In two trials,[248,253] the proportion of patients who withdrew due to adverse events was numerically higher in the apomorphine arms compared with placebo arms (5–10 percent versus 1 percent); in the other trial,[249] none of the patients withdrew due to adverse events. Other trials[250,252] failed to report whether any patients withdrew due to adverse events. The most common adverse event reported across trials was nausea[148,248,249,252,253] ranging from 7.0 percent[252] to 44 percent[253] in the apomorphine arms and from 0.4 percent[248] to 5.0 percent[249] in the placebo arms. Other commonly reported adverse events were headache, dizziness, and yawning. In general, these events had occurred numerically more frequently in apomorphine arms than in placebo arms.[248,252,253]

Efficacy. The three trials[248,252,253] that measured the mean percentage of successful intercourse attempts found that this parameter was higher among patients who received apomorphine compared with those who received placebo; this finding was statistically significant. The mean percentage of successful intercourse attempts observed in apomorphine groups in these trials ranged from 38 percent[248] to 51 percent,[253] whereas the corresponding treatment response observed in the placebo groups ranged from 28 percent[248] to 34 percent.[252] The difference for each comparison between apomorphine and placebo groups in the three trials was statistically significant ($p \leq 0.01$). The results for the above-mentioned endpoint, whether based on responses obtained from patients or from their partners, did not differ.[252,253]

Two trials[252,253] showed that patients who received apomorphine had a statistically significant higher percentage of attempts resulting in erections firm enough for intercourse than those in placebo group. For example, in one trial[252] the percentages of attempts resulting in erections firm enough for intercourse in the apomorphine (3 mg) and placebo groups were 46.9 percent and 32.3 percent respectively ($p < 0.001$). In the other trial, [253] the corresponding percentages were 53.1 (apomorphine 5 mg) and 34.5 (placebo), respectively ($p \leq 0.01$).

The mean IIEF score for the "Erectile Function (EF) domain" obtained from two trials[249,253] were not consistent. For example, in the first trial,[249] differences in mean IIEF "EF" domain scores between patients receiving apomorphine and placebo were not statistically significant (13.81 versus 13.24; $p = 0.52$). In contrast, the authors of the other trial[253] observed a statistically significantly greater mean IIEF score ("erectile function" domain) in the apomorphine group compared with placebo (actual mean IIEF values were not provided; $p \leq 0.01$).

There was no statistically significant difference between apomorphine and placebo groups in the proportion of patients who answered "yes" to the GEQ ("*Has the treatment you have been taking over the past two or four weeks improved your erections?*") combined with an improvement of ≥ 5 points in the IIEF "EF" domain (22.92 percent versus 17.31 percent, $p = 0.48$).[249]

The proportion of patients with positive response on rigidity (≥ 40 percent) was numerically greater in the apomorphine compared with the placebo group (4/6 versus 0/6).[250]

Apomorphine mono (dose/dosing 1) versus apomorphine mono (dose/dosing 2). In total, two trials compared different doses/dosing of apomorphine in patients with ED. [252,253]

Harms. The incidence of several adverse events such as nausea, yawning, and dizziness across trials was numerically greater in patients receiving higher doses (4–6 mg) than lower doses of apomorphine (2–3 mg).[252,253] In one trial,[253] a dose-optimization schedule (2–6 mg) was associated with fewer events of nausea (30 percent of patients) than the fixed doses of

apomorphine (5 and 6 mg: 38 and 49 percent of patients, respectively). Statistical test results for significance were not reported.

Efficacy. Neither of the two trials[252,253] identified a dose-response effect on the percentages of successful intercourse attempts and attempts resulting in erections firm enough for intercourse. For example, in one trial[252] the percentage of successful intercourse attempts was similar in patients who received 3 and 4 mg doses of apomorphine (48.4 versus 49.6 percent, respectively; $p > 0.4$). In the other trial,[253] the percentage of successful intercourse attempts was numerically similar for patients in two dose-escalation (2–4 mg and 2–4 mg to 5–6 mg) and two fixed-dose (5 mg and 6 mg) apomorphine groups, ranging from 45.1 percent (2–4 mg) to 50.9 percent (5 mg).

Apomorphine mono versus sildenafil mono. Five trials compared the efficacy/safety of apomorphine monotherapy to that of sildenafil monotherapy[114,117,120,148,159]

Harms. In two trials,[117,159] the number of patients who experienced any adverse event(s) was numerically greater in the sildenafil groups (94.0 and 35.7 percent, respectively) in comparison with the apomorphine groups (64.0 versus 21.8 percent, respectively). In another trial,[120] the proportions of patients with any adverse events in sildenafil and apomorphine groups were 7 percent (3/43) and 14 percent (6/43), respectively. One trial[117] explicitly stated that none of the patients had died during the trial and reported that five patients had had at least one serious adverse event; of these patients, three were receiving sildenafil (deterioration of arthritic shoulder in one patient and myocardial infarction/atrial fibrillation in two patients) and two were receiving apomorphine (myocardial infarction and deterioration in Dupuytren's contracture). In another trial,[159] serious adverse events occurred in two patients from the sildenafil group (exacerbation of chronic bursitis and stroke) and in two patients from the apomorphine group (stricture of the urethra and sudden cardiac death). The number of patients with vasodilation was numerically higher in the 50 mg sildenafil than in the 3 mg apomorphine group (6 versus 0)[148]

In three trials,[117,120,159] the number of patients who withdrew due to adverse events ranged from one[159] to three[117] for the apomorphine arms and from zero[120,159] to two[117] for the sildenafil arms.

Some specific adverse events that occurred in one trial in sildenafil versus apomorphine groups were headache (16 versus 5 percent) and nausea (3.2 versus 5.6 percent).[117] In another trial,[159] the proportions of patients with headache in the sildenafil versus apomorphine groups were 10.3 versus 3.2 percent, respectively.

Efficacy. All five trials[114,117,120,148,159] measuring the number of successful intercourse attempts showed that the mean percentage of successful intercourse attempts was higher in patients who had received sildenafil (range 62.7–81.0 percent) compared with those receiving apomorphine (range 28.3–62.7 percent). The observed differences were statistically significant. In fact, in three trials,[117,120,159] the percentage of successful intercourse attempts in the sildenafil groups was about twice as that in the apomorphine groups. For example, in one trial,[117] the percentages of successful intercourse attempts in sildenafil and apomorphine groups were 75.1 percent (95 percent CI: 69.2–81.0) and 35.3 percent (95 percent CI: 29.4–41.3) respectively, with a mean difference of 39.7 percent (95 percent CI: 33.0–46.5) between the two groups. In the other trial,[120] the corresponding values of the mean percentage of successful intercourse attempts in the sildenafil (50–100 mg) and apomorphine (2–3 mg) groups, regardless the dose, were 63.7 and 32.1 percent, respectively ($p < 0.01$). Similarly, in another trial,[114] overall, patients receiving sildenafil (50–100 mg) had a statistically significantly greater mean percent of successful intercourse attempts than those receiving apomorphine (2–3 mg) (73.1 versus 62.7 percent, $p = 0.0004$).

The use of sildenafil was shown to be more efficacious than apomorphine in improving (i.e., increasing) IIEF scores for "erectile function" as well as for other domains (e.g. "intercourse satisfaction," "overall satisfaction").[117,148,159] For example, the mean IIEF score values for the "EF" domain in patients who received sildenafil and apomorphine were 25.2 (95 percent CI: 23.7–26.7) and 15.9 (95 percent CI: 14.4–17.3), respectively, with a mean difference of 9.3 (95 percent CI: 7.6–11.1) between the two groups.[117] In the other trial,[159] the corresponding least square mean values for the IIEF "EF" domain were 23.1 (95 percent CI: 21.8–24.4) and 15.7 (14.5–17.0), with a mean difference of 7.2 (95 percent CI: 5.5–8.8).

The proportions of patients who answered "yes" to questions 1 and 2 of GAQ (Question 1: "Compared with having no treatment at all for your erection problem, has the medication you have been taking over the past 4 weeks improved your erections?"; Question 2: "Compared with having no treatment at all for your erection problem, has the medication you have been taking over the past 4 weeks improved your ability to have sexual intercourse?") were numerically higher in the sildenafil group than in the apomorphine group (94.8 and 93.9 percent versus 51.7 percent and 48.7 percent, respectively).[117] Similarly, in the other trial,[159] statistically significant differences were observed between patients receiving sildenafil and apomorphine with respect to GAQ–Q1 (88.7 percent versus 43.1 percent, $p < 0.0001$).

In the same trials,[117,159] the mean EDITS scores for patient satisfaction were higher in patients receiving sildenafil (82.5 and 74.0, respectively) compared with those receiving apomorphine (46.8 and 47.0, respectively).

According to results obtained from two trials,[117,120] more patients preferred sildenafil than apomorphine. The percent of patients who preferred sildenafil over apomorphine across these trials ranged from 65.1 percent[120] to 96.6 percent.[117] In contrast, the percentage of patients who preferred apomorphine over sildenafil ranged from 2.3 percent[120] to 3.4 percent.[117]

Apomorphine (combined with phentolamine and/or papaverine) versus sildenafil.

Harms. In this trial,[251] the overall rates of adverse events in apomorphine combined with papaverine and phentolamine (APP), a combination of phentolamine and papaverine, and a combination of apomorphine and phentolamine, and sildenafil were 25.0, 19.1, 17.1, and 15.0 percent, respectively. Only one patient developed a serious adverse event (i.e., right nephrectomy) in the APP arm. The most frequently reported adverse events in this trial were rhinitis (4.8–15 percent) and headache (2.4–5.0 percent), the highest percentages observed in the APP arm. The authors of this trial did not report the proportion of patients in each arm that withdrew due to adverse events.

Efficacy. One trial,[251] found no significant differences (one-tailed $p > 0.05$) between the combined apomorphine (either with phentolamine or phentolamine and papaverine) and sildenafil arms for most of the outcomes (e.g. mean SEP VAS rigidity, duration, and satisfaction scores, proportion of successful vaginal penetration, and mean satisfaction score based on GAQ scale).

Quantitative Synthesis - Meta-analysis of Trials

Apomorphine mono versus placebo. Five trials[248-250,252,253] were considered to be eligible for meta-analysis. However, no meta-analysis could be performed because numerical information was lacking such as standard deviations (or standard errors)[248-253], pre-crossover data [252], mean values[253] for percent successful intercourse attempts and the IIEF-EF domain.

Apomorphine versus sildenafil. Trials (all crossover design) comparing the efficacy and safety profiles of apomorphine and sildenafil were not meta-analyzed because of clinical

heterogeneity with respect to populations and outcomes.[114,117,120,148,159] For example, in two trials the patient populations were nonarteriogenic[114] and arteriogenic.[120] Types of patients studied in the third trial could not be ascertained.[117] The patient population of the one remaining trial[159] was comprised of those with ED of "mostly psychogenic," "mostly organic," and "mixed" etiology. Apomorphine dose(s) administered in one of the trials[117] were not reported.

Injection Treatments - Intracavernosal Injection

Literature Search

Forty-two trials (in 43 publications) met eligibility criteria as randomized trials of intracavernosal injection (IC) therapy for treatment of men diagnosed with ED.[119,172,255-280,280-294] One trial was reported in two publications [261,276] and one publication described two trials (Aversa et al. 1996; studies: a and b).[267]

Overview of Trials

Among the 42 unique trials, 32 used a crossover design (n = 1957; range: 7 to 240 subjects) and 10 a parallel design (n = 1074, range: 30 to 296 subjects).

Populations

ED was primarily of physiologic origin (58 percent). Amongst ED patients, vascular disease and diabetes were the most commonly reported underlying conditions. Three trials exclusively enrolled men with previous radical prostatectomy or cystectomy (n = 159 subjects). Only eight trials reported smoking status, two trials ethnicity, and none reported body weight (e.g. body mass index).

Interventions

IC alprostadil (PGE_1) was evaluated alone or in combination with numerous other pharmacologic agents. One specific alprostadil combination (alprostadil plus papaverine plus phentolamine) was also tested alone or in combination with other pharmacologic agents. Other types of evaluated IC were papaverine; papaverine plus phentolamine, with or without additional sexual counseling; moxisylate; sodium nitroprusside; linsidomine; linsidomine plus urapidil; papaverine plus sildenafil; and vasoactive intestinal peptide plus phentolamine. For a full description of treatment interventions in these individual trials refer to Evidence Table F-5 (Appendix F).

Study Quality and Reporting

Information on pharmaceutical funding was provided for nine trials. Only three studies specifically reported the use of an intention-to-treat analysis. None of the trials reported methods of allocation concealment. Study withdrawals, drop-outs or lost to followup were reported in 33 trials and were 13 percent (16 percent in crossover studies and 6 percent for parallel studies). The majority of the trials were considered to be of low quality with total Jadad score < 3. Only six of the 43 trials received a score of four, and none received a score of five. Twenty-nine trials received a score of two or less. In addition, many studies reported physiologic (e.g. degree or duration of penile rigidity) rather than clinically validated outcomes (IIEF, SEP, GAQ–Q1).No study assessed therapies beyond 12 weeks.

Outcomes

Many of the 42 trials measured only physiologic efficacy outcomes (e.g. penile rigidity). Of the clinically relevant outcomes, more commonly reported were quality of erections achieved at home, without regard to whether the patient was able to achieve successful sexual intercourse, (e.g. “improvement” in erections, “full response,” full erection,” or “grade 4 or 5 erections”).

Finally, two studies reported on whether erections were "valid for intromission," and one on whether patients were "satisfied with treatment." Trials that reported clinically relevant efficacy outcomes or harms are emphasized in the Outcomes section below.

Qualitative Synthesis

Tables 12–14 illustrate the results.

PGE_1 versus no treatment. One trial, involving men who had undergone nerve-sparing radical retropubic prostatectomy, compared efficacy and harms of PGE1 to those of no treatment.[265]

Harms. In total, 6.7 percent and 13.3 percent of participants treated with PGE_1 reported prolonged erection and hematoma, respectively. No untreated participants reported these adverse event s.

Efficacy. In total, 66.7 percent of participants receiving PGE_1 had improved erections versus 20 percent of those who did not receive any treatment. The absolute risk difference (RD) between the two groups was 47 percent (95 percent CI: 13–80).

PGE_1 versus placebo. Six trials compared efficacy and/or harms of PGE1 versus placebo.[266,268,274,281,282,292]

Harms. Penile pain was reported in four trials and occurred numerically more commonly in participants treated with PGE_1. In one trial, penile pain was reported by 22.7 percent of the participants treated with PGE_1 [271] and in another in 13.3 percent of the participants.[282] Neither study reported data on pain for the placebo groups. A third trial reported pain to have occurred in 35 percent of the participants who received PGE_1 versus 0 percent of the placebo-treated participants[266] The fourth trial observed similar proportions of patients with pain between the treatment groups (PGE_1: 11.7 percent versus placebo: 10.9 percent).[274] Prolonged erection or priapism was reported by 15 percent [266] and 2.5 percent [271] of the PGE_1 –treated participants. In placebo-treated subjects, none of the participants had priapism in the first trial, and no priapism-related data were reported for the second trial. In a single trial, hematoma was reported for 1.5 percent of injections with PGE_1, with no data reported for the placebo group.[282]

Efficacy. In four crossover trials, between 28.9 and 66 percent of participants reported improved erections in the PGE_1 treatment groups. In two of these trials, placebo-treated participants did not experience improved erections [266,268] The other two trials did not report any outcomes data for the placebo groups.[281,292]

In one parallel trial, none of the placebo-treated participants reported improved erections, as compared with 35 percent of the participants treated with PGE_1. The observed pattern conformed a dose-response trend (17 percent with 2.5µg PGE_1, 27 percent with 5µg, 45 percent with 10µg, and 50 percent with 20µg).[271]

PGE_1 versus PGE_1 (comparison of timing of treatment initiation or dose delivery). One trial compared the harms related to fast versus slow PGE1 injection (i.e., 5-second injection versus 60-second injection).[270] A second trial, involving men who had undergone non–nerve-sparing radical prostatectomy, compared the efficacy and harms of early versus late post-prostatectomy PGE1 treatment (i.e., 1–3 months post-operatively versus 4–12 months post-operatively).[256]

Harms. In the first trial, 54.5 percent of those receiving fast PGE_1 injections reported pain during injection versus 18.2 percent of those receiving slow injections.[270] In the second trial, 8.3 percent of participants who received early PGE_1 treatment reported prolonged erections versus 0 percent of those who received late PGE_1 treatment.[256]

Efficacy. In total 72.2 percent of participants receiving early PGE_1 treatment reported improved erections versus 43.2 percent of those receiving late PGE_1 treatment.[256]

PGE_1 versus papaverine. Four trials compared the efficacy and/or harms of PGE1 versus papaverine,[287,288,291,293] Only one trial of intracavernosal injection evaluated the outcome of sexual intercourse success.[291]

Harms. In three trials that reported penile pain, two[288,291] showed statistically nonsignificant differences between PGE_1 and papaverine (8.5 percent versus 4.7 percent, and 46 versus 44 percent, respectively). [288,291] The third trial reported more frequent occurrence of pain in the papaverine participants (32.7 percent versus 11.5 percent, RD 21 percent, 95 percent CI: 6.0–37.0).[287] All four trials reported the incidence of priapism. In one trial, this occurred in 10 percent of the participants treated with PGE_1 versus 6.7 percent of those treated with papaverine.[293] In two trials no cases of priapism occurred in either treatment group. [287,288] In the fourth trial, no priapism occurred among PGE_1-treated subjects versus 0.8 percent of the participants among papaverine-treated subjects.[291]

Efficacy. In one trial[291], the proportions of PGE_1- and papaverine-treated patients achieving at least one successful intercourse attempt over 4 weeks of treatment were similar (31 percent versus 33 percent).

In four trials, from 26.4 to 80.8 percent of the PGE_1–treated participants reported improved erections, as compared with 10 to 63.5 percent of papaverine-treated subjects. The estimates of RR favouring PGE_1 over papaverine were statistically significant in three trials [288,291,293] and marginally significant in the fourth trial.[287]

PGE_1 plus papaverine versus phentolamine plus papaverine. One trial compared efficacy and harms of papaverine plus PGE1 versus papaverine plus phentolamine.[289]

Harms. In total, 16.3 percent of the papaverine plus PGE_1 participants reported pain versus 0 percent of the papaverine plus phentolamine participants. Approximately 8 percent of the participants in each treatment group reported prolonged erection.

Efficacy. In total, 77.6 percent of participants allocated to papaverine plus PGE_1 reported improved erections versus 57.1 percent of participants allocated to papaverine plus phentolamine.

PGE_1 versus papaverine plus phentolamine. One trial compared the efficacy and harms of PGE1 versus papaverine plus phentolamine.[266]

Harms. In total, 35 percent of PGE_1 participants reported pain versus 15 percent of papaverine plus phentolamine participants. There was no difference in prolonged erections between the two treatments (15.0 percent versus 18.3 percent; RD -3.0 percent, 95 percent CI: -17.0 to 10.0)

Efficacy. In total, 50 percent of participants treated with PGE_1 reported improved erections versus 56.7 percent of those treated with papaverine plus phentolamine.

PGE1 versus trimix. (see papaverine plus phentolamine plus PGE_1 versus PGE_1 below)

PGE_1 versus moxisylate. Two trials compared the efficacy and harms of PGE1 to moxisylate.[262,293] In both trials, PGE1 was shown to be more effective than moxisylate.

Harms. In the first study, compared with participants in the moxisylate group, those in the PGE_1 group experienced the following events more frequently: pain during injection (14.8 versus 25 percent), pain during erection (4.9 versus 23.5 percent), pain after erection (4.9 versus 19.1 percent), prolonged erection (1.6 versus 4.4 percent), and bleeding (4.9 versus 14.7 percent), whereas, the occurrence of dizziness/hypotension was numerically more common in moxisylate-treated participants (8.2 versus 1.5 percent). Not all differences were statistically significant. In

the second study, prolonged erection appeared more common in the participants treated with PGE_1 (3.3 versus 10 percent)

Efficacy. In the first trial, 85.3 percent of the participants treated with PGE_1 reported improved erections versus 60.7 percent of the moxisylate-treated participants.[262] In the second trial, the rates of improved erection in PGE_1 and moxisylate groups were 40 percent and. 6.7 percent, respectively.[293]

PGE_1 versus sodium nitroprusside. One trial compared the efficacy and harms of PGE1 with three different doses of nitroprusside (100µg, 300µg, or 400µg).[278]

Harms. In total, 6.7 percent of the participants in PGE_1 group reported pain during injection versus 0 percent of those in each of the nitroprusside group. About 4.0 percent of the participants treated with PGE_1 reported dizziness versus 10, 8 and 3 percent for each of the nitroprusside groups(100µg, 300µg, and 400µg, respectively).

Efficacy. In total, 20 percent of the participants treated with PGE_1 reported full rigidity. Nitroprusside 100µg was reported to be ineffective in producing erections. In the 300µg and 400µg nitroprusside groups, 15 percent and 14.3 percent of the participants, respectively had full rigidity.

PGE_1 versus linsidomine. Three trials compared the efficacy and harms of PGE1 to linsidomine.[273,279,284]

Harms. In one trial, 17.5 percent of participants receiving PGE_1 reported penile pain. Similar data for the linsidomine-treated subjects was not provided. In the linsidomine group, moderate to severe headache was reported by 7.5 percent of the subjects.[284] In a second trial, 7.5 percent of PGE_1 participants reported pain during injection versus 2.5 percent of linsidomine subjects.[273]

Efficacy. Between 30 and 65 percent of the participants treated with PGE_1 had improved erections compared with 7.5–12.5 percent of those treated with linsidomine.

PGE_1 versus linsidomine plus urapidil. One trial compared the efficacy and harms of PGE1 to linsidomine plus urapidil.[273]

Efficacy. In total, 40 percent of participants randomly assigned to PGE_1 therapy reported improved erections versus 25 percent of those randomly assigned to linsidomine plus urapidil therapy.

Harms. In total, 7.5 percent of participants in each treatment group reported pain during injection, while 0 percent of those receiving PGE_1 and 12.5 percent of those receiving linsidomine plus urapidil reported severe hypotension.

PGE_1 versus PGE_1 plus lidocaine. One trial compared the efficacy and harms of PGE1 injections with or without lidocaine.

Harms. The proportions of participants reporting pain in PGE_1 plus lidocaine versus PGE_1 only groups were 45.4 percent and 86.4 percent, respectively.

Efficacy. In total 63.6 percent of the participants allocated to PGE_1 plus lidocaine reported improved erections versus 27.3 percent of those allocated to PGE_1 alone.

PGE_1 versus PGE_1 plus procaine. One trial compared the efficacy and harms of PGE1 injections with and without procaine (10mg or 20mg).[280]

Harms. Of participants allocated to PGE_1 plus procaine, 62.5 percent reported moderate to severe pain compared with 83.3 percent of those allocated to treatment with PGE_1 only. The occurrence of severe pain was reported by 16.6 percent versus 45.8 percent of the participants, respectively.

Efficacy. In total, 66.7 percent of those assigned to receive PGE_1 plus procaine reported improved erections versus 66.7 percent of those assigned to receive PGE_1 only.

PGE_1 versus PGE_1 plus sodium bicarbonate. One trial compared the harms of PGE1 injections with or without sodium bicarbonate.[269]

Harms. In total, 70 percent of participants assigned to the PGE_1 plus sodium bicarbonate group reported pain versus 80 percent of those assigned to the PGE_1 group. The incidence of pain in PGE_1 plus sodium bicarbonate group was reduced compared with PGE_1 alone group but the between-group difference was not statistically significant (70 percent versus 80 percent, RD -10 percent, 95 percent CI: -48.0-28.0).

Efficacy. The efficacy was not reported

PGE_1 plus sexual counseling plus sildenafil versus PGE_1 plus sildenafil. One trial compared the efficacy and harms of PGE1 plus sexual counseling plus adjunctive open label oral sildenafil versus PGE1 plus adjunctive open label sildenafil in men who had undergone non-nerve sparing radical retropubic prostatectomy or radical cystectomy.[294]

Harms. The frequency of adverse events was similar for PGE_1 plus counseling plus sildenafil versus PGE_1 plus sildenafil groups, including moderate pain (34.4 percent versus 42.8 percent), severe pain (13.7 percent versus 10.7 percent), prolonged erection (17.2 percent versus 17.8 percent), and hematomas (6.9 percent versus 10.7 percent). There were no withdrawals among the participants allocated to PGE_1 plus counseling plus sildenafil. In contrast, 29 percent of those treated with PGE_1 plus sildenafil withdrew (3 of 8 withdrawals were due to prolonged pain after injections).

Efficacy. Mean score on the IIEF "EF domain" after 18 months of treatment was significantly higher in men allocated to PGE_1 plus counseling plus sildenafil versus those allocated to PGE_1 plus sildenafil (26.5 versus 24.3, $p < 0.05$).

Papaverine versus placebo. None of the identified studies compared papaverine monotherapy to placebo. One trial reported the efficacy and harms of papaverine plus PGE1 versus PGE1 alone.[289] Papaverine plus PGE1 was not shown to be more effective and it was associated with more frequent pain than PGE1 alone.

Harms. In total 34.2 percent of participants allocated to papaverine plus PGE_1 reported pain versus 18.4 percent of those allocated to PGE_1 alone. The incidence of prolonged erection was reported by 15 percent and 18.3 percent of the participants in each group, respectively.

Efficacy. In total, 73.7 percent of participants allocated to papaverine plus PGE_1 reported improved erections versus 60.5 percent of those allocated to PGE_1 alone.

Papaverine versus PGE_1 (see PGE_1 versus papaverine, above).

Papaverine versus moxisylate. One trial compared the efficacy and harms associated with the use of papaverine versus moxisylate.[293]

Harms. In total, 6.7 percent of the papaverine-treated participants reported prolonged erection versus 3.3 percent of the moxisylate-treated participants ($p \geq 0.05$).

Efficacy. In total, 10 percent of the papaverine-treated participants reported improved erections versus 7 percent of the moxisylate-treated participants ($p \geq 0.05$).

Papaverine followed by sildenafil versus sildenafil followed by papaverine. One trial compared the efficacy and harms for a single 30 mg dose of papaverine followed by a single 50 mg dose of sildenafil versus a single 50 mg sildenafil dose followed by 30 mg papaverine.[172]

Harms. Adverse events were reported for both treatment groups combined, including priapism (10 percent), headache (4 percent), blurred vision (2 percent), and dyspepsia (2 percent).

Efficacy. Data on clinically relevant outcomes were not reported.

Moxisylate versus placebo. One trial compared the efficacy and harms for moxisylate versus placebo.[285]

Harms. Participants receiving moxisylate reported prolonged erection (1.6 percent), pain (3.3 percent), faintness (3.3 percent), hypotension/nausea/bradycardia (1.6 percent) and hot flushes (1.6 percent). Though no participants receiving placebo experienced any of these side effects, these differences were not statistically significant.

Efficacy. In total, 86.9 versus 27.9 percent of moxisylate and placebo participants, respectively, reported improved erections (RR = 3.12, 95 percent CI: 2.06-4.72).

Moxisylate versus PGE_1 (see PGE_1 versus moxisylate, above).

Moxisylate versus papaverine (see papaverine versus moxisylate, above).

Phentolamine plus PGE_1 versus PGE_1. Two trials compared phentolamine plus PGE1 versus PGE1 alone for efficacy and/or harms (Aversa 1996; studies: a and b).[267]

Harms. In the single trial that reported prolonged erection,[267] 4.2 percent of participants in each treatment group reported this adverse effect.

Efficacy. In the first trial, 54.2 percent of participants randomized to phentolamine plus PGE_1 reported improved erections versus 20.8 percent of those randomized to PGE_1.[267] The corresponding proportions reported for the other study were 60 versus 30 percent, respectively.[267]

Papaverine plus phentolamine versus placebo. One trial compared the efficacy and harms of papaverine plus phentolamine versus placebo.[266]

Harms. In total, 15 and 18.3 percent of the participants randomized to papaverine plus phentolamine reported the occurrence of pain and prolonged erection, respectively. None of the participants in placebo group experienced these adverse events.

Efficacy. In total, 56.7 percent of participants randomized to papaverine plus phentolamine reported improved erections versus 0 percent of those randomized to placebo.

Papaverine plus phentolamine versus papaverine plus phentolamine plus sexual counseling. One trial compared the efficacy and harms of papaverine plus phentolamine versus papaverine plus phentolamine plus sexual counseling.[257]

Harms. Results for harms in this study were pooled for the two treatment groups. 12 percent of the men discontinued the treatment due to prolonged erection. Priapism was reported in three (4.3 percent), hematoma in four (5.7 percent), and curvature of the penis in one participant (1.4 percent).

Efficacy. The mean values on a self-rated erections score (scale 0–100) for papaverine plus phentolamine versus papaverine plus phentolamine plus sexual counseling groups were 79 versus 84 percent, respectively.

Trimix versus PGE_1. Two trials compared the efficacy and harms of trimix versus PGE1 alone.[255,272] In the first trial, 32 men (mean age: 61 years) with ED of at least 6 months of duration (etiology not reported) refractory to in-clinic injection of papaverine plus phentolamine, were randomized in a crossover fashion to 40µg of PGE1 versus 17.64 mg papaverine plus 0.58 mg phentolamine plus 5.8µg PGE1.[272] Another trial enrolled 180 men (mean age: 51 years) with ED at least 6 months' duration, predominately of organic cause, of whom 20 percent had complete ED.[255] Men in this trial were randomized in a crossover fashion to 20µg of PGE1 alone versus one of nine different dose combinations of papaverine (range 5mg–20mg) plus phentolamine (1 mg) plus PGE1 (2.5–10µg).

Harms. In the first trial, 12.5 percent of participants randomized to trimix reported pain versus 40.6 percent of those allocated to PGE_1.[272]. In the second trial, corresponding proportions

were 14.4 percent (for trimix) versus 17.3 percent (for PGE_1).[255] Only the second trial reported data on priapism, which occurred in 5.0 percent of participants allocated to trimix versus 0.6 percent of those allocated to PGE_1.[255]

Efficacy. About half (50 percent) of the participants randomized to trimix reported grade 4 or 5 erections versus 21.9 percent of those randomized to PGE_1 alone.[272]

There was no difference between trimix and PGE_1 for erections of either grade 4 or 5 (trimix: 66.7 percent versus PGE_1: 67.8 percent), or for improvement in self-rated erection compared with home (trimix: 83.2 percent versus PGE_1: 84.9 percent, $p = 0.85$). There was no statistically significant difference in efficacy outcomes between PGE_1 and any individual trimix dose combination.[255]

Trimix plus atropine versus trimix. One trial compared the efficacy and harms of trimix versus trimix plus atropine.[264] Addition of atropine to trimix did not reduce pain or improve erections compared with trimix alone.

Harms. In total 55.3 percent of participants allocated to trimix plus atropine reported pain versus 50 percent of those allocated to trimix alone.

Efficacy. Each treatment group reported improved erections in 45.6 percent of the participants.

Trimix plus sodium bicarbonate versus trimix. One trial compared the efficacy and harms of trimix injections with and without sodium bicarbonate.[283]

Harms. In total pain was reported by 5.3 percent of the participants receiving trimix plus sodium bicarbonate compared with 57.9 percent of those in the group treated with trimix alone.

Efficacy. The difference between the rates of improved erection in participants allocated to trimix plus sodium bicarbonate versus trimix alone was not statistically significant (78.9 percent versus 68.4 percent; RD 11 percent, 95 percent CI:-17.0–38.0).[283]

Vasoactive intestinal peptide (VIP) plus phentolamine versus placebo. Two trials compared the efficacy and harms of vasoactive intestinal peptide (VIP) plus phentolamine versus placebo. [260]

Harms. Compared with participants receiving placebo, those randomized to VIP plus phentolamine reported more frequent bruising (12.3 percent versus 43.1 percent), bleeding at injection site (5.1 percent versus 20.5 percent) urethral bleeding (2.6 percent versus 12.3 percent), flushing (13.3 percent versus 74.4 percent), palpitation (0 percent versus 7.7 percent), and tachycardia (0.5 percent versus 5.1 percent).

The participants in the placebo group reported bleeding at the injection site. There was no statistically significant difference between the treatment groups with respect to pain during injection (4.6 percent versus 8.2 percent), priapism (0.5 percent versus 0 percent), or headache (3.6 percent versus 1.5 percent).

Efficacy. Three hundred and four men with ED were screened for response to in-clinic or home administration of 25µg VIP plus either 1mg or 2 mg of phentolamine.

Based on the phentolamine dose to which responses were observed, 240 participants were randomized in a crossover design to active treatment versus placebo. Efficacy results were reported only for the 172 men who received at least one dose of active drug and placebo.

Seventy-two percent of injections in men allocated to VIP plus 1 mg phentolamine produced grade 3 erections (suitable for sexual intercourse) versus 13 percent in men allocated to placebo ($p < 0.001$). The proportions of participants with grade three erections in VIP plus 2 mg phentolamine and placebo groups were 65 and 16 percent, respectively ($p < 0.001$)

Tables 13–15 illustrate the results presented in this section.

Quantitative Synthesis

There was a large degree of clinical heterogeneity in the potentially eligible IC trials with regard to patient characteristics (e.g. proportion with psychogenic versus physiologic ED, exclusion of nonresponders during screening phase), interventions (e.g. number, dose, and duration of treatment), and assessed outcomes (see Outcomes section above). Therefore, meta-analyses were not performed.

Injection Treatments - Subcutaneous Injections

Literature Search

Three trials (four publications)[295-298] were identified and included in the review. One trial was reported in two publications.[295,296]

Overview of Trials

All three studies used a crossover design. (Evidence Table F-7, Appendix F)

Populations

In these studies, ED etiology was primarily of psychogenic (69 percent) origin. Obesity, hypertension, and hypercholesterolemia were the most commonly reported underlying diseases. Mean duration of ED in one trial was 8 years.

Interventions

The evaluated SC injection treatments were Melanotan II,[295] PT-141 (cyclic heptapeptide melanocortin analog) (n=25), [298] and apomorphine (n=12). [297] In all studies, SC therapy was administered in a clinic and subjects were monitored or kept under observation from 30 minutes up to 24 hours.

Study Quality and Reporting

None of the studies reported the source of pharmaceutical funding. None of the trials reported methods of allocation concealment. Study withdrawals, drop-outs or participants lost to followup were reported in all trials. All trials were double-blind. All trials received a Jadad score of 3 (Evidence Table F-6, Appendix F).

Outcomes

Three eligible studies assessed clinical efficacy (e.g. improvement in erections) and harms. (Tables 15 and 16)

Qualitative Synthesis

Melanotan II versus placebo. One small trial enrolling 20 subjects, 10 men with psychogenic ED and 10 men with organic ED, compared the efficacy and harms of Melanotan II (SC) to placebo [295]. Melanotan II was administered by the investigator in doses between 0.025 mg/kg and 0.157 mg/kg in a double blind, placebo-controlled fashion. Subjects were monitored by RigiScan in the clinic and at home for a total of 6 hours.

Harms. Men administered Melanotan II reported an increased frequency of nausea (38.5 percent versus 9.8 percent), yawning and stretching (56.4 percent versus 12.2 percent). [295]

Efficacy. 17 of the 20 subjects administered Melanotan II reported a "subjectively apparent erection" on at least one of two injections of Melanotan II. The number of subjects with improved erections following administration of placebo was not reported. Overall, erectile activity (based on RigiScan activity) was reported in 69 percent (27/39) of Melanotan II injections compared with 2 percent (1/41) of placebo injections. In a subgroup analysis of the 10 subjects with organic ED, nine men treated with Melanotan II reported a "subjectively apparent

erection" versus one placebo treated subject [296]. Erectile activity was reported in 63 percent (12/19) of Melanotan II injections compared with 2 percent (1/21) of placebo injections.

PT-141 versus placebo. One small trial that enrolled 25 subjects with moderate to severe ED who had an inadequate response to sildenafil compared the efficacy and harms of PT–141 (SC) to placebo[298]. PT-141 was administered in doses of 4 or 6 mg, utilizing a placebo-controlled three-way crossover design[298]. Patients were kept under observation until 24 hours after the dose administration.

Harms. Men who were administered PT-141 reported an increased frequency of nausea (4 mg: 24 percent versus 6 mg: 36 percent versus placebo: 0 percent) and headache (4 mg: 36 percent versus 6 mg: 27 percent versus placebo: 0 percent) compared with placebo.

Efficacy. Clinically and statistically significant erectile response (assessed by RigiScan) in the presence of visual sexual stimulation was observed following the administration of single dose of 4 or 6 mg PT-141, relative to placebo. A greater than two-fold increase in the duration of base rigidity $\geq$ 60 percent, compared with placebo, was reported in 82 percent of subjects receiving the 4 mg dose and 84 percent of patients receiving the 6 mg dose.

Apomorphine versus placebo. One small trial enrolling 12 subjects with coital erectile failure of at least 6 months compared apomorphine (SC) to placebo.[297]

Harms. Eight subjects reported side effects, including yawning, drowsiness and nausea. Two participants experienced extreme nausea and hypotension, with one transiently losing consciousness after the 1.0 mg apomorphine dose.

Efficacy. Eleven out of the 12 subjects exceeded a change of 1cm in circumference after injection).

Quantitative Synthesis

No meta-analysis was performed due to the clinical heterogeneity with regard to intervention types.

Intra-urethral Suppositories

Literature Search

Seven RCTs (in seven publications) were eligible and were included in the review.[299-305]

Overview of Trials

Of the seven trials,[299-305] one reported only physiologic outcomes (timing and degree of penile rigidity as measured by RigiScan) and no harms data.[305] Therefore, the remaining six trials are described in more detail in this section. Of five studies, four assessed clinically relevant efficacy outcome such as home sexual intercourse success [299,300,302,304] and one trial reported on whether in-clinic erections were judged sufficient for intercourse. Of these six trials,[299-304] two were cross-over design (n=345; range: 111-234 participants) and four were parallel design (n=1726, range: 60-996 participants). No studies assessed therapies beyond 12 weeks. (Evidence Table F-7, Appendix F)

Populations

Among the six trials reporting clinical efficacy and/or harms data, the mean age of the subjects was 60.4 years (n=6 trials reporting). Racial characteristics were reported in only one trial. ED etiology was of physiologic origin in the four studies reporting. Vascular disease and diabetes were the most commonly reported underlying diseases. Mean duration of ED was approximately 4 years. In four trials reporting, 56 percent of men reported previous treatment for ED. No trials reported smoking status and body weight (e.g. body mass index), both risk factors of ED.

Interventions

IU treatment interventions evaluated in eligible trials were alprostadil, prazosin, and the combination of the two agents.

Among alprostadil interventions, one 3 month trial of IU alprostadil utilized a fixed dose of 1000µg .[301] Three trials utilized fixed doses of alprostadil from 125 to 1000µg administered at home based on each subject's response to various doses or a dose titration.[300,302,304] The home treatment phases of these trials were 3 weeks and 3 months,[302,304] respectively. In another trial, subjects received single in-clinic administrations of two of four alprostadil doses (125, 250, 500 and 1000µg) over a 2 to 4 week period.[303] In a sixth trial, subjects started at either 250 or 500µg alprostadil for 4 weeks with subsequent dose titration so that final dose at 12 weeks ranged from 125 to 1000µg.[299] Pubic bands were allowed as optional adjunct therapies in two trials.[299,300]

In one trial that evaluated a prazosin intervention, subjects received single in-clinic administrations of two of four prazosin doses (250, 500, 1000 and 2000µg) over 2 - 4 week period.[303]

Finally, in the single trial that evaluated a combined alprostadil/prazosin intervention, subjects received single in-clinic administrations of two of nine possible IU alprostadil/prazosin dose combinations over a 2 to 4 week period.[303]

Study Quality and Reporting

Information on pharmaceutical funding was reported to have been provided for five[299,300,302-304] of the six trials. One trial[301] did not report a funding source. None of the trials reported

methods of allocation concealment. Participant withdrawals, drop-outs or lost to followup were reported in all trials and ranged from 7 percent to 42 percent. The majority of the trials were considered to be of low quality as assessed by the Jadad scale. Only one of the six trials received a Jadad score of 3. The remaining trials received a score of 2 or less. (Table C-1, Appendix C)

Outcomes

Both clinical efficacy (e.g. sexual intercourse success, improvement in erections) and harms (e.g. penile pain) outcomes were assessed in all six trials. [299-304] More commonly reported were quality of erections achieved at home, without regard to whether the patient was able to achieve successful sexual intercourse ("improvement" in erections, "full response," full erection," or "grade 4 or 5 erections"). All six trials reported data on penile or urogenital pain and three trials reported results on prolonged erections or priapism/fibrosis.

Qualitative Synthesis

Summary of qualitative synthesis for this section in presented also in Tables 17-19.

Alprostadil versus placebo. Three trials compared the efficacy and harms of IU alprostadil to placebo. [302-304]

Harms. In the first trial, compared with men in placebo group, alprostadil-treated men had an increased frequency of penile pain (3.3 percent versus 32.8 percent) and minor urethral trauma (1.0 percent versus 5.2 percent).[304] Urinary tract infection occurred in fewer than 1 percent of participants in both groups. No cases of prolonged erection, priapism or fibrosis were observed in either treatment group.

In the second trial, men randomized to IU alprostadil reported an increased frequency of urogenital burning (6.4 percent versus 0 percent), but statistically nonsignificant increase in risk of penile pain (5.1 percent versus 1.2 percent), dizziness (2.6 percent versus 0 percent), prolonged erection (1.3 percent versus 0 percent), and testicular pain (2.6 percent versus 0 percent).[302]

Minor urethral trauma was reported by 1.3 and 1.2 percent of men allocated to IU alprostadil and placebo, respectively.

There were no cases of priapism or fibrosis, or urinary tract infection in either treatment group.

In the third trial, penile pain was reported by 1.7, 23.6, 20.5, 20.9 and 17.0 percent of men allocated to placebo, 1000µg, 500µg, 250µg, and 125µg IU alprostadil, respectively, [303] The corresponding proportions for reporting testicular pain were: 0.4, 1.8, 4.4, 4.4, and 2.0 percent.

Urethral pain was reported by 1.7, 9.1, 8.0, 5.1, and 1.0 percent of the men allocated to placebo, 1000µg, 500µg, 250µg, and 125µg IU alprostadil, respectively.

Efficacy. Men randomized to IU alprostadil reported that 50.4 percent of their sexual intercourse attempts during the 3 month treatment period were successful versus 10.1 percent for men allocated to placebo. Sixty-two percent of men allocated to IU alprostadil reported at least one successful sexual intercourse attempt during the study period versus 18.2 percent of men allocated to placebo.

In the second trial, men randomized to IU alprostadil reported that 51.1 percent of their sexual intercourse attempts during the 3 month treatment period were successful versus 7.5 percent for men allocated to placebo. In the third trial,[303] 31 percent of men reported erections sufficient for intercourse (grade 4 or 5) with 500µg IU alprostadil versus 14.1 percent of the men

treated with 125µg IU alprostadil. Results were not provided for 250µg and 1000µg alprostadil doses.

Alprostadil (250µg) versus alprostadil (starting dose: 500µg). One trial [299] compared the efficacy and harms of initiating IU alprostadil treatment at doses of 250µg and 500µg.

Harms. In the 4 weeks prior to IU alprostadil dose titration, 14.5 percent of men allocated to an initial dose of 250µg reported penile pain versus 27.7 percent of those allocated to an initial dose of 500µg ($p < 0.05$). During this period, there was no difference between treatment groups for urethral pain (250µg: 1.2 percent versus 500µg: 2.4 percent) or hypotension/dizziness (250µg: 2.4 percent versus 500µg : 3.6 percent).

Efficacy. Seventy-seven percent of men allocated to an initial dose of 250µg versus 69 percent of those allocated to an initial dose of 500µg elected to increase their dose at 4 weeks. Pooled clinical efficacy results were presented for treatment groups, namely the proportion of men during the study period with at least one successful sexual intercourse attempt (68.1 percent) and the proportion with erections sufficient for intercourse (grade 4 or 5) (73.5 percent).[299]

Alprostadil (IU) versus alprostadil (IC). Two trials compared the efficacy and harms of IU alprostadil versus IC alprostadil.[300,301]

Harms. In the first trial, men allocated to IU alprostadil were less likely to report urogenital pain than those allocated to IC alprostadil (6.7 percent versus 46.7 percent) with statistically nonsignificant differences between the treatment groups for urethral bleeding (3.3 percent versus 0 percent) or dizziness (6.7 percent versus 0 percent). [301] In the second trial, there was no statistically significant difference between the two treatment groups with regard to penile pain (25.0 percent versus 33.8 percent), prolonged erections (0 versus 2.9 percent), or local bleeding (2.9 versus 1.5 percent).[300]

Efficacy. In one trial, men randomized to IU alprostadil reported 55.0 percent successful intercourse attempts versus 85.1 percent for those allocated to IC alprostadil.[301] Furthermore, 53.3 percent of men allocated to IU alprostadil reported at least one successful sexual intercourse attempt during the study period versus 86.7 percent of men allocated to IC alprostadil. In the second 3-week trial, 61.8 percent of men randomized to IU alprostadil reported at least one erection sufficient for intercourse during at home use versus 92.6 percent of those allocated to IC alprostadil.[300]

Alprostadil (IU) versus prazosin (IU). One trial compared the efficacy and harms of IU alprostadil versus IU prazosin.[303]

Harms. Penile pain was reported by 23.6, 20.5, 20.9 and 17.0 percent of men allocated to 1000µg, 500µg, 250µg, and 125µg IU alprostadil, respectively versus 5.5, 0.7, 1.4 and 1.1 percent of men allocated to 2000µg, 1000µg, 500µg, and 250µg IU prazosin, respectively. [303] Urethral pain was reported by 9.1, 8.0, 5.1, and 1.0 percent of men allocated to 1000µg, 500µg, 250µg, and 125µg IU alprostadil, respectively versus 0, 2.0, 2.0, and 2.1 percent of men allocated to 2000µg, 1000µg, 500µg, and 250µg IU prazosin, respectively.

Efficacy. In this trial, each of 234 participants received single administrations of two of four potential alprostadil doses (125, 250, 500 and 1000µg) and two of four potential prazosin doses (250, 500, 1000 and 2000µg). Thirty-one percent of men with 500µg IU alprostadil reported erections sufficient for intercourse (grade 4 or 5) versus 14.1 percent with 125µg IU alprostadil versus 3 percent of men with 2000µg prazosin. Results were not provided for the 250µg and 1000 µg alprostadil doses or for the 250µg, 500µg, and 1000µg prazosin doses.

Prazosin (IU) versus placebo. One trial compared the efficacy and harms of prazosin versus placebo.[303]

Harms. Penile pain was reported by 5.5, 0.7, 1.4 and 1.1 percent of men allocated to 2000, 1000, 500, and 250µg IU prazosin, respectively, versus 1.7 percent of those allocated to placebo. Urethral pain was reported by 0, 2.0, 2.0, and 2.1 percent of men allocated to 2000, 1000, 500, and 250µg IU prazosin, respectively, versus 1.7 percent of those allocated to placebo.

Efficacy. In this trial, 3 percent of men assigned to 2000µg IU prazosin reported erections sufficient for intercourse versus 0.4 percent of those assigned to treatment with placebo. Results were not provided for the 250, 500, and 1000µg prazosin doses, though it was stated that 2000µg was the most efficacious prazosin dose.

Alprostadil (IU) plus IU prazosin versus IU alprostadil versus IU prazosin versus placebo. One trial compared the efficacy and harms of IU alprostadil plus IU prazosin versus IU alprostadil versus IU prazosin versus placebo.[303] All combinations of IU alprostadil plus IU prazosin appeared to improve erections more than IU prazosin or placebo.

Harms. The proportions of patients with penile pain among those allocated to various alprostadil/prazosin combinations were: 23.9(125µg/250µg), 23.4 (125µg/500µg), 23.4 (250µg/250µg), 17.0 (250µg /500µg), 27.3 (250µg /1000µg), 23.2 (500µg /500µg), 23.1 (500µg/1000µg), 31.6 (500µg /2000µg), and 26.9 percent (1000µg /1000µg). The proportions of patients with penile pain who were allocated to various doses of IU alprostadil were: 23.6 (1000µg), 20.5 (500µg), 20.9 (250µg), and 17.0 percent (125µg). The corresponding proportions for various doses of IU prazosin were: 5.5 (2000µg), 0.7 (1000µg), 1.4 (500µg) and 1.1 percent (250µg). Of the placebo-treated patients, 1.7 percent experienced penile pain.

The corresponding proportions of patients with urethral pain with respect to various alprostadil/prazosin combinations were: 6.5, 10.6, 8.5, 8.5, 11.4, 7.1, 1.9, 5.3, and 13.5 percent respectively. The corresponding proportions of men with urethral pain for various doses of IU alprostadil were: 9.1, 8.0, 5.1, and 1.0 percent, respectively. The proportions for various doses of IU prazosin were: 0, 2.0, 2.0, and 2.1 percent respectively. Urethral pain was experienced by 1.7 percent of the placebo-treated patients.

Efficacy. Erections sufficient for intercourse were reported by 30.4 percent of men assigned to 125/500µg alprostadil/prazosin versus 31.9 percent with 250/500µg alprostadil/prazosin, 35.7 percent with 500/2000µg alprostadil/prazosin, 31.1 percent with 500µg alprostadil, 14.1 percent with 125µg alprostadil, 3 percent with 2000µg prazosin, and 0.4 percent with placebo. Results were not provided for the other six alprostadil/prazosin combinations tested, for the 250 and 1000µg alprostadil doses, or for the 250, 500, and 1000µg prazosin doses. However, it was stated that 500/2000µg was the most efficacious alprostadil/prazosin dose, 500µg was most efficacious alprostadil dose, and 2000µg was the most efficacious prazosin dose.

Quantitative Synthesis

There was a large degree of clinical heterogeneity among the eligible IU trials with regard to patient characteristics (e.g. inclusion/exclusion criteria), interventions (e.g. fixed or flexible dosing, dose titration, treatment duration per individual ranging from single administration to 3 months), and assessed outcomes (see Outcomes section above). Therefore, meta-analyses on these studies were not performed.

Topical Treatments

Literature Search

Twelve unique trials (11 publications) were identified as eligible for evaluating topical treatments in ED patients and were included in the review.[144,306-315] One publication[306] described and reported two distinct trials in patients with mid to moderate (trial a) and severe ED (trial b). Additional studies of topical testosterone are described in the Hormonal Treatment section.

Overview of Trials

Of the 12 trials, five reported only physiologic efficacy outcomes, such as in-clinic assessment of degree or duration of penile rigidity.[307-311] The remainder of this section emphasizes results from the seven trials that assessed validated and clinically relevant efficacy outcomes such as sexual intercourse success or improvement in erections at home.[144,306,312-315] Of these seven trials, three used crossover and four used parallel design. None of these studies assessed therapies beyond 6 months. (Evidence Table F-8, Appendix F)

Populations

Patient characteristics presented are based on data from all 12 unique trials. The mean age of the subjects was 59 years. Racial characteristics were reported in only three trials. The majority of the subjects were Caucasians (86 percent). ED etiology was primarily of physiologic origin (59.7 percent). Vascular disease and diabetes were the most commonly reported underlying causes of ED. Mean duration of ED was approximately 2.7 years, (three trials reporting). Only two trials reported smoking status and none of the trials reported data on obesity.

Interventions

Topical treatments evaluated in the seven trials that reported clinical efficacy outcomes were alprostadil[306], nitroglycerine;[313,315] aminophylline plus isosorbide dinitrate plus co-dergocrine;[312,314] minoxidil;[313] and sildenafil.[144]

In the first two trials (studies a and b)[306], the administered alprostadil doses were 50µg, 100µg, 200µg or 300µg. In one trial, 2.5 gm of 10 percent nitroglycerine ointment was applied twice daily to the penile shaft for 2 months.[313] In another, subjects applied a plaster to the penile shaft one hour prior to anticipated sexual activity that released 10 mg nitroglycerine per 24 hours.[315]

In two trials, subjects received 2 gm doses of 3 percent aminophylline plus 0.25 percent isosorbide dinitrate plus 0.05 percent co-dergocrine cream, to be applied to the penile shaft and glans penis 15 minutes before anticipated sexual activity.[312,314]

In one trial, subjects applied 1 mL of 2 percent minoxidil solution twice daily on the glans penis.[313]

Finally, in one trial, subjects applied 0.5 gm of 1 percent sildenafil gel applied to the glans penis five minutes before expected sexual activity. Participants were followed for up to 2 weeks, though it was not clear whether or not they received more than one dose.[144]

Study Quality and Reporting

Sources of pharmaceutical funding was provided for four trials. The remainder of trials did not report a funding source. Treatment allocation concealment was usually unclear. One trial

reported adequate allocation concealment during randomization. [312]. Only one trial received a total Jadad score of 4 and none received a score of 5. The remaining trials received scores of 3 or 2. (Table C-1, Appendix C)

Outcomes

Only the seven studies[144,306,312-315] that assessed clinical efficacy outcomes (e.g. IIEF-EF domain scores, sexual intercourse success, improvement in erections) are described here. Of the trials reporting the clinical efficacy outcomes, only four reported results for sexual intercourse success. More commonly reported outcomes were quality of erections achieved at home.

Qualitative Synthesis

Summary of the results presented in this section is also available in Tables 20–22

Topical Alprostadil versus Placebo.

Harms. According to data reported from one trial (study a),[306] in patients with mild to moderate ED, any adverse events were more frequent in those allocated to alprostadil given at 50µg (66.7 percent), 100µg (66.7 percent) or 200µg (77.5 percent) versus placebo (52.5 percent) the corresponding proportions in the second trial with patients with severe ED (study b) for alprostadil given at 100µg, 200µg, 300µg versus placebo were 30, 60, and 51 versus 11 percent respectively. The incidence of adverse events and withdrawals due to adverse events in both patient populations conformed a dose-response trend and that urogenital pain and hypotension occurred numerically more frequently with alprostadil than with placebo.

Efficacy. The success rate of vaginal penetration was assessed in two trials of mild to moderate (study a) and severe patients (study b).[306] Within men with severe ED (study b), compared with those allocated to placebo, who reported a 15.6 percent success rate of vaginal penetration at study end, success rates for men allocated to alprostadil were 32.3 percent for 100µg, 36.2 percent for 200µg, and 38.6 percent for 300µg, with none of the between group differences reaching statistical significance. In men with mild to moderate ED (study a), men allocated to placebo reported a 55.3 percent success rate, while the success rates in alprostadi groups were 69.4 percent for 50µg ($p > 0.05$ versus placebo), 69.1 percent for 100µg ($p>0.05$ versus placebo), and 82.9 percent for 200µg ($p = 0.01$ versus placebo).

Topical Nitroglycerine versus Placebo. Two trials compared the efficacy and harms of nitroglycerine to placebo.[313,315]

Harms. In the first trial, men allocated to nitroglycerine ointment compared with placebo reported more adverse events (frequent burning at the application site: 12.6 versus 0 percent; hypotension: 10.3 versus 0 percent).[313] In the second trial, men allocated to nitroglycerine plaster had more frequent headache (35.4 versus 1.1 percent) and smarting pain (23.2 versus 1.1 percent) compared with placebo.[315] In addition, 6 percent of men allocated to nitroglycerine withdrew from therapy due to adverse events (severe pain) versus 0 percent of placebo subjects.

Efficacy. In one trial of men with physiologic ED (n=132 randomized), 20.7 percent of those allocated to 2.5 g nitroglycerine ointment twice daily over 2 months reported improved erections versus 1.7 percent of those allocated to placebo. [313] In a second trial, men with predominately psychogenic ED and at least partial in-clinic erectile response to intracavernosal papaverine (n=19) were allocated to 10 mg nitroglycerine plaster administered at least one hour prior to anticipated sexual activity for up to 6 doses not more often than once daily versus placebo plaster. Among those in the nitroglycerine plaster group, 16.7 percent reported improved erections versus 11.1 percent of those in the placebo plaster group.[315]

Topical Nitroglycerine versus Minoxidil. One trial (n=132 participants) compared the efficacy and harms of nitroglycerine ointment to minoxidil.[313]

Harms. Men assigned to received nitroglycerine ointment group reported more frequent side effects than did men in the minoxidil group, including more frequent burning at the application site (12.6 versus 6 percent) and hypotension (10.3 versus 0 percent).[313]

Efficacy. Among men in the nitroglycerine ointment group, 20.7 percent reported improved erections versus 44.0 percent of those in the minoxidil group.

Topical Aminophylline plus Isosorbide dinitrate plus Co-dergocrine versus Placebo. Two crossover trials compared the efficacy and harms of Aminophylline plus Isosorbide dinitrate plus Co-dergocrine versus placebo.[312,314] In the first trial (n=36), men with predominately physiologic ED were assigned to receive 2 gm of 3 percent aminophylline plus 0.25 percent isosorbide dinitrate plus 0.05 percent co-dergocrine mesylate taken once during a 7 day period versus placebo.[314] In the second trial (n=14), men with predominately psychogenic ED who previously responded to IC injections were allocated to 2 ml doses of 3 percent aminophylline plus 0.25 percent isosorbide dinitrate plus 0.05 percent co-dergocrine mesylate or placebo.[312]

Harms. None of the patients had prolonged erection or priapism, clinically significant cardiovascular adverse events (such as postural dizziness), headache, or pain at site of application.[314] The other trial did not report any data on harms.[312]

Efficacy. In the first trial, among men assigned to active treatment, 58.3 percent reported erection sufficient for successful intercourse versus 8.3 percent of those allocated to placebo.[314] In the second trial, men assigned to the active treatment reported that they experienced erections adequate for intercourse after 3.9 percent of treatment applications versus after 5.3 percent of placebo applications. All successful applications for both the active treatment and placebo groups occurred in a single participant.[312]

Minoxidil versus Placebo. One crossover trial (n=132) compared the efficacy and harms of minoxidil to placebo.[313]

Harms. Compared with placebo, men allocated to minoxidil reported more frequent burning at the application site (6 versus 0 percent). No hypotension was reported by either the minoxidil or placebo-treated participants.

Efficacy. Among men allocated to minoxidil, 44.0 percent reported improved erections versus 1.7 percent of those allocated to placebo.

Topical Sildenafil versus Oral Sildenafil. One trial (n=80) compared the efficacy and harms of topical sildenafil to oral sildenafil.[144]

Harms. In men assigned to receive topical sildenafil, four (10 percent) reported mild headache. In those assigned to receive oral sildenafil, two participants (5 percent) developed severe headache, one participant (3 percent) reported disturbed visual function, and one participant (3 percent) experienced severe dyspepsia.

Efficacy. Among men assigned to the topical sildenafil plus oral placebo group, 12.5 percent reported improved erections versus 70.0 percent for men assigned to the oral sildenafil plus topical placebo group.

Quantitative Synthesis

No meta-analysis could be performed because of substantial degree of clinical heterogeneity across the trials with regard to patient characteristics, interventions, and the assessed outcomes.

Hormonal Treatments

Literature Search

There were 20 unique studies (in 20 publications) that met eligibility criteria.[5,77,145,170,231,316-330] One study was reported in two publications[317,318] and will be referred as Seftel et al. 2004.[317] Two distinct trials were reported in one publication (studies: a and b).[145] The summary of results for efficacy and harms of two trials [5,77] comparing combination of PDE-5 inhibitors versus PDE-5 inhibitors alone (and placebo) are presented also in the section for Question 1.

Overview of Trials

Three trials used crossover, [322,323,326] and the remaining 17 used parallel design. Treatment duration in several trials was 6 months[319,321,323,330] and in one trial 12 months.[316] (Evidence Table F-9, Appendix 9)

Populations

The mean age of the subjects in the trials was approximately 57 years. Racial characteristics were reported in only three trials with the majority of the subjects being Caucasians. ED etiology was physiologic in 89 percent of men, psychogenic in 4 percent, and mixed in 7 percent. Not all trials were comprised of exclusively patients with ED.[5,77,145,231,322,326,329] Several trials required a minimum duration of ED for study entry, of 3 months,[5] 5 months,[329] or 6 months.[77,145,231,326] Few trials were comprised of special populations: HIV positive men (n=74),[325] men with major depressive disorder (n=32),[328] obese men with type 2 diabetes (n=48),[324] and men with hypopituitarism (n=9).[323]

While trials generally enrolled men with hypogonadism and/or andropause, the specific sexual dysfunction and testosterone entrance criteria across trials varied widely. With respect to testosterone, all but three trials[145,323,326] mandated that participants have levels below a specified threshold. Specific entrance criteria regarding total serum testosterone levels varied: 200-350 ng/dl,[322] $\leq$300 ng/dL,[317,318,320,327,329] $\leq$340-350 ng/dL,[231,328] <400 ng/dL,[5] <436 ng/dL,[324] and <500 ng/dL.[325] Additional trials required that participants have a low total testosterone (range of thresholds from 232 to 434 ng/dL) in combination with a low free testosterone,[77] low free androgen index,[330] a high SHBG,[321] or a free testosterone index between 0.3 and 0.5.[316](Tables 23-26)

Interventions

Of the 21 trials involving testosterone therapy for treatment of male ED, most assessed testosterone monotherapy including oral,[145,316,319,324] intramuscular (IM),[325,326,328] gel,[231,317,320,327] patch,[317,320,327,330] and cream forms.[322,329] Five trials studied testosterone in combination with a phosphodiesterase inhibitor.[5,77,145,231] Two other trials studied a cream combining testosterone, isosorbide dinitrate and co-dergocrine.[322,329] Finally, one trial compared dihydrotestosterone gel versus placebo.[321]

Study Quality and Reporting

Information on pharmaceutical funding was provided for seven trials.[5,316,317,320,321,327,330] Only three studies reported using an intention to treat analysis.[5,316,317] Three of the trials reported

adequate allocation concealment[319,322,325] and six trials an appropriate double-blinding method.[5,316,321,322,325,329] There was adequate description of study withdrawals, drop-outs by treatment group in eight trials.[5,231,321,324,325,327,328,330] Three trials received a total Jadad score of 5,[5,321,325] two trials received a score of 2,[316,330] and four received a score of 3.[322,327,329,331] The remainder received a score of 2 or less.

Outcomes

The eighteen eligible trials utilized diverse efficacy outcome measures. Seven trials reported data on frequency of successful sexual intercourse attempts.[5,77,231,317,322,326,329] Three other trials reported data on the frequency of full erection during intercourse or the ability to maintain erection during sexual intercourse,[321,326,328] and three trials reported intercourse satisfaction.[77,231,319] Other reported outcomes were IIEF–EF[5,77,145,319,324] and the Male Erectile Dysfunction Quality of Life questionnaire.[330] Two trials reported data for sexual performance defined as the frequency of days with either orgasm, erection, masturbation, ejaculation and/or intercourse in the past week.[320,327]

Finally, several trials reported data on erections (e.g. frequency of erections,[323] improvement in erections,[77,316,325] satisfaction with erections,[327] and full erections with sexual interest).[322] With respect to harms outcomes, five trials reported no adverse effects data.[5,316,323,324,326] Several trials reported that adverse effects were absent[231] or were negligible and without a difference in frequency between treatment groups.[77,145,319] Data on specific adverse events were reported in only a minority of trials, including skin irritation,[329,332] increased PSA,[77,317,322,329,330] headache,[145,319,321,322,329] and worsening of lower urinary tract symptoms.[317]

Qualitative Synthesis

Oral testosterone versus no treatment. In one open label trial outcomes for efficacy and harms were compared between oral testosterone and no treatment.[324] In this study, 48 diabetic men aged 45-65 years, with ED, increased abdominal girth, and symptoms of mild androgen deficiency, (total testosterone <15.1 nmol/L) were randomized to either 120 mg oral testosterone undecanoate taken daily for 3 months or no treatment. Subjects were excluded from the trial if they had prostate abnormality or any illness considered likely to impair sexual function.

Harms. No adverse events were reported for this trial.

Efficacy. There was a statistically significant improvement in mean IIEF-5 scores (1=absent, 2=mild, 3 = mild to moderate, 4 = moderate, and 5 = severe) at 3 months in testosterone-treated patients compared with those with no treatment assigned (1.06 versus 2.25, $p < 0.05$).

Oral testosterone versus placebo. The outcomes for efficacy and harms associated with the use of oral testosterone versus placebo were compared in two trials.[316,319] In the first trial, 150 men aged 60–74 years, with symptoms attributed to androgen decline, including decreased libido and erectile quality, and free testosterone <6 pg/ml, were randomized to either 160 mg oral testosterone undecanoate taken daily for 6 months, or 2 gm propionyl-L-carnitine plus 2 gm acetyl-L-carnitine daily or placebo.[319] Exclusion criteria were prostate enlargement, elevated PSA, and significant LUTS. In the second trial, 76 men aged 60-86 years, with at least two symptoms on the ADAM questionnaire, total testosterone <8 nmol/L, and a free testosterone index (FTI) between 0.3 and 0.5, were randomized either to 80 mg oral testosterone undecanoate taken twice daily for 12 months or placebo.[316] Patients with a history of prostate cancer, elevated PSA, and significant LUTS were excluded.

Harms. In the first trial, the difference in the occurrence of adverse events between the two treatment groups was not statistically significant. Epigastralgia was reported in 2.5 percent of testosterone-treated versus 2.2 percent of placebo-treated subjects. In the second trial, the occurrence of adverse events was not reported.

Efficacy. In the first trial[319],men assigned to receive testosterone had median IIEF sexual intercourse satisfaction scores (range 0–15) of 5 (range 3-10) at 6 months ($p < 0.01$). The corresponding median score for patients receiving placebo was 4 (range 3–5). The median IIEF–"EF domain" scores at 6 months of followup for men assigned to receive testosterone and placebo were 16 (range 6–29) and 8 (range 5–21), respectively.[319] In the second trial, 86 percent and 93 percent of men in the testosterone and placebo group, respectively, reported that their erections were "less strong" at 12 weeks of the followup.[316]

Oral testosterone versus oral testosterone plus sildenafil. One trial evaluated and compared the efficacy and harms between oral testosterone alone and oral testosterone combined with sildenafil.[145] This study enrolled 20 men (mean age: 56 years) with ED of >6 months duration and symptoms of partial androgen deficiency (mean baseline total testosterone 7.3 nmol/L) who failed to respond to 50-100 mg sildenafil given twice weekly for 2 weeks. These men were randomized to 2 months of treatment with either oral testosterone undecanoate alone (120 mg/d) or oral testosterone undecanoate (120 mg/d) plus sildenafil (50-100 mg). Patients with prostate hypertrophy, prostate cancer, and mammary carcinoma were excluded.

Harms. The study reported that apart from mild headache occurring in three patients taking sildenafil 100 mg, no serious adverse events were observed.[145]

Efficacy. Men in the oral testosterone group reported no significant change in their IIEF–5 scores from 9.9 (SD 1.4) at baseline to 11.1 (1.5) at 2 months ($p = 0.27$), whereas men in the oral testosterone plus sildenafil group scored 10.1 (1.3) at baseline and 15.0 (1.4) at 2 month followup ($p < 0.01$).

Oral testosterone versus propionyl-L-carnitine plus acetyl-L-carnitine. One trial evaluated and compared the efficacy and harms for oral testosterone versus propionyl-L-carnitine plus acetyl-L-carnitine.[319] In this study, 150 men aged 60-74 years, with symptoms of androgen decline, and free testosterone below 6 pg/mL, were randomized to receive either 160 mg oral testosterone undecanoate daily for 6 months or 2 gm propionyl-L-carnitine plus 2 gm acetyl-L-carnitine daily or placebo.[319] Exclusion criteria were prostate enlargement, elevated PSA, and significant LUTS. Results comparing testosterone and propionyl-L-carnitine plus acetyl-L-carnitine are reported here.

Harms. The occurrence of adverse events was not statistically significantly different between the two treatment groups. Epigastralgia was reported in 2.5 percent of the testosterone-treated versus 0 percent of propionyl-L-carnitine plus acetyl-L-carnitine-treated subjects. Mild headache was reported for 2.2 percent of the propionyl-L-carnitine plus acetyl-L-carnitine-treated subjects versus 0 percent for testosterone-treated subjects.

Efficacy. At 6 months, in men assigned to receive testosterone, the median IIEF–"EF domain" score changed from 8 (range 5-19) at baseline to 16 (range 6-29) (within-group difference: $p < 0.01$). The corresponding median score in those assigned to the propionyl-L-carnitine plus acetyl-L-carnitine group changed from 8 (range 5–22) to 24 (range 8–29) (within-group difference: $p < 0.01$).

Oral testosterone plus sildenafil versus sildenafil. One trial evaluated and compared the efficacy and harms outcomes of oral testosterone plus sildenafil compared with sildenafil

alone.[145] This study enrolled 20 men (mean age: 56 years) with ED of > 6 months and symptoms of partial androgen deficiency (mean baseline total testosterone 7.3 nmol/L) who partially responded to previous sildenafil therapy (50-100 mg twice weekly for 2 weeks). The men were randomized to receive a 2-month treatment with either oral testosterone undecanoate (120 mg daily) plus sildenafil (50-100 mg) or sildenafil alone. Patients with prostate hypertrophy, prostate cancer, and mammary carcinoma were excluded.

Harms. Apart from mild headaches occurring in three patients taking sildenafil 100 mg, no serious adverse events were observed.

Efficacy. At 2 months of followup, the difference in mean IIEF–5 scores between patients who received the oral testosterone plus sildenafil versus the sildenafil monotherapy groups was not statistically significant (17.5 versus 15.9, $p \geq 0.05$).

Intramuscular Testosterone (IM) versus placebo. Four trials compared the efficacy and harms of IM testosterone and placebo.[323,325,326,328]

In the first trial,[323] nine gonadotropin-deficient males aged 15 years or older (range 16-20) and currently being treated for hypopituitarism, only 3 of whom had partners, were randomized to 1 cc IM testosterone enanthate every 2 weeks versus 2000 units human chorionic gonadotropin three times weekly versus placebo. The active treatment arms each lasted for at least 6 months, while the placebo treatment lasted for 2 months.

In the second trial,[326] 18 men, aged 45-74 years, with ED) were randomized either to IM testosterone enanthate 200 mg given twice weekly for 6 weeks or IM placebo. Patients with major disorders, a history of substance abuse, obesity, or major psychopathology were excluded from the trial.

In the third trial,[325] 74 HIV-positive men (CD4 <400), with ED or substantial loss of sexual desire, with low-to-normal levels of total testosterone (<22.6 nmol/L if the patient had AIDS plus wasting or fatigue, or otherwise <17.4 nmol/L) and at least one mood symptom of hypogonadism, were randomized either to IM testosterone cypionate 400 mg given twice daily for 6 weeks or placebo.

In the fourth trial,[328] 32 men ≥ 35 years (mean age: 52 years) with depression and total testosterone ≤ 350 ng/dL were randomized either to IM testosterone enanthate 200 mg given once weekly for 6 weeks or IM placebo. Patients with psychiatric disorders or abnormal prostate exam result (men aged > 50 years) were excluded.

Harms. In two trials,[323,326] no adverse events were reported. In the third trial,[325] men who received testosterone were more likely to report acne (testosterone: 20.5 percent versus placebo: 0 percent). Differences between men in the testosterone and placebo groups with respect to the occurrence of irritability (17.9 versus 17.1 percent) and testicular atrophy (5.1 versus 0 percent), were not statistically significant. In the fourth trial,[328] it was reported that no adverse events occurred except that one placebo-treated subject had a MI.

Efficacy. In the first trial,[323] weekly frequency of erections in the testosterone and placebo treatment groups were 7.9 (SD 6.1) and 4.9 (SD 3.3), respectively. The between-group difference was not statistically significant.

In the second trial,[326] results were based on 12 (67 percent) men who completed all assessments. At week 6, men in the IM testosterone group reported a median number of “sex with partner” of 1.25 times per week versus 0.54 times per week for men in the placebo group (between-group difference: $p \geq 0.05$). There was no difference in the degree of erection during

sex with partner (scale 1–6, with = "none" and 6 = "full"), with a mean score of 5.5 for each group, or in the degree of erection during masturbation.

In the third trial,[325] results were reported for the 52 men (70 percent) who completed the treatment schedule. Within this group, 62.5 percent of men who received testosterone versus 20 percent of those who received placebo reported that their erectile function was much or very much improved (RR = 3.12, 95 percent CI: 1.25–7.82).

In the fourth trial,[328] the difference in frequency (1 = less than 1 per month" and 2 = 1–2 per month") of full erections during one month between men in the IM testosterone and IM placebo groups was not statistically significant (1.77 versus 1.53)

Testosterone (IM) versus human chorionic gonadotropin (IM). One trial compared the efficacy and harms of IM testosterone versus IM human chorionic gonadotropin. [323] In this trial, 9 gonadotropin-deficient men aged 15 years or older (range 16–20) being treated for hypopituitarism, were randomized to 1 cc IM testosterone enanthate given every 2 weeks versus 2000 units of human chorionic gonadotropin 3 times weekly versus placebo. The active treatment arms each lasted for at least 6 months, while the placebo treatment lasted for 2 months.

Harms. No adverse event data were reported.

Efficacy. The weekly frequency of erection was not different between the two groups of testosterone and human chorionic gonadotropin treatment (7.9 versus 8.2).

Gel testosterone versus placebo. The efficacy and harms of gel testosterone versus placebo were compared in one trial [317] In this trial, 406 hypogonadal men (total T <300 ng/dL) aged 20–80 years (mean age: 58 years) reporting one or more symptoms of low testosterone deficiency (i.e. fatigue, decreased muscle mass, reduced libido), were randomized to 50 mg gel testosterone (Testim) daily versus 100 mg gel testosterone (Testim) daily versus 24.4 mg patch testosterone (Androderm) versus placebo.

Harms. In total, 29.3 percent of men receiving 50 mg gel testosterone; 36.8 percent receiving 100 mg gel testosterone and 40.4 percent receiving placebo reported at least one treatment-related adverse event (including application site reactions, BPH, increase in blood pressure, increase in hematocrit, gynecomastia, headache, hot flashes, insomnia, mood swings, or spontaneous erections). These differences were not statistically significant. One participant from the group treated with 50 mg gel testosterone, five in the group treated with 100 mg gel testosterone, and none treated with placebo withdrew due to an adverse event.

Efficacy. At day 30, among men with sexual partners (63 percent of randomized men), 24 percent of placebo-treated men reported an increase from baseline in the number of days in the past week with sexual intercourse, compared with 31 percent of 50 mg gel testosterone-treated men ($p < 0.05$ versus placebo) and 39 percent of 100 mg gel testosterone men ($p = 0.0096$ versus placebo).

Gel testosterone versus patch testosterone. The efficacy and harms of gel testosterone versus patch testosterone was compared in three trials.[317,320,327] In the first trial,[327] 227 men aged 19-68 years (mean age: 58 years) with total testosterone levels <10.4 nmol/L (300 ng/dL) were randomized to 50 mg gel testosterone (Androgel) given daily versus 100 mg gel testosterone (Androgel) given daily versus 5 mg patch testosterone (Androderm) given daily. Patients with increased PSA, significant skin disease, and substantial under- or overweight were excluded.

The other two trials [317,320] had similar protocols. The inclusion criteria were low total testosterone ($\leq$10.4 nmol/l[320] and $\leq$300 ng/dL[317]) and/or symptoms of hypogonadism (i.e. fatigue, decreased muscle mass, reduced libido, or "reduced sexual functioning" of nonmechanical

origin). Both trials randomized men to 50 mg gel testosterone (Testim) daily versus 100 mg gel testosterone (Testim) daily (deliver a daily dose of 5 and 10 mg testosterone, respectively). The first of these trials included an additional group randomized to 5 mg patch testosterone (Andropatch),[320] and the second trial randomized two additional groups to 24.4 mg patch testosterone and placebo.[317]

In the first of these trials,[320] men were to remain on their initially assigned treatment dose throughout the 90 day study, but in the second trial,[317] titration from the initial gel testosterone dose was possible at 60 days.

Harms. In the first trial,[327] skin irritation was reported by 5.7 percent of men who received 50 mg gel testosterone, 5.3 percent of those who received 100 mg gel testosterone, and 65.8 percent of those who received patch testosterone. Urogenital adverse events (e.g. prostate enlargement, increased PSA) were reported by 9.6 percent of men who received 50 mg gel testosterone, 5.1 percent of those who received 100 mg gel testosterone, and 0 percent of those who received patch testosterone.

In the other two trials,[317,320] approximately 30–35 percent of men who received either of the gel testosterone groups versus 60 percent of those who received patch testosterone reported at least one treatment-related adverse event. Most common adverse events were skin application site reactions and less frequent events were BPH, increase in blood pressure, increase in hematocrit, gynecomastia, headache, hot flashes, insomnia, mood swings, or spontaneous erections. The second of these trials[317] reported that withdrawals due to adverse events occurred in one 50 mg gel testosterone subject, five 100 mg gel testosterone subjects, and 15 patch testosterone subjects. In the same trial, two patients in the patch testosterone arm were diagnosed with prostate cancer.[317]

Efficacy. In the first trial,[327] patients in the gel testosterone group experienced slightly greater sexual enjoyment compared with those receiving the testosterone patch ($p = 0.0113$).

In the second trial,[320] compared with baseline, men in the 50 mg gel testosterone, 100 mg gel testosterone, and patch testosterone groups experienced 38, 50 and 33 percent improvement in "sexual performance" (within-group comparison: $p < 0.05$; between-group comparisons: $p \geq 0.05$). Similarly, all three groups significantly improved from baseline, but without between-group differences for the domains of sexual motivation and sexual desire. Although spontaneous erections were significantly increased in frequency compared with baseline in both gel testosterone groups, and not in the patch testosterone group, there were no significant between-treatment group differences.

In the third trial,[317] at baseline approximately 20 percent of men reported having no sexual partner available, and approximately 45 percent reported no sexual intercourse during the past week. At day 30, among men with sexual partners for whom these data were reported (61 percent of randomized men), 31 percent of 50 mg gel testosterone men reported an increase from baseline in the number of days in the past week with sexual intercourse versus 39 percent of 100 mg gel testosterone men (versus 50 mg, $p \geq 0.05$, and versus patch, $p = 0.03$) and 21 percent of patch testosterone men (versus 50 mg group, $p \geq 0.05$).

Gel testosterone versus gel testosterone plus tadalafil. One trial compared the efficacy and harms of gel testosterone versus gel testosterone plus tadalafil.[231] This trial enrolled 69 hypogonadal men (total testosterone <3.4 ng/ml) aged 34-78 years (mean: 59 years), who had >6 months of ED and a history of nonresponse (i.e. poor IIEF score or persistent patient/partner dissatisfaction) to 20 mg tadalafil. Men were randomized to 50 mg gel testosterone (Testogel)

daily for 4 weeks followed by concurrent treatment with tadalafil 20 mg twice weekly for 9 weeks versus 50 mg gel testosterone (Testogel) daily for 10 weeks followed by concurrent treatment with tadalafil 20 mg twice weekly for 3 weeks. All treatments were open label.

Harms. No adverse events were observed.

Efficacy. At 10 weeks, there was no difference between treatment groups in mean IIEF intercourse satisfaction score (13.1 +/- 0.8 versus 12.8 +/- 0.9, WMD = 0.30, 95 percent CI: -0.10 to 0.70). After 13 weeks, 66.7 percent of patients were rated sufficient to good for successful intercourse completion in group one versus 63.6 percent in group two (RR = 1.05, 95 percent CI: 0.68– 1.62), and 47.6 percent of patients were rated sufficient to good for intercourse frequency in group one versus 59.1 percent in group two (RR = 0.81, 95 percent CI: 0.46–1.42).

Gel testosterone plus sildenafil versus sildenafil. This double-blind trial[5] studied 75 men aged 26–79 years (mean age: 58 years) with ED of >3 months, and total testosterone <400 ng/dL. The men, refractory to prior sildenafil therapy were randomized to 1 percent gel testosterone daily plus 100 mg sildenafil once daily for each day with sexual activity as needed for 12 weeks versus 100 mg sildenafil as needed. Exclusion criteria were: history of prostate cancer, prostate disease with diminished urine flow rate, neurologic ED, substance abuse, or significant or uncontrolled medical or psychiatric conditions.

Harms. One subject in gel testosterone plus sildenafil arm withdrew due to adverse events. There were no withdrawals due to adverse events among patients receiving sildenafil alone.

Efficacy. In men receiving gel testosterone plus sildenafil, the mean number of successful sexual attempts (per week) ranged from 1.7 to 2.1. The corresponding range for those receiving sildenafil was 1.5-2.4 per week. At the end of the study, the proportions of men with scores of 4-5 on IIEF–Q3/Q4 was statistically nonsignificantly greater in the combination therapy group than in the sildenafil only group (51.4 versus 39.4 percent; RR = 1.30, 95 percent CI: 0.77–2.21). Men who received gel testosterone plus sildenafil had greater mean change from baseline in the IIEF "EF" domain score compared with those receiving sildenafil and placebo. The between-group differences were statistically significant at week 4 (4.4 versus 2.1, 95 percent CI: 0.3–4.7).

Cream testosterone versus cream testosterone plus isosorbide dinitrate plus co-dergocrine. One trial compared the efficacy and harms of cream testosterone versus cream testosterone plus isosorbide dinitrate plus co-dergocrine.[322] In this two phase crossover trial, 42 men aged 41-67 years (mean: 54 years) with ED, decreased libido and total testosterone 200-350 ng/dl were randomized to 0.8 percent cream testosterone versus 0.8 percent cream testosterone plus 0.5 percent isosorbide dinitrate plus 0.06 percent co-dergocrine. Each treatment was to be applied daily at bedtime to the penile shaft and glans; if intercourse was going to occur then the cream was applied 15 minutes before intercourse. Each arm of the crossover lasted 30 days.

Harms. Five men who received combination therapy reported a mild transient headache versus none who received cream testosterone alone. No significant increase in PSA occurred.

Efficacy. In total 67 percent of men who received cream testosterone plus isosorbide dinitrate plus co-dergocrine reported a complete response to treatment (full erection and sexual interest compared with 31 percent of men who received cream testosterone alone (RR = 2.15, 95 percent CI: 1.31–3.55). Among men with psychogenic ED (n = 19), 84.2 percent of those who received combination therapy reported a complete response versus 57.9 percent of those who received cream testosterone alone (RR =1.45, 95 percent CI: 0.95–2.24). Among men with vascular ED (n=18), 55.6 percent of those who received combination therapy reported a complete response versus 11.1 percent of those who received cream testosterone alone (RR = 5.00, 95 percent CI:

1.27–19.68). Among men with neurogenic ED (n = 5), two who received combination therapy reported a complete response versus none who received cream testosterone alone. Among all men with complete responses, those who received cream testosterone plus isosorbide dinitrate plus co-dergocrine reported a mean of 6.46 (SD 2.7) full erections with satisfactory intercourse per month versus 4.05 (SD 1.8) for men who received cream testosterone only (WMD = 2.41, 95 percent CI: 1.43 to -3.39).

Cream testosterone plus isosorbide dinitrate plus co-dergocrine versus placebo. One trial compared the efficacy and harms of cream testosterone plus isosorbide dinitrate plus co-dergocrine versus placebo.[329]) In this trial, 89 men aged 35-65 years (mean: 54 years) with more than 5 months of decreased libido and of decreased frequency and quality of sexual erections, and total testosterone <300 ng/dL, were randomized to 0.8 percent cream testosterone plus 0.5 percent isosorbide dinitrate plus 0.06 percent co-dergocrine versus placebo. Each treatment was applied twice daily to the shoulder for two months. Patients with abnormal rectal exam results, PSA >4 ng/ml, and urine flow rate <12 ml/second were excluded.

Harms. Among men who received combination treatment, 11.1 percent reported headaches, 2.2 percent reported skin irritation (versus 0 percent for placebo subjects). Neither treatment group reported priapism.

Efficacy. Of men who received combination therapy, 40 percent reported at least one full erection with successful intercourse during followup versus 0 percent of those who received placebo. No men who received placebo reported full erections after two months of treatment in any ED etiology subgroup, whereas among men who received combination treatment, full erections were reported by 68.8 percent of men with psychogenic ED (n = 11/16), 11.1 percent of men with vascular ED (n = 1/9), 37.5 percent of men with neurogenic ED (n = 3/8), and 25 percent of men with mixed ED (n = 3/12). Men who received combination therapy also reported improved enjoyment with partner and satisfaction with intercourse.

Patch testosterone versus placebo. The efficacy and harms of patch testosterone versus placebo were evaluated and reported in two trials.[317,330] The design and study population of the first trial[317] are described elsewhere in two other sections: Gel Testosterone versus Placebo and Gel Testosterone versus Patch Testosterone. In the second trial,[330] 39 "borderline" hypogonadal men (total testosterone <10 nmol/l or a free androgen index <30 percent) aged 40–77 years (mean: 62 years) were randomized to 6 months of treatment either with 5 mg patch testosterone (Testoderm) once daily or placebo.

Harms. In the first trial,[317] 62.7 percent of men assigned to the patch testosterone group versus 40.4 percent of those in the placebo group had at least one treatment-related adverse event. Withdrawals due to a skin reaction occurred in 15 percent of patch testosterone subjects, but not in placebo subjects.

In the second trial,[330] 15 percent of patch testosterone subjects and 5.3 percent of placebo subjects had an increased hematocrit. One subject assigned to the placebo group developed angina.

Efficacy. In the first trial,[317], among men with sexual partners (62 percent of randomized men), 24 percent of men receiving placebo reported an increase from baseline in the number of days in the past week with sexual intercourse, compared with 21 percent of men receiving patch testosterone ($p \geq 0.05$, versus placebo).

In the second trial,[330] men who received placebo had a statistically significantly greater decline from baseline in their Male Erectile Dysfunction Quality of Life questionnaire

(MEDQoL) score (range 0-100) compared with men who received patch testosterone (from 61.4 at baseline to 61.8 at followup for patch testosterone versus from 54.2 at baseline to 43.6 at followup for placebo) (p = 0.017).

Patch testosterone plus sildenafil versus sildenafil. One open label trial compared the efficacy and harms of patch testosterone plus sildenafil versus sildenafil.[77] This trial enrolled 20 men aged 48-66 years (mean age: 56 years), with arteriogenic ED of ≥ 6 months duration, and refractory to prior sildenafil therapy, The inclusion criteria were: total testosterone 10-13 nmol/L and free testosterone 200-300 pmol/lL, no response to previous treatment with 100 mg patch testosterone, and an IIEF erectile function score of less than 24 in response to 100 mg sildenafil. Men with a history of hematological disorders or prostate disease were excluded. Men were randomized to 5 mg patch testosterone daily plus 100 mg sildenafil, as needed for one month versus placebo patch daily plus 100 mg sildenafil, as needed.

Harms. Data on adverse events was not reported.

Efficacy. Men who received placebo patch plus sildenafil did not improve in erectile function compared with baseline on any IIEF question or domain reported. Those in the combination group (patch testosterone plus sildenafil) had a greater endpoint percentage of successful intercourse attempts (data not provided), higher "EF domain" scores (21.8 +/- 2.1 versus 14.2 +/- 0.7, WMD = 7.60, 95 percent CI 6.23–8.97), an increased number of sexual intercourses (2.8 +/- 0.9 versus 1.5 +/- 0.5, WMD = 1.30, 95 percent CI 0.66–1.94), greater intercourse satisfaction (12.1 +/- 1.6 versus 7.7 +/- 1.2, WMD = 4.40, 95 percent CI 3.16–5.64), and more frequently reported that treatment had improved their erections (80 versus 10 percent, RR = 8.00, 95 percent CI: 1.21–52.69).

Dihydrotestosterone gel versus placebo. One trial compared the efficacy and harms of dihydrotestosterone gel versus placebo.[321] This trial enrolled 120 men with nocturnal penile tumescence no more than once weekly, at least one symptom of andropause (decreased libido, ED, "urinary disorder," asthenia, or depressed mood), and total serum testosterone <15 nmol/L and/or SHBG >30 nmol/L. Men were randomized to daily dihydrotestosterone gel versus placebo for 6 months. Dihydrotestosterone gel was initiated at 125 mg daily and could be titrated to 250 mg daily after 30 days according to DHT levels.

Harms. Of men who received dihydrotestosterone gel, 5 percent reported mild headache (versus 3.3 percent for placebo) and 3.3 percent reported mild depression (versus 3.3 percent for placebo).

Efficacy. At baseline and 6-month followup, participants rated their ability to maintain erection during intercourse on a scale of 1–6, in which 2 = "75 percent of intercourses" and 3 = "50 percent of intercourses. Mean scores reported for participants who received dihydrotestosterone were 2.26 at baseline and 3.24 at 6 months, whereas those for the participants in the placebo group were 2.53 at baseline and 2.81 at followup (p = 0.04 for mean change from baseline between treatment groups).

Quantitative Synthesis

There was a large degree of clinical heterogeneity in the eligible testosterone trials with regard to patient characteristics (e.g. characterization of sexual dysfunction, testosterone level), interventions (e.g. specific testosterone formulation, dose and duration of treatment, use of testosterone monotherapy or combination), and outcomes assessed (e.g. various definitions of sexual intercourse success, and of erection improvement). Therefore, no MA was performed.

Other Treatments (Off Label)

Literature Search

There were 21 (in 22 publications) unique studies reporting on different off label oral treatments that met the eligibility criteria of this review.[265,333-353]
Note: Korenman et al. (1994)[349] is a reprint of Korenman et al. (1993).[345]

Overview of Trials

The trials evaluated the following treatments: phentolamine (one additional trial of phentolamine is described in the Sildenafil section[124]),[333,338] trazodone,[336,337,339,341,344] cabergoline,[162,350] pentoxifyling (in 4 reports),[340,343,345,349] and miscellaneous medications. The latter consisted of treatments with moclobemide,[334] isoxsuprine,[335] opiate antag,[342] ACE,[346] moxonidine,[347] dehydropiand,[348] tetrahydrobiopterin (BH4),[353] Myoinositol,[351] and Tianeptine.[352] (Table F-10, Appendix F)

Phentolamine. Two trials investigated the effect of phentolamine in comparison to placebo.[333,338] One of the trials was used a crossover design (n = 5)[333] and the other a parallel design (n = 44).[338] Subjects in these trials were generally older than 18 years, with ED of at least 3 months of duration and various etiologies (the majority with organic causes). Total Jadad score was 3 for both trials.[333,338] The allocation concealment was unclear for both trials. The trial outcomes were patient diary[338] and RigiScan measures on nocturnal erectile activity.[333]

Harms. One trial reported one adverse event occurring in a patient taking 60 mg dose.[338] In another trial, no adverse events occurred.[333] No serious adverse events were reported in any of these trials.

Efficacy. Forty to 50 percent of patients improved their erections with higher doses of phentolamine (40 and 60 mg) compared with 30 and 20 percent with lower dose (20 mg) or placebo respectively.[338]

Oral phentolamine (40 mg, 3 consecutive nights) administered before sleep increased the number of erectile events with rigidity of at least 60 percent lasting at least 10 minutes ($p = 0.02$), and the rigidity activity unit (RAU) per hour of sleep both at the base ($p = 0.023$) and the tip of the penis ($p = 0.019$), which were not different from changes after administration of placebo.[333]

Trazodone versus other active treatment versus placebo. Five trials reported on the effect of treatment with trazodone (n = 333, range: 34-100 participants).[336,337,339,341,344] The trials were conducted in Belgium,[336] Turkey,[341,344] the Netherlands,[339] and US.[337] Total Jadad score ranged from 1[341] to 4[339] with a mean of 2.8.

Four studies used a parallel[336,339,341,344], and one crossover design.[337] Trazodone was administered at doses of 50 mg,[337,344] 150 mg,[339,341] or 200 mg[336] per day. Aydin et al. (1995)[341] compared the effect of trazodone to oral testosterone (120 mg/d), hypnosis or placebo. Kurt et al. (1994) compared trazodone to ketanserin and mianserin (antiserotoninergic agents).[344] Subjective measures such as self reported questionnaires to address improvement in erection with treatment were used in four trials.[336,337,341,344] The outcomes based on RigiScan measurements (i.e. NTP, rigidity) were reported in two trials.[336,339]

Harms. In one trial, numerically more patients in the trazodone group reported dry mouth (25.0 percent), drowsiness (18.8 percent), and fatigue (14.6 percent) compared with the placebo

group (16.7, 12.5, and 8.3 percent, respectively).[337] Another study reported 50 percent more withdrawals due to adverse events in trazodone group versus the placebo group.[339] In the trazodone arm of one trail, five patients experienced sedations; no information on adverse events for other groups (i.e., testosterone, hypnosis, and placebo) was reported. [339] In a trial comparing the efficacy and harms of trazodone to mianserin,[344] two patients (8 percent) withdrew due to adverse events from the mianserin treatment group and two patients (8 percent) in the trazodone group developed serious adverse events (priapism and sedation).

Efficacy. Improvement in erection measured by Index of Sexual Satisfaction was 19 and 24 percent in trazodone and placebo groups, respectively.[337] One study reported minor improvement from baseline in trazodone group but the between-group (versus placebo) difference for base rigidity (> 60 percent), nocturnal erection, or morning erection, was not statistically significant.[336] For one trial, improved erections were observed in 66, 60, 80, and 39 percent of the patients treated with trazodone, testosterone, hypnosis, and placebo, respectively.[341]

The proportions of patients with positive response (3 or more successful intercourse attempts during 30 days and rigidity ≥ 30 minutes) at the end of 30 days of treatment with 50 mg trazodone, 20 mg ketanserin, 10 mg mianserin, and placebo were 65.2, 19.1, 31.6, 13.6 percent, respectively.[344]

Cabergoline versus placebo. Two trials were identified with a total of 452 participants randomly assigned to treatment with cabergoline (n = 225) or placebo (n = 222).[162,350] The trials were conducted in Germany[350] and Iran.[162] The German study recruited patients with no organic cause of ED. The Iranian study recruited non-responders to previous sildenafil therapy. The mean age of participants was approximately 40 years. Total Jadad scores for the two trials were 3[350] and 5.[162] The allocation concealment was unclear in one[350] and adequate in the other.[162] Both studies were parallel design and placebo controlled. The dose of cabergoline was 0.5 mg per day[350] or 0.5–1 mg.[162] In both trials, the IIEF was used to measure baseline severity and treatment effect.

Harms. The number of patients with any adverse events was greater in cabergoline group (12.2 percent versus 2.0 percent, p = 0.001).[162] Withdrawals due to adverse events were higher in the active arm versus placebo in the study which reported this information (5.9 versus 1.01 percent).[162] No information on serious adverse events was reported in any of these trials.

Efficacy. Both trials reported numerically or statistically significant improvements in the results with cabergoline 0.5 mg versus placebo. The German study reported a change of 11.7 in mean scores of erectile domain of IIEF from baseline in comparison to a change of 6.9 in the placebo group. In the Iranian trial, patients improved by 5 points in the Intercourse Satisfaction domain of the IIEF.[162] The improvement in Q3 (frequency of penetration), and Q4 (ability to maintain the erection after sexual penetration) was 45.5 and 51.4 percent in the cabergoline arm versus 15 and 20 percent in the placebo arm, respectively.[162]

Pentoxifylline. Three parallel design studies were included (n = 114, range 18–60).[340,343,345] Mean age of participants was approximately 60.6 years. The trials were conducted in Turkey[340] and US.[343,345] The trial duration ranged from 2 to 3 months.

Total Jadad score ranged from 1[340] to 2.[343,345] Allocation concealment methods were unclear in all three studies.

All three trials were placebo controlled administering 1.2 g/day of pentoxifylline and evaluating subjective measures of improvement in erection. One study also included RigiScan outcomes (i.e., NPT, penile rigidity).[343]

Pentoxifylline versus Placebo.

Harms. The adverse events including nausea and headaches were transient and mild.[340] Harms data was not presented in the other two trials.[343,345]

Efficacy. Full erection (sufficient for penetration) was achieved in 10 versus 0 percent[340], and in 78 versus 0 percent [345]. One trial[343] reported a slight decrease in average percent rigidity after 3 months of treatment with pentoxifylline.

Miscellaneous treatments of ED. Nine trials were identified (n = 449, range: 11–176 participants) that evaluated miscellaneous off label medications for treatment of ED.[334,335,342,346-348,351-353] Information on the participants' characteristics, intervention and outcomes is presented in Table 32.

These were five parallel-arm [334,346,348,351,353] and four crossover trials.[335,342,347,352] Eight trials were placebo controlled[334,335,342,346,348,351-353] and one trial used active medication as comparator.[347]

Funding sources were reported for only three trials.[334,347,352] One trial had no source of support.[335]

Total Jadad scores ranged from 2[335,346,353] to 4.[348] The methods for allocation concealment were unclear in all studies.

The mean IIEF scores were measured in four trials.[346-348,351] Other self-reported outcomes related to erection were assessed in four trials[334,335,342,352] One trial assessed and reported only rigidity measures (RigiScan).[353]

Harms. see Table 27.

Efficacy. see Table 27.

Question 3a. What Are the harms of Pharmaceutical Treatments for Male Patients with ED?

Specific Adverse Events
Oral Medications: PDE–5 inhibitors

Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION)

In total, 194 records were identified that discussed incidence of NAION in men treated with sildenafil. Of these, 10 records reporting on cases of nonarteritic anterior ischemic optic neuropathy (NAION) were included in this review.[354-363] These records were seven case reports[354-359,363], two case series[361,362], and one retrospective cohort study.[360] The remaining records not reporting NAION were excluded.

This review identified 19 cases of NAION reported between 1999 and 2007. Findings of the retrospective cohort study, of 4,157,357 veterans 50 years of age or older indicated that men who were prescribed PDE-5 inhibitors over the period of 2 years were not at increased risk of being diagnosed with NAION compared with those who were not prescribed PDE-5 inhibitors (RR = 1.02, 95 percent CI: 0.92–1.12).[360] Note that for possible NAION, the corresponding relative risk was statistically significant (RR = 1.34, 95 percent CI: 1.17–1.55). In all cases except for one,[362] the administered minimum dose of sildenafil was 50 mg. Overdose of sildenafil was reported in two case reports.[354,363] Further details can be found in Table 28.

Injection Treatments

Penile Fibrosis (Non-randomized studies: observational studies and clinical trials)

In total, 20 non-randomized studies (retrospective observational cohort, and clinical trials) reporting the absence or presence of penile fibrosis in long-term followup (at least 6 months) met the eligibility criteria for inclusion in the review (in 20 publications).[364-383] Of these, 13 were clinical trials of prospective design[364-366,368-371,376-378,380,381,383] and seven were retrospective cohort studies.[367,372-375,379,382]

The number of subjects included in the 20 studies ranged from 10[370] to 1089.[374] The majority of the study subjects were middle aged (mean age range: 50-62 years). Four trials included special population subgroups such as patients diagnosed with diabetes,[366,369] multiple sclerosis,[381] and prostate cancer followed by prostatectomy.[367] One study evaluated ICI therapy in geriatric men (age >65 years).[382]

Prostaglandin (PGE_1) alone or in combination with other vasoactive agents (papaverine and/or phentolamine) was evaluated in 15 studies.[364-378] Papaverine alone or in combination with phentolamine (or verapamil) was evaluated in 13 studies.[366,367,369,371,373,374,376,377,379-383] The duration of treatment ranged from 3 months[368] to 10 years.[366] In the majority of studies, the approximate frequency of PGE_1 injections was up to twice per week with a mean dose of 20 μg or lower.[365,370,372,375,378]

Of the 20 studies, five explicitly reported the absence of new cases of fibrosis.[367,368,370,371,378] and six studies reported the incidence of fibrosis to be under 5 percent.[373,376,377,379-382]

The proportion of patients with fibrosis in studies that used PGE_1 alone after at least one year of followup ranged from 4.4 percent[365] to 23.3 percent.[372] In two of these studies no cases of fibrosis were observed.[370,378] For example, one retrospective cohort study in Australian men[372] reported an incidence of fibrosis in 57 of the 245 patients (23.3 percent) who had been treated with PGE_1 2–60µg (mean 13µg) for 2 years on average. The total amount of PGE_1 ($p = 0.0062$) and the total number of injections ($p = 0.0032$) over the whole treatment period were statistically significantly greater in the men with fibrosis. However, there were no significant differences between the men who developed fibrosis and men who did not with regard to duration of followup, injection frequency, or dose per injection.[372] In contrast, in another prospective trial,[365] only three (4.4 percent) of the 68 PGE1-treated patients (the mean PGE1 dose: 11.6µg) developed fibrosis after at least one year of followup. Of these three patients, only one patient injected PGE_1 more frequently and at a higher dose (20-60µg every 2-3 days) than it was prescribed (one injection 10-20µg per 5-7 days).

The largest study that evaluated and compared adverse events in patients receiving ICI injections with different medications was a retrospective U.S. study of 1089 patients who had received either 5-10µg PGE_1, trimix (1.47µg PGE_1 plus 4.41 mg papaverine plus 0.5 mg phentolamine), papaverine plus phentolamine, or 10µg PGE_1 plus 30 mg papaverine for up to 80 months. This study investigated reasons for attrition in each treatment group. Of the subjects discontinuing the treatment, penile scarring/nodules was the reason for study withdrawal in 23 percent (6/26), 11 percent (4/36), and 10 percent (8/75) of the subjects receiving triple therapy (PGE_1/papaverine/ phentolamine), combination papaverine and phentolamine therapy, and PGE_1 monotherapy, respectively. None of the patients receiving the combination of PGE1 with papaverine developed penile scarring/nodules.[374] In a controlled trial conducted in Taiwan,[377] 51 patients with ED (mean age: 58 years) received self-injections either with 20µg PGE_1 or 30 mg papaverine for about 12 months (range: 1.5-30.5 months). Two patients (3.9 percent) developed fibrosis after 60 mg papaverine injections. No cases of fibrosis were observed in patients after PGE_1 injections.[377] Similarly, in a trial conducted in Turkey,[376] 69 patients with ED (mean age: 52.6 years) were divided to receive injections either with 10µg PGE_1 (n = 13 patients) or 15-30 mg papaverine (n = 56 patients) for approximately 12 months. Two patients (3.6 percent) in the papaverine group developed fibrosis versus none in the PGE_1 group. In a retrospective North American cohort study,[373] 108 ED patients received self-injections with either 30 mg papaverine (n = 21 patients), the combination of 25 mg papaverine with 0.83 mg phentolamine (n = 77), or PGE_1 (n = 2 patients) were followed-up for 5 years. Only one of the 108 subjects developed fibrosis (the assigned intervention not reported). (Table 29)

Chapter 4. Discussion

This evidence report summarized, critically appraised, and compared the evidence on clinical benefits and harms associated with the administration of different types of pharmaceutical agents in the treatment of erectile dysfunction (ED).

Strength of the Evidence

Erectile dysfunction is a complex condition related to psychosocial and biological factors. It is difficult to reliably document and measure the degree of treatment success in patients diagnosed with this condition. Most of the validated and clinically relevant efficacy outcomes assessed in clinical trials of ED patients are subjective.

The strength of evidence regarding the utility of routine endocrinological blood tests found in this review was limited in terms of the both amount and quality of data. The studies were heterogeneous with respect to patient population characteristics, diagnostic methods, estimates of prevalence, and laboratory methods used (e.g. cut-off values, total, free, or bioavailable hormonal levels).

The placebo-controlled randomized trials that evaluated the efficacy and harms of PDE–5 inhibitors provided large amount of evidence and consistently indicated that patients who received PDE–5 inhibitors experienced greater improvements in erectile dysfunction compared with placebo-treated patients. The magnitude of benefit was clinically relevant and statistically significant. The methodological and reporting quality of the evidence provided by these trials was better than that for other studies (e.g. trials with active control arms or trials evaluating sublingual apomorphine, injections, topical, hormonal, or off-label therapies). Most of these trials enrolled ED patient populations with a broad spectrum of etiologies or comorbidities and assessed the same set of clinically relevant and validated outcome measures. Given the reported exclusion criteria for these trials, their results may not be readily applicable to ED patients with major chronic disorders (e.g. cancer, CVD, diabetes, psychiatric disorders, hepatic or renal diseases) or post-surgery patients, because the magnitude of clinical benefit conferred by PDE-5 inhibitors in such patients is relatively modest.[384-386] Furthermore, vardenafil trials may have been comprised of more responsive patients due to the fact that about half of these trials excluded patients refractory to prior sildenafil therapy, thereby limiting the applicability of the results to a broader population of ED patients. On average, trials that evaluated injected (e.g. intracavernosal, subcutaneous), intra-urethral, topical, or other treatments were of relatively lower methodological and reporting quality.

A common limitation of these trials was a failure to assess and/or report clinically relevant treatment efficacy outcomes used for the measurement of the degree of erectile dysfunction (e.g. mean scores for International Index of Erectile Function, Sexual Encounter Profile, Global Assessment Question regarding improved erection). The most commonly assessed efficacy outcomes in these trials were penile rigidity (using RigiScan) and the quality of erections achieved at home. The trials did not report information on the methods used for randomization, blinding, and allocation concealment. Many study results may have been biased in favor of active treatment, because the analyzed samples predominantly included responders and excluded many randomized participants from their efficacy analyses. There was substantial heterogeneity across the hormonal treatment trials with respect to the diversity of patient populations (variations in inclusion/exclusion criteria; not

all patients had ED), treatment interventions (type of intervention, mode of administration, dose, dosing regimen, duration), and the assessed outcomes.

In general, the reporting of harms was less consistent and detailed than that of efficacy outcomes. For example, the occurrence of any or serious adverse events was not reported in many trials. The definition of a serious adverse event may have varied across the trials. Some trials reported only most frequently encountered or treatment-related adverse events, the ascertainment of which may be prone to subjective judgment. In some instances, it was not explicitly defined whether the number and percentage referred to the actual number of adverse events or to the number of patients with at least one adverse event. In open label trials, patients or investigators may have over- or under-reported the incidence of adverse events because of their knowledge of the assigned treatment. Moreover disease-specific complications in patients with comorbidities and/or disorders known to cause ED could have been overlooked. In many cases, the statistical test results for between-group differences in adverse events were not reported, thereby limiting the interpretability of the data.

The reviewed evidence indicated that there is a lack of long-term efficacy and harms data associated with treatments for ED. This is especially important in the case of oral PDE–5 inhibitors and associated harms, given their prevalent use by men in the Western world (e.g. 7 percent of American men aged 56-65 years in 2002).[30] Overall, duration of followup for the majority of reviewed trials was not sufficient to permit the reliable assessment of long-term (>6 months) treatment-related outcomes in patients with ED. The duration of followup for many of the PDE–5 inhibitor trials did not exceed 12 weeks. The long-term safety data obtained from retrospective observational studies is not as conclusive as that obtained from well-conducted long-term large randomized trials, which have fewer methodological limitations.

The reviewed evidence consisted of randomized trials using either parallel-arm or crossover design. Although crossover trials are efficient in terms of resources and study power, they require additional caution and careful interpretation of results. For example, one problem inherent in all crossover trials is a potential for a carryover effect, which could be minimized by employing an adequate washout period between alternative treatment periods.[387] Although most of the authors reported the duration of washout periods (about 1–2 weeks), it is not clear what minimum length of time would be sufficient to avert or minimize carryover effects from the different types of treatment in patients with ED.

Question 1: What is the Clinical Utility of Routine Blood Tests—Testosterone, Prolactin, Luteinizing Hormone, Follicle-stimulating Hormone—in Identifying and Affecting Therapeutic Outcomes for Treatable Causes of ED?

The current evidence does not clarify the role of routine hormonal blood tests in all men who present with ED, nor does it clarify whether testing should occur before initiation of a first-line PDE–5 inhibitor treatment versus a more selective approach guided by elevated clinical suspicion for endocrinopathies. The signs and symptoms indicative of hypogonadism may include decreased testes size, alteration in secondary sexual characteristics, decreased libido, changes in mood, a chronic fatigued state or reduced physical performance, as well as altered hematocrit, high- and low-density lipoproteins, or cholesterol.[388] Also, it remains unclear whether testing for prolactin, LH, and FSH endocrinopathies is justified as a stand-alone diagnostic strategy if testosterone levels are within the normal limits.

In total, 21 unique studies were reviewed to summarize information needed for determining the clinical utility of routine testosterone, prolactin, luteinizing hormone (LH) and follicle-stimulating hormone (FSH) testing in ED patients. Overall, the heterogeneous nature of the data precludes the reliable evaluation of the utility and limitations of endocrinological testing in the ED population.

Prevalence of Endocrinological Abnormalities

In the reviewed studies, the prevalence of hypogonadism in the ED population varied widely, with reported rates ranging from 1.72 to 24.1 percent. The total, free and calculated testosterone levels were used as primary measures inconsistently, limiting the ability to meaningfully pool data across studies. The effect of age on the prevalence rates of hypogonadism may not be readily determined. For example, the descriptive analysis did not reveal the patients' age to be an important factor in explaining the observed variation in the prevalence rates of hypogonadism across studies. In contrast, within-study age-stratified results reported for three trials demonstrated that the prevalence rates of hypogonadism (i.e., low free serum testosterone) among men aged 50 years or older were almost doubled compared with the corresponding rates among men below age 50.[38,64,73] Similarly, there was a wide variation in the prevalence rates of hyperprolactinemia (1.42–14.3 percent). In general, the evidence is inconsistent in indicating what subgroups of ED patients are more likely to have hypogonadism. Very few studies consistently indicated that patients referred to urology clinics for ED who had had decreased libido, testicular damage/abnormality, arterial disease, insulin resistance, or diabetes were more likely to have hypogonadism. The evidence is less consistent with respect to such factors as severity of ED, duration of ED, or sexual disorders (e.g. premature ejaculation).

The wide variation in the prevalence rates of hypogonadism and hyperprolactinemia could be explained by between-study differences in age distribution, types of tests (e.g. measurements of total, free, or bioavailable hormone levels), diagnostic criteria, and many other concurrent conditions that can influence blood testosterone levels.

Efficacy of Hormonal Treatments

Both studies[5,77] that evaluated efficacy of hormonal treatment compared a combination hormonal treatment (i.e., testosterone gel or patch plus PDE–5 inhibitor) to monotherapy with a PDE–5 inhibitor, and were conducted exclusively in hypogonadal patients refractory to prior PDE–5 treatment. Results from these trials indicated greater improvements in erectile outcomes based on International Index of Erectile Function–Erectile Function domain scores (i.e., erection frequency, erection firmness, penetration ability, and erection confidence), favoring patients who received a combination of testosterone and PDE–5 inhibitors versus those who received PDE–5 inhibitors alone.[5,77] These results warrant a cautious interpretation. For example, one of these trials[77] used an open-label design and had low quality methodology and reporting (total Jadad score of 1), thereby limiting the interpretability of the results. These studies were conducted only in ED patients refractory to PDE–5 inhibitor treatments, so the results may not be readily applicable to patients with a partial response or to those naïve to PDE–5 inhibitor treatments. Studies that are more methodologically sound are needed to determine definitively the efficacy of hormonal treatments relative to PDE–5 inhibitors (or any other first-line treatment) in patients with ED and concurrent endocrinological abnormalities.

Clinical Practice

Evidence regarding accurate identification of men who would benefit from testosterone replacement therapy is scarce. Thus, there is no universally accepted method of identifying men with clinically relevant hypogonadism affecting erectile function and the implications of androgen status for erectile dysfunction and its treatments remains controversial.[389] Given the current gaps in knowledge, the most adequate and cost-effective laboratory test for hormonal evaluation is unclear. This problem is reflected in two differing guideline statements.[14,39] The American Urological Association recommends testosterone testing based on initial clinical assessment results or failure of prior management with PDE-5 inhibitors,[14] while the European Urological Association mandates testosterone measures (bioavailable or calculated-free testosterone begin preferred over total levels) for all men with ED.[39] These two groups have similar guidelines, which suggest that further endocrinological laboratory investigations including prolactin, LH, and FSH testing are indicated when low testosterone levels are detected. Optimal approaches from a clinical and resource-allocation standpoint remain to be determined. Regardless of the results, clinicians need to direct their initial efforts towards correctly identifying and treating, if possible, an underlying cause of ED, whether it is an endocrine or non-endocrine cause.

Questions 2–3: What are the Benefits and Harms of Pharmaceutical Treatments for ED? Oral Medications - PDE–5 Inhibitors

PDE–5 Inhibitors Versus Placebo

Efficacy. Overall, the evidence consistently indicated that patients with ED who received these agents (i.e., sildenafil, vardenafil, or tadalafil), compared with those on placebo, experienced greater improvements in the clinical measures of erectile function such as the mean scores for the International Index of Erectile Function (IIEF) "Erectile Function domain" (i.e., erection frequency, erection firmness, penetration ability, and erection confidence), IIEF–Q3/Q4 (i.e., penetration ability and maintenance frequency), and Sexual Encounter Profile (SEP)–Q2/Q3 (i.e., the per-patient proportion of successful intercourse attempts). The evidence was also consistent in favor of PDE–5 inhibitors over placebo in showing the clinical benefit with respect to the proportion of patients with improved erection (GAQ–Q1). Sildenafil, vardenafil, and tadalafil also demonstrated consistent statistically significant clinical benefits over placebo with regard to mean total scores for the specific IIEF domains such as "Intercourse Satisfaction" (i.e., intercourse frequency, satisfaction, and enjoyment) and "Overall Satisfaction" (i.e., overall satisfaction and relationship satisfaction). Results obtained from the same trials suggested that the effects of sildenafil and tadalafil did not differ from that of placebo for the IIEF domains of "Sexual Desire" (i.e., desire frequency and desire level) and "Orgasmic Function" (ejaculation and orgasm frequency). In a few trials, patients treated with vardenafil had improved in the domains of "Sexual Desire" and/or "Orgasmic Function" compared with placebo-treated patients.[183,194,199,204] Furthermore, all trials that reported patient satisfaction with a medication (i.e., mean Erectile Dysfunction Index of Treatment Satisfaction scores) showed statistically significant improved scores for patients who received sildenafil or tadalafil compared with those who received placebo. None of the vardenafil trials reported scores for the Erectile Dysfunction Index of Treatment Satisfaction (EDITS). The results of meta-analyses conducted in this review were consistent with those of qualitative assessments in that they indicate statistically significant improvements in PDE–5 inhibitor-treated (regardless of dose/dosing regimen) patients versus placebo-treated patients with respect to the mean change/endpoint scores of IIEF "EF domain," IIEF–Q3/Q4, SEP–Q2/Q3, as well as with respect to the proportion of patients with improved erection (GAQ–Q1).

Harms. In general, all three PDE–5 inhibitors were described as well-tolerated drugs whose use was associated with adverse events mainly of a mild or moderate nature. Overall, the occurrence of any all-cause adverse events tended to be higher either numerically or with a statistical significance in patients treated with PDE–5 inhibitors as compared with those treated with placebo. The most commonly observed all-cause adverse events for all three PDE–5 inhibitors were headache, flushing, dyspepsia, and rhinitis. The incidence of serious adverse events was poorly reported. Numerically, there was no obvious imbalance with respect to the occurrence of serious adverse events between patients who received PDE–5 inhibitors and those who received placebo. The result of meta-analysis agreed with those for the qualitative assessment of harms in their indication of an increased risk of any adverse events in patients who received PDE–5 inhibitors (regardless of dose/dosing regimen) compared with those who received placebo.

Two meta-analyses also showed that there were no statistically significant differences with respect to the occurrence of serious adverse events or withdrawals due to adverse events between vardenafil- and placebo-treated groups. Compared with placebo, the use of either sildenafil or vardenafil was associated with an increased risk of either headache or flushing. In addition, patients treated with vardenafil or sildenafil, in comparison with those treated with placebo, were at increased risk of dyspepsia and visual disturbances, respectively.

Dose-response Effect of PDE–5 Inhibitors

Efficacy. In general, the degree of efficacy in improving erectile function (e.g. scores for the IIEF "EF domain" or individual item scores, SEP–Q2/Q3 scores, percentage of patients who responded "yes" to GAQ–Q1) tended to increase with the doses of PDE–5 inhibitors. The observed trends were either numerical or statistically significant. Formal statistical test results for differences in efficacy between dose-specific arms for PDE–5 inhibitors were not provided in many trial reports, which complicated the interpretation. The observed dose-response trends in efficacy were less obvious for tadalafil trials, in which the degree of improvement in erectile function was numerically similar in patients who received three doses of tadalafil (20 mg, 10 mg, and 5 mg). According to our meta-analyses, in sildenafil trials the proportion of patients with improved erection (GAQ–Q1) was greater for men who received 50 mg compared with those who used a 25 mg dose. The difference for the corresponding proportions between 50 mg and 100 mg groups favored the higher 100 mg dose but was not statistically significant. Although the mean IIEF "EF" domain score and the proportion of "yes" responses to GAQ–Q1 among patients treated with vardenafil favored the 20 mg dose over the 10 mg dose, the differences did not reach the statistical significance.

Harms. The incidence of any all-cause adverse events in sildenafil (25 mg versus 50 mg versus 100 mg) and vardenafil (5 mg versus 10 mg versus 20 mg) trials had a numerical pattern of dose-dependence, indicating that adverse events occurred more frequently at the higher doses. The dose-response pattern for the effect of tadalafil (10 mg versus 20 mg) was not obvious. The meta-analyses conducted on vardenafil trials showed an increased risk of any adverse events in patients treated with the 20 mg versus the 10 mg dose. The difference for the proportion of patients with serious adverse events between the two doses of vardenafil was not statistically significant. Neither the rate of withdrawal resulting from adverse events nor specific adverse events (i.e., headache, flushing, dyspepsia) differed between the two doses. The meta-analyses of sildenafil trials revealed no statistically significant differences in the incidence of specific adverse events (i.e., headache, flushing, or visual disturbances) between the 25 mg, 50 mg, and 100 mg sildenafil groups. The meta-analysis of tadalafil trials found a statistically significant increase in the risk of any adverse events for patients in the 20 mg group relative to those in 10 mg group.

Dosing Regimens of PDE–5 Inhibitors

Efficacy. Different dosing regimens of PDE–5 inhibitors were evaluated in sildenafil (fixed dose of 50 mg versus flexible dose of 50 mg or 100 mg)[157] and tadalafil (20 mg "on demand" versus 20 mg "scheduled")[214,232] trials. The results of both sildenafil and tadalafil trials indicated no difference in the degree of clinical benefit experienced by patients randomly assigned to different dosing regimens (fixed versus flexible, or "on demand" versus "scheduled"). The benefits were observed for the IIEF "EF" domain or individual item scores, SEP–Q2/Q3 scores, and the percentage who responded "yes" to GAQ–Q1.

Harms. There were no obvious differences in the occurrence of adverse events between "on demand" versus "scheduled" intakes of tadalafil.

PDE–5 Inhibitors – Mono versus PDE–5 Inhibitors – Combined Therapy

Efficacy. The results suggest that sildenafil used in combination with other therapies may be clinically more beneficial than sildenafil used as monotherapy. In these trials, the administration of sildenafil combination therapies was associated with statistically significant improvements in IIEF "EF" domain and individual IIEF (Q1–Q15) scores as well as in the mean duration of rigidity (≥60 percent) of the penis and the proportion of patients with improved erection (GAQ–Q1), relative to sildenafil monotherapy.

Harms. Based on the limited data from only one trial,[162] there was a statistically significant greater proportion of patients with at least one any adverse event (all-cause) in the sildenafil combination therapy (with cabergoline) group compared with the sildenafil monotherapy group. In two trials,[162,173] more patients withdrew due to adverse events in the combined (with either cabergoline or alfuzosin) treatment groups than in the monotherapy groups.

PDE–5 Inhibitors Versus Other Treatments

Efficacy. Improvements in erectile function (IIEF-"EF domain" scores) observed in 4 head-to-head trials comparing sildenafil, vardenafil, and tadalafil were inconclusive. In these trials, more patients preferred tadalafil over sildenafil or vardenafil. The mean duration from dosing to attempted sexual intercourse was also longer for tadalafil. The patients' preference in favor of tadalafil could partially be explained by a longer acting duration of tadalafil compared with sildenafil or vardenafil observed in these trials. The half-life for tadalafil, sildenafil, and vardenafil is about 17.5 hours, 4 hours, and 4-5 hours, respectively. Furthermore, unlike sildenafil, the absorption of tadalafil is not influenced by food, making it more convenient.[390,391]

Compared with other treatments (i.e., continuous positive air pressure [CPAP], phentolamine, alfuzosin, Ro70–0004), sildenafil was shown to be associated with either statistically significant or numerically greater improvements in the mean IIEF "EF" domain and IIEF–Q3/Q4 scores, the rate of improved erections (GAQ–Q1), and the mean duration of rigidity.(>60 percent).[124,132,155,173] The four trials comparing sildenafil to apomorphine[114,117,120,159] suggest that sildenafil is more effective in improving several outcomes including mean percentage of successful intercourse attempts, mean IIEF scores, and patient satisfaction. Sildenafil had a beneficial clinical effect similar to that of apomorphine in combination with either phentolamine or with phentolamine plus papaverine.[251] One explanation for this observed pattern could be that the effect of apomorphine might have been optimized by combining apomorphine with phentolamine alone or also with papaverine.

Harms. The incidence of any adverse events showed no statistically significant difference between patients treated with sildenafil, tadalafil, and vardenafil.[103,121,163] The limited amount of evidence obtained from one trial[103] suggested that groups treated with sildenafil or tadalafil did not differ in the proportion of patients with serious adverse events. In another trial,[124] limited data indicated that fewer patients treated with sildenafil had any adverse events (all-cause) or serious adverse events compared with patients treated with

phentolamine. Rates of withdrawal due to adverse events were also numerically lower in the sildenafil groups than in either the phentolamine[124] or the alfuzosin group.[173] The incidence of any adverse events in three trials[114,117,120] was poorly reported and was numerically greater in patients treated with sildenafil than in those treated with apomorphine. In one trial,[251] the proportion of patients with any adverse events was numerically lower in the sildenafil arm compared with the apomorphine combination arms (with phentolamine).

Sublingual Agents – Apomorphine

Apomorphine Versus Placebo

Efficacy. Overall, results from the five placebo-controlled trials indicated statistically significant improvements with respect to measures of erectile function (e.g. mean percentage of successful intercourse attempts, percentage of attempts resulting in erections firm enough for intercourse, rigidity ≥40 percent, and the mean IIEF "Erectile Function" domain score) in patients treated with apomorphine compared with those who received placebo. Clinically significant differences were seen in the mean percentage of improved erectile function with apomorphine compared with placebo arms.

Harms. There was insufficient information on the occurrence of any adverse events in these trials to allow comparison of incidence of harms across apomorphine and placebo groups. Adverse events such as nausea, headache, dizziness, and yawning occurred more frequently among patients who received apomorphine than among those who received placebo. The results from two trials suggested that the use of apomorphine was not associated with an increased incidence of any serious adverse events compared with the use of placebo.[248,250]

Dose-response Effect of Apomorphine

Efficacy. Limited evidence from two trials indicated that the mean percentage of successful intercourse attempts did not differ across groups who received various doses of apomorphine treatment (e.g. 3mg, 4 mg, 5 mg, 6 mg, 2–6 mg). This observation suggests that the efficacy of apomorphine may not be dose-related.

Harms. In multiple-dose trials, the occurrence of nausea, yawning, dizziness, vomiting, and glossitis was numerically greater in patients who received higher doses of apomorphine.[248,252,253]

Intracavernosal Injections

Prostaglandin E1 (PGE1)

Efficacy. The administration of PGE_1 was shown to have improved erections more frequently relative to no treatment, placebo, papaverine, moxisylate, linsidomine, sodium nitroprusside, or the combination of linsidomine and urapidil. The rates of improvement in erection for patients receiving PGE_1, sexual therapy, or the combination of papaverine plus phentolamine were found to be similar. Patients who received PGE_1 alone experienced rates of improved erection similar to those among patients who received papaverine combined with phentolamine, while improved erection was less frequent after treatment with PGE_1 plus papaverine. Limited detailed evidence suggests that trimix was at least as effective as PGE_1

alone. Compared with trimix alone, the combination of trimix and sodium bicarbonate improved erections, while trimix combined with atropine did not produce such benefit. The interpretation of results from trials using trimix is complicated, because concentrations of the three constituents varied from study to study.[392]

Harms. Penile pain occurred more frequently in patients treated with PGE_1 than among those treated with placebo, moxisylate, or the combination of papaverine and phentolamine. The pain associated with the treatment was significantly less frequent when the PGE_1 was injected slowly, or in combination with either lidocaine or procaine, but not when injected in combination with sodium bicarbonate. The combination of papaverine and phentolamine was less frequently associated with pain in comparison with either PGE_1 alone or PGE_1 plus papaverine. The treatment with trimix was associated with priapism more frequently relative to treatment with PGE_1. The variation in rates of priapism may additionally depend on proper testing of the agent in the office setting, dose adjustment process for use at home, teaching sessions during which the patient administers his own injection under supervision, patient compliance, instruction handouts, and/or missed injections.

Subcutaneous Injections

Melanotan II, PT-141 (cyclic heptapeptide melanocortin analog), Apomorphine

Efficacy. The trial results indicated greater improvements on RigiScan in patients who received either melanotan II[295] or PT–141[298] compared with those who received placebo.

Harms. Although adverse events were generally mild, subcutaneous treatments were associated with an increased risk of nausea and headache in comparison with placebo.

Intraurethral Suppositories

Alprostadil

Efficacy. The use of IU alprostadil was shown to be associated with a higher sexual intercourse success rate compared with placebo.

Harms. Patients receiving IU alprostadil had an increased risk of local pain compared with those who received placebo. The followup period of the trials did not exceed 3 months, so the relative benefits and harms of long-term treatment with IU suppositories remain unclear.

Topical Treatments

Alprostadil, Nitroglycerine, Aminophylline, Isosorbide Dinitrate, and Co-dergocrine

Efficacy. Although the use of topical alprostadil was associated with improvements in erection and a higher sexual intercourse success rate relative to placebo, the magnitude of this improvement might be small (about 10 percent) and limited to men with mild to moderate ED. Patients who used nitroglycerine plaster before planned intercourse did not have improved erections in comparison with those who used placebo. Nitroglycerine

ointment produced only a small improvement in erections. Fewer patients who used nitroglycerine ointment or placebo improved compared with those who took minoxidil. Results for topical aminophylline plus isosorbide dinitrate and co-dergocrine were contradictory, improved erections being found in only one of two trials.

Harms. Adverse events, including local pain, was statistically significantly more frequently in patients treated with topical alprostadil compared with those treated with placebo. Patients who used nitroglycerine plaster before planned intercourse experienced a higher frequency of pain and headaches than those who used placebo. The use of nitroglycerine ointment was associated with increased pain and hypotension.

Hormonal Treatments

Testosterone

Efficacy. The effectiveness of testosterone regarding to improve erectile function and sexual intercourse satisfaction was inconsistent compared with placebo. Differences in patient inclusion criteria (e.g. not all trials were comprised of exclusively of ED patients), methods of evaluation, interventions (e.g. mono versus combination treatment, cream, patch, gel, injections), outcome definitions, and use of subjective measures (e.g. IIEF, SEP), could explain some of the discrepancies in results across the studies evaluating the efficacy of testosterone. The intramuscular administration of testosterone was shown to have improved erectile function compared with placebo in only one of four small trials. The "patch" testosterone did not improve sexual function compared with placebo. However, in men with poor response to previous use of sildenafil, testosterone patch plus sildenafil significantly improved the sexual intercourse success rate and satisfaction compared with placebo and sildenafil alone. Gel testosterone (50 mg and 100 mg doses) was found to have increased sexual intercourse frequency compared with placebo. The 100 mg dose of gel testosterone also significantly improved sexual intercourse frequency versus patch testosterone. The use of combination cream of testosterone, isosorbide dinitrate, and co-dergocrine was associated with an increased rate of successful sexual intercourse and improved erections compared with placebo or cream testosterone alone. The application of dihydrotestosterone gel was related to an increased rate of successful sexual intercourse compared with that of placebo.

Although there is insufficient head-to-head data, the gel formulation of testosterone may be a more effective treatment compared with other formulations of testosterone.

Harms. Patients receiving testosterone patch had a higher rate of having application site skin reactions than those with placebo. The use of gel testosterone did not show a dose-related increase in adverse events. The use of combination cream containing testosterone, isosorbide dinitrate, and co-dergocrine was associated with an increased risk of mild headaches compared with placebo or cream testosterone alone. The short-term followup precluded ascertainment of the incidence of prostate cancer. In one trial,[317] two patients who had been treated with patch testosterone, developed prostate cancer.

Other Treatments (Off-label use)

For summary of trials refer to Evidence Table F-10 (Appendix F).

Phentolamine

Efficacy. The results indicated either numerical or statistically significant improvements in erectile function (i.e., percent of successful intercourse attempts, base/tip rigidity >60 percent for ≥ 10 minutes) were associated with the use of phentolamine relative to placebo. There was no between-group difference for tumescence activity units.[333] With insufficient data, statistical test results, and a small number of studies, the trial results are inconclusive regarding the efficacy of phentolamine relative to placebo.

Harms. Due to the lack of sufficient amount of harms data it is not clear if patients taking oral phentolamine are at higher risk of developing adverse events.

Trazodone

Efficacy. Evidence regarding efficacy of trazodone relative to placebo to treat ED was insufficient (i.e., only 5 smaller-scale trials) and inconsistent. In general, the use of trazodone was not associated with improved erectile function compared with placebo.[336,337,339,341] Note that in one trial,[344] patients on trazodone experienced statistically significant improvement in erectile response (i.e., at least 3 successful intercourses within 30 days of treatment) compared with those on placebo, ketanserin, or mianserin. Since this trial was not double blind, it is hard to judge if the observed differences were truly due to the treatment administered or to other extraneous factors. The current American Urological Association Practice Guidelines Committee (AUA PGC) does not recommend the use of trazodone in the treatment of ED.[14]

Harms. Limited evidence suggests that the use of trazodone may be associated with an increased risk of adverse events (priapism, sedation, headache) and higher rates of withdrawal due to adverse events compared with placebo.

Cabergoline

Efficacy. The limited amount of evidence suggests that the use of cabergoline was associated with numerically or statistically significantly improved mean scores of IIEF "EF" domain and IIEF–Q3/Q4 compared with placebo. Additional evidence from trials using different doses is needed to corroborate or disprove these findings.

Harms. In general, treatment with cabergoline was well tolerated. Nevertheless, there were higher frequencies of adverse events and withdrawals due to adverse events in the active treatment groups than in the placebo groups.

Pentoxifylline

Efficacy. The results of the trials were inconsistent, one[340] indicated statistically significant improvements in peak systolic velocity; and the other trial[343] yielded no difference in the frequency of morning erections, nocturnal penile tumescence, or penile rigidity in patients receiving pentoxifylline compared with those on placebo. Another trial[345] demonstrated an increased number of successful coital episodes for the active treatment group of patients. However no formal statistical test results were presented to substantiate the findings. Given the above-mentioned limitations, more evidence is needed to draw more definitive conclusions regarding the relative efficacy of pentoxifylline.

Harms. No harms data were reported for two trials.[343,345] Some of the reported treatment-related adverse events in one trial[340] were nausea and headache. The harms profile of pentoxifylline in treating ED remains unclear.

Miscellaneous Agents

Efficacy. Overall, the limited amount of evidence suggested that naltrexone, tianeptine, tetrahydrobiopterin, and dehydroepiandrosterone may be more efficacious than placebo in improving early morning erections, proportion of patients with successful intercourse attempts, duration of rigidity (>60 percent), and mean total IIEF domain-specific scores, respectively.[342,348,352,353] The evidence regarding the efficacy of moclobemide, isoxsuprine, angiotensin-converting enzyme (ACE), and myoinositol/folic acid was less conclusive.[334,335,346,351] The degree of erectile response was not statistically significantly different for isoxsuprine or ACE relative to placebo.[335,346] Although moxonidine was shown to be more effective in increasing deep penile diameter and artery velocities compared with metoprolol, this result may have been biased because this trial did not employ double blind techniques to adequately mask the treatment modality.[347] More trials using a double-blind design are needed to corroborate these findings.

Harms. The limited amount of evidence suggested that the number of patients with adverse events was greater in the treatment groups than in the placebo groups. No definitive conclusions can be made at this time.

Question 2a-b: Do Specific Patient Characteristics (e.g. Origin, Severity, or Duration of ED, and Comorbid Conditions) Affect Prognosis or Treatment Success for ED Patients?

Origin of ED

There was a consistent clinical benefit (i.e., IIEF "EF" domain and GAQ–Q1) in patients receiving sildenafil, tadalafil, or vardenafil compared with placebo regardless of their origin of ED (i.e., organic, psychogenic, and mixed). This suggests that quite a broad etiologic spectrum of ED patients could potentially benefit from using these agents to improve the clinical symptoms of ED. This review of evidence did not reveal the presence of any obvious treatment effect modification by the origin of ED. However, these results were obtained from only a few trials, so the evidence warrants a cautious interpretation. Additional trials conducted in these subgroups using uniformly defined clinical outcomes would help to draw more definitive conclusions.

Baseline Severity of ED

The use of PDE–5 appeared to elicit a better improvement in erectile function (i.e., higher endpoint scores on IIEF "EF domain," IIEF–Q3/Q4, GAQ–Q1) for patients with mild or moderate baseline severity of ED (IIEF score: 11–25) than for those with severe forms of ED (IIEF score $\leq$ 10).

Duration of ED

There is a paucity of evidence on the relative efficacy of PDE–5 inhibitors according to the duration of ED. Only a few trials (i.e., sildenafil versus placebo) reported the efficacy analysis stratified according to the duration of ED with consistent clinical benefits for all patients irrespective of the duration of ED. Furthermore, the two trials in diabetic men with ED[94,101] did not reveal any trends in efficacy (IIEF–Q3/Q4 and GAQ–Q1) across the ED duration strata. The evidence is still inconclusive whether or not the duration of ED is an important prognostic factor for the degree of treatment success (e.g. endpoint IIEF "EF" domain scores, proportion of patients with IIEF >25 at followup).

Distinct Clinical Subgroups

Evidence on incremental therapeutic benefits associated with the use of PDE–5 inhibitors was consistent across a broad spectrum of patients with ED. The obvious clinical benefit of PDE–5 inhibitors relative to placebo in treating ED was observed not only in the trials that included a broad spectrum of patient population with ED but also in the trials restricted to specific clinically defined homogenous groups of patients with ED (e.g. diabetes, depression, prostate cancer, spina bifida, stable CAD, Parkinson's disease, CHF, LUTS, MS, renal transplants, arterial hypertension, prostatectomy, and no prior treatment for ED). The results of meta-analyses conducted for this review also showed that the use of sildenafil in patients with diabetes, depression, or hypertension led to improvements with respect to IIEF–Q3/Q4, GAQ–Q1, and percentage of successful intercourse attempts.

Questions 3a: Specific Harms of Pharmaceutical Treatments in Male Patients With ED

Non-arteritic Anterior Ischemic Optic Neuropathy (NAION) in Men Treated With PDE–5 Inhibitors

This review aimed to search and identify studies reporting the occurrence of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) in men treated with sildenafil. Reports included case reports and case series but the absence of denominators precluded the calculation of rates of NAION for sildenafil-exposed versus nonexposed populations. The incidence rates and their ratios (i.e., RRs and 95 percent CIs) for NAION calculated and reported in one cohort study provided inconclusive evidence. Most cases of NAION reported in the reviewed case reports and case series had been treated with 50 mg or higher doses of sildenafil. Moreover, the occurrence of overdose (200 mg) was reported for two NAION cases. The observed trend may suggest potential for an increased risk of NAION in men receiving high doses of sildenafil. Overall, given the insufficient amount and low methodological quality of the identified evidence, it is not clear whether or not men receiving long-term treatment with sildenafil are at increased risk of developing NAION relative to those not receiving this treatment.

Fibrosis in Men Treated With Injection Treatments

Penile fibrosis, scarring, and indurated nodularity have been reported to be associated with long-term use of ICI with papaverine. There is less data regarding the effect of PGE_1 on the incidence of penile fibrosis. Penile fibrosis and scarring can lead to abnormal penile curvature with erections and subsequent discontinuation of therapy.[372] Since RCTs are of insufficient duration to adequately assess the risk of penile fibrosis, this review evaluated the evidence from 20 retrospective observational studies and clinical trials that reported the incidence of penile fibrosis. The incidence of fibrosis varied widely and was not consistent across studies of treatments with papaverine, triple therapy (Trimix) and PGE_1. The design of the identified studies and many confounding factors precluded a comparison of the rates of fibrosis between patients receiving injections of PGE_1 versus papaverine alone or in combination. The rates of fibrosis may depend on the type and dose of medication, frequency of injections, at home versus office injections, and presence of priapism.[393,394] Evidence regarding the relative incidence of penile fibrosis amongst patients treated with different types of injection therapies is inconclusive. The conduct of well-designed trials is needed to determine the incidence, severity, and health impact of penile fibrosis in long-term ICI users. Moreover, it is important to determine whether there is a medication-, dose- or frequency-response effect of injections. Further evidence is required on whether different injection strategies (e.g. alternating sites) would help to further reduce risk of fibrosis. Penile fibrosis is a complication of ICI and all ED patients receiving this treatment need to be warned of the risk of fibrosis and be examined periodically for fibrotic changes in the penis.

Methodological and Logistic Limitations of the Systematic Review

This review had methodological and logistic limitations. Some of the important limitations are listed here.

In many cases, the methodological and/or reporting quality of the primary studies was poor, as judged by the Jadad scale and the Schulz allocation concealment component. For example, the adequacy of methods used for randomization, treatment allocation concealment, or blinding could not be ascertained for majority of the reviewed studies. In turn, the absence of this information compromised the valid interpretation of the study results.

There was substantial heterogeneity with respect to efficacy/harms outcomes, types of interventions, diverse concurrent clinical conditions, and reporting quality across the reviewed studies. Clinical and/or methodological heterogeneity limited the extent of statistical pooling of the efficacy- and harms-related data.

In crossover trials, pre-crossover quantitative data was usually not reported making it difficult to incorporate the results into the meta-analyses.

Primary studies did not always provide sufficient quantitative information (e.g. standard deviations, mean endpoint estimates of treatment efficacy, statistical test results) needed to pool the individual trial results and to judge the treatment-related between-group differences in the outcomes. Due to limited resources and the timelines of this review, the authors of individual studies could not be contacted for additional information that was not provided in the reports.

Empirical evidence has shown that harms occurring during a trial are generally underreported. Overall, the occurrence and details of adverse events was poorly reported in the primary studies. Many trial reports did not provide the data on the incidence of any all-cause adverse events and serious adverse events. Moreover, the types of adverse events across the trials, as well as the definition of adverse events and in particular serious adverse events were not reported consistently from study to study. The authors often did not provide statistical test results for the between-group differences in adverse events. Thus, the reviewers resorted solely to qualitative judgment.

This review did not investigate the effectiveness and harms of interventions such as natural health products, vacuum constriction devices, penile prosthesis implants, surgery, or lifestyle modifications. This review also did not include trials in ED patients with spinal cord injury.

The interpretation of the study results was complicated by the lack of well accepted guideline(s) regarding the magnitude of clinically important (or meaningful) difference for a given validated outcome. It is well recognized that the interpretation based solely on the statistical test results may be misleading. The clinically important difference for a valid and relevant outcome may or may not be statistically significant and the opposite also holds true. In many cases, study authors did not report whether the study power to detect a pre-specified minimally relevant clinical difference was estimated.

The evidence needed to evaluate the utility of routine endocrinological testing administered to the ED population is sparse and inconclusive.

Future Research Recommendations

Efforts are needed to improve the quality of reporting primary studies (i.e., randomized trials). The CONSORT Statement could be considered as a reporting guide for authors reporting trials and journals that publish ED-related research.[395]

Future studies should focus on both short- and long-term (6 months or longer) clinically relevant valid treatment outcomes. Such studies could clarify important unanswered questions involving both realms of efficacy and harms as well as evaluate relative sustainability of the clinical benefit conferred by different treatment modalities. Additional research should evaluate patient preferences, satisfaction, and compliance with different treatments, including PDE-5 inhibitors. Well designed longer-term RCTs evaluating the effects of PDE–5 inhibitors or other therapies will allow better documentation of the incidence of specific adverse events (e.g. mortality, cardiovascular events, visual disturbances, NAION, penile fibrosis). In light of the presence of comorbidities or causes underlying ED, the comparison of cause-specific therapies (administered alone or in combination) with the first-line treatment(s) in terms of efficacy and safety profiles is warranted. The trials should be more population-based to maximize the degree of external validity of their results.

More trials in clinically homogenous subgroups of ED patients presenting with concomitant conditions (e.g. diabetes, cardiovascular disease, prostate cancer, high blood pressure) are needed to better explore and characterize potential treatment effect modification. Additional investigations of treatment effects in patient subgroups defined by severity, duration, and etiology of ED are also warranted as are therapeutic trials in different ethnic groups of patients with ED.

More efforts are needed to elucidate the minimum clinically important difference (MCID) for the validated and clinically relevant outcomes (e.g. mean scores on IIEF, SEP, proportion of patients with improved erection) for various situations (e.g. patient subgroups, instruments used to measure change in the outcome, self-, partner- or investigator-reported).

Further research is warranted to determine the utility of routine endocrinological blood tests (e.g. serum testosterone, prolactin levels). This would involve studies with large and representative samples of ED patients to estimate precisely the age-stratified prevalence rates for endocrinological abnormalities (e.g. hypogonadism, hyperprolactinemia) and to determine subgroups (or risk factors) of patients with ED who have increased risk of hypogonadism. Ultimately, routine endocrinological blood tests (e.g. total, free, bioavailable) need to be standardized.[396]

Ideally, studies of testosterone used for the treatment of ED should enroll men with testosterone deficiency. If men with higher testosterone levels are to be included in these trials, stratified analyses should be conducted based on baseline testosterone levels. More data from large trials regarding the safety of long-term use of testosterone therapy is needed for more definitive conclusions.

Future trials of intracavernosal injection treatments should focus on clinically relevant efficacy and harm-related outcomes such as the degree of ED/treatment satisfaction (e.g. scores for International Index of Erectile Function, Erectile Dysfunction Index of Treatment Satisfaction), sexual intercourse success rate (Sexual Encounter Profile scores), penile pain, fibrosis, and priapism. The analyses should include all randomized participants in order to reduce the potential for selection bias (i.e. intention-to-treat analysis).

Tables and Figures.

Summary Tables

Table 1: Population Characteristics of Studies Measuring Hypogonadism in Men with Erectile Dysfunction

Study details[1]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum Levels	Test time	Cut-off (T)	Normal range (T)	Assay
Jaffe 1996	Prospective	Clinic	NR	55.3		hypertension	TT, BT, PRL, LH, FSH	morning	TT: <3ng/mL BT: <1 ng/ml	NR	RIA
Citron 1996	Prospective	Endocrinology	NR	61.2 ±8.9	27–79	Secondary hypogonadism	TT, FT, BT, LH	NR	<2.3 ng/ml	2.3–9.9 ng/ml	RIA
Hatzichristou 2002	Prospective	Andrology outpatient clinic	NR	56 ± 14		DM, cardiovascular disease, urinary tract pathology, neurological disease, endocrine pathology	TT, PRL	NR	NR	NR	NR
Martinez-Jabaloyas 2006	Prospective	Urology clinic	IIEF–EF	55 ± 10		DM, dyslipidemia, hypertension, ischemic cardiopathy	TT, FT, LH, FSH, PRL	morning 8–10 a.m	TT: <2.8 ng/ml FT: <0.228 ng/ml	2.8–8 ng/mL	NR
Acar 2004	Prospective	NR	IIEF–5	47±10.1		chronic disease	TT, PRL, FSH, LH	morning after 8 hours fasting	<3ng/ml (2x)	NS	ECLA

[1]Baseline serum levels: TT = total testosterone; FT = free testosterone; BT: bioavailable testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = folicule-stimulant hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (cmi); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA)
* calculated free testosterone
Scales: Sex Health Inventory for Men (SHIM); Sexual Functioning Questionnaire (SFQ); International Index of Erectile Function (IIEF–5) and Aging Males Symptoms (AMS)

Study details[1]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum Levels	Test time	Cut-off (T)	Normal range (T)	Assay
Earle 2003	Prospective	Department of Endocrinology and Diabetes	NR	54.9	16–82	NR	TT, PRL LH and FSH if low TT	1st test NR 2nd test if TT low in first test, taken in the morning	NR	11–37 nmol/L	RIA
Rhoden 2002	Prospective	Department of urology, andrology devision	IIEF–5	60	40–60	NR	TT	morning 08:00–10:00	<2.4 ng/mL	2.4–8.3 ng/mL	RIA
Bunch 2002	Retrospective	Outpatients	NR	64.6 ± 10.8	51–85	DM, IHD, hypertension, hyperlipidemia, depression, sleep apnea, CVA, AF, hypothyroidism, prostate cancer, CRF, head tumors, compression fractures	TT, LH	NR	<3 ng/ml	<60: 3–8.9; >60: 2–7.2 ng/ml	RIA
Fahmy 1999	Prospective	ED clinic	sexual activity questionnaire	NR		NR	TT, FSH, PRL	morning (9–11 am)	10 nmol/L	NR	NR
Buvat 1997	Retrospective	NR	NR	NR		NR	TT, PRL	morning post 20 min rest	3 ng/ml (low 2–3; lowest <2)	NR	RIA
Akpunonu 1994	Prospective	Primary care clinics	NR	55.4±10	24–76	Renal Failure, DM	TT, PRL, LH, FSH	ns	<10 nmol/L	10–34.7 nol/L	NR
Drinka 1993	Prospective	Outpatient department	NR	71.7 ± 6		NR	FT	morning (fasting)	<9 pg/mL	9–25 pg/ml	RIA

Study details[1]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum Levels	Test time	Cut-off (T)	Normal range (T)	Assay
Johnson 1992	Prospective	Urology clinic	NR	NR		NR	TT, PRL, LH	NR	<3 ng/dl	2.2–7.7 ng/dl	RIA
El-Sakka 2005	Prospective	Endocrinology clinic	IIEF	Endocrinopathy (297) -51.9 ± 12.2 No endocrinopathy (951) -52.3 ± 11.7		Obesity, diabetes, hypertension, ischemic heart disease, dyslipidemia, Cerebrovasular stroke	TT, PRL, LH, FSH	morning	<2.8 ng/mL (3x)	2.8–8.8 ng/mL	ECLA
Tsujimura 2005	Prospective	Sexual function clinic	AMS, IIEF–5	56 (median)	50–79	NR	TT, LH, FSH, PRL	Morning 09:00–11:00	<3.7 ng/mL (11nmol/L)	2.7–10.7 ng/ml	RIA
Guay 1991	Prospective	Endocrinology clinic	–	NR		NR	TT, LH, FSH	morning	NR	TT >3 ng/mL FT 50–200 pg/mL	RIA
Forsberg 1990	Prospective	Department of urology and clinic for sexual therapy	NR	47 (median)		Vascular disease, DM	TT. LH, FSH, PRL	same time of day	Low <10 nmol/L Borderline 10–15 nmol/L	NR	NR
Reyes-Vallejo 2006	Prospective	NR	NR	55.2	30–79	Hypercholester-olemia, DM, hypertension, CAD, depression	TT, FT, FSH, LH, PRL	NR	<3 ng/mL	NR	ECLA
El-Sakka 2006	Prospective	Andrology clinic	IIEF	53.9 ± 8.5	26–86	overweight, DM, hypertension, IHD, dyslipidemia,	TT, PRL	morning	<2.8 ng/mL (3x)	2.8–8.8 ng/mL	ECLA

Study details[1]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum Levels	Test time	Cut-off (T)	Normal range (T)	Assay
						psych. Dis.					
Hwang 2007	Prospective	Community	IIEF–5	NR		smoking	cFT, TT, BT, FSH, LH, PRL	9–12 in the morning	≤11nmol/l	>11nmol/l	NR
Low 2006	Prospective	Community	IIEF–5	59.3 ± 7.38		depression	cFT, TT, BT, PRL, LH	before 11 AM	TT: ≤11nmol/l FT: <0.02 nmol/dl BT: <0.2 nmol/dl	NR	direct CMI
Guay 2007	Retrospective	clinic	SHIM	NR		DM, metabolic syn., IHD, hyperlipidemia, neurological dys., pelvic surgery	FT	NS	<10 pg/mL	NS	RIA
Zohdy 2007	Retrospective	NR	IIEF–5	40.3 ± 8.9	20–56	NR	TT	morning	<2.8 ng/ml	2.8–8 ng/mL	ECLA

Table 2: Prevalence of Hypogonadism in Men with Erectile Dysfunction (serum total testosterone)

Study Details[2]	Study Design	Setting	T Mean (SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hypogonadism n	Hypogonadism N	Hypogonadism %	Test time	Cut-off (TT)	Normal Range	Assay
Studies performed in North America													
Akpunonu 1994 (USA)	Prospective	Primary care clinics	14±5.1 nmol/L	6.3 ± 6.5 mcg/L	10.6±5.8 IU/L	14.7±8.6 IU/L	51	212	*24.1*	NR	<10 nmol/L	10–34.7	-
Johnson 1992 (USA)	Prospective	Urology clinic	NR	NR	NR	NR	7	330	*2.12*	NR	<3 ng/ml	2.2–7.7 ng/ml	RIA
Citron 1996 (USA)	Prospective*	Endocri-nology	173 ± 44 ng/dl	NR	5.3±2.8mIU/ml	NR	11‡	167	*6.59*	NR	<2.3 ng/dl	2.3–9.9	RIA
Bunch 2002 (USA)	Retrospective*	Out-patients	177.73 ± 78.36 ng/dL	NR	6.8±9.1 mIU/ml	NR	29‡	201	*14.42*	NR	<3 ng/dl	3–8.9	RIA
Study performed in South America													
Rhoden 2002 (Brazil)	Prospective	Departme nt of urology, andrology devision	530 ± 201 ng/ml	NR	NR	NR	27	520	*5.19*	morning	<2.4 ng/dl	2.4–8.3 ng/dl	RIA
Studies performed in Europe													
Buvat 1997 (France)	Retrospective	Urology clinic	NR	NR	NR	NR	68	1022	*6.65*	morning	<3 ng/ml	–	RIA

[2]Baseline serum levels: T = total testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (CMI); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA)
* All patients in those studies were diagnosed with ED and hypogonadism at baseline; ‡secondary hypogonadism caused by hypothalamic-pituitary structural abnormalities;
¥approximately 2/3 of men on this study were using testosterone gel

Study Details[2]	Study Design	Setting	T Mean (SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hypogonadism n	Hypogonadism N	Hypogonadism %	Test time	Cut-off (TT)	Normal Range	Assay
Hatzichristou 2002 (Greece)	Prospective	Andrology clinic	NR	NR	NR	NR	22	1276	*1.72*	NR	–	–	-
Martinez-Jabaloyas 2006 (Spain)	Prospective	Urology clinic	19.6± 7.1	NR	NR	NR	8	165	*4.85*	08:00 – 10:00 in the morning	<2.8 ng/ml	2.8–8 ng/mL	CMI
Forsberg 1990 (Sweden)	Prospective	Depart-ment of urology and clinic for sexual therapy	NR	NR	NR	NR	13	100	*13.0*	NR	<10 nmol/L	–	-
Fahmy 1999 (UK)	Prospective	ED clinic	NR	NR	NR	NR	19	90	*21.1*	morning	<10 nmol/L	–	-
Acar 2004 (Turkey)	Prospective	NR	4.9±1.7	10.6 ± 6.4	5±3.9	6.9±7.7	29	262	*11.1*	morning	<3 ng/ml	–	ECLA
Studies performed in Asia and Australia													
Earle 2003 (Australia)	Prospective	Depart-ment of endocrinol ogy and diabetes	7.8 (1–10) [101 men with low TT]	48–7800 µg/L [7 men with hith PRL	20 (10–56) U/L [18 men with high LH]	NR	83	1455	*5.70*	1st test NR 2nd test if TT low in first test, taken in the morning	<11 nmol/l	12–37 nmol/l	RIA
Tsujimura 2005 (Japan)	Prospective	Sexual function clinic	Low TT (43): 2.2± 0.5 Normal TT (47): 4.5 ±	13.7 ± 15.4 ng/mL	10.7±9.5 ng/ml	4.0±2.4 ng/ml	43	90	*47.7*	morning	<3.17 ng/ml	2.7–10.7	RIA

Study Details[2]	Study Design	Setting	T Mean (SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hypogonadism			Test time	Cut-off (TT)	Normal Range	Assay
							n	N	%				
			1.1										
Low 2006 (Malaysia)	Prospective	Primary care	17.4±6.5	NR	NR	NR	49	242	*20.2*	NR	<11 nmol/l	–	CMI
Studies performed in the Middle East													
El-Sakka 2005 (Egypt)	Prospective	Andrology clinic	1.8±0.9 ng/mL	34 ± 13.9 ng/mL	NR	NR	187	1248	*15.0*	morning	<2.8 ng/ml	2.8–8.8	ECLA
El-Sakka 2006 (Egypt)	Prospective	Andrology clinic	Baseline: 5.1±1.3 Final visit: 3.5 ±1.3	NS	NR	NR	16	305	*5.25*	morning	<2.8 ng/ml	2.8–8.8	ECLA
Low 2006 (Malaysia)	Prospective	Primary care	17.37±6.49 nmol/L	NR	NR	NR	49	242	20.2	before 11 AM	≤11nmol/l	NR	direct chemiluminescent
Zohdy 2007 (Saudi-Arabia)	Retrospective	NR	3.9±1.7 ng/ml	NR	NR	NR	54	158	*34.2*	morning	<2.8 ng/ml	2.8–8.0	ECLA

Table 3: Prevalence of Hypogonadism in Men with Erectile Dysfunction (serum free or calculated testosterone)

Study Details[3]	Study Design	Setting	T Mean(SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hypogonadism			Test Time	Cut-off (FT)	Normal Range	Assay
							n	N	%				
Drinka 1993 (USA)	Prospective	Outpatient department	NR	NR	NR	NR	6	48	12.50	morning (fasting)	<9 pg/mL*	9–25 pg/ml	RIA (analog)
Guay 2007 (USA)	Prospective	Primary care	With IR – 13 pg/mL No IR – 15.5 pg/mL	NR	NR	NR	39	154	25.32	NR	<10 pg/mL*	–	RIA (analog)
Low 2006 (Malaysia)	Prospective	Community	0.035 ± 0.012 nmol/L	NR	NR	NR	38	242	15.70	morning (fasting)	<0.0225 nmol/dl*	–	direct CMI
Martinez-Jabaloyas 2006 (Spain)	Prospective	Urology clinic	0.34± .1 nmol/L	NR	NR	NR	29	165	17.58	morning 8–10 a.m	0.228 ng/ml*	–	CMI

[3]Baseline serum levels: T = total testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (cmi); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA)
* calculated free testosterone

Table 4: Prevalence of Hypogonadism in Men with Erectile Dysfunction (serum bioavailable testosterone)

Study Details[4]	Study Design	Setting	T Mean(SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hypogonadism n	Hypogonadism N	Hypogonadism %	Test time	Cut-off (FT)	Normal Range	Assay
Low 2006 (Malaysia)	Prospective	Community	0.84 ± 0.28 nmol/L	NR	NR	NR	1	242	0.41	morning (fasting)	<0.2 nmol/dl	–	direct CMI

Table 5: **Population Characteristics of Studies Measuring Hyperprolactinemia in Men with Erectile Dysfunction**

Study Details[5]	Study Design	Setting	ED Scale	Age Mean (SD)	Age Range	Comorbidity	Serum levels	Test time	Cut-off (PRL)	Normal Range (PRL)	Assay
Jaffe 1996 (Israel)	Prospective	Outpatient clinic	NR	55.3		hypertension	TT, BT, PRL, LH, FSH	at least 2hrs post awakening	>20 ng/ml	NR	EIA
Netto 1993 (Brazil)	Prospective	Outpatient clinic	NR	55	31–69	NR	PRL	morning	20 ng/ml	NR	RIA
Hatzichristou 2002	Prospective	Andrology outpatient	NR	56 ± 14		DM, cardiovascular	TT, PRL	NR	NR	NR	NR

[4]Baseline serum levels: T = total testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (cmi); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA)
* calculated free testosterone

[5]Baseline serum levels: T = total testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence; 2X: test was performed twice
Assay: chemiluminescent microparticle immunoassay (cmi); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA), enzyme immunoassay (EIA)
Scales: Sex Health Inventory for Men (SHIM); sexual functioning questionnaire (SFQ);
* calculated free testosterone, ‡if 1st test elevated, serial measurements in a rested state at 0, 30, 60, and 90 minutes

Study Details[5]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum levels	Test time	Cut-off (PRL)	Normal Range (PRL)	Assay
(Greece)		clinic				disease, urinary tract pathology, neurological disease, endocrine pathology					
Acar 2004 Turkey)	Prospective	NR	IIEF–5	47±10.1		chronic disease	TT, PRL, LH, FSH	morning after 8 hours fasting	>18ng/ml (2x)	NR	ECLA
Earle 2003 (Australia)	Prospective	Department of endocrin-ology and diabetes	NR	54.9	16–82	NR	TT, PRL LH and FSH if low TT	morning‡	≥25 mcg/L	<25 mcg/L	RIA
Buvat 1997 (France)	Prospective	Urology clinic	NR	NR		NR	TT, PRL	morning post 20 min rest	20 ng/ml (high 20–35; highest >35)	NR	RIA
Akpunonu 1994 (USA)	Prospective	Primary care clinic	NR	55.4±10	24–76	Renal failure, DM	TT, PRL, LH, FSH	NR	>20 mcg/l	0–20 mcg/l	NS
Johnson 1992 (USA)	Prospective	Urology clinic	NR	NR		NR	TT, PRL, LH	NR	≥18 ng/ml	NR	NR
El-Sakka 2005 (Egypt)	Prospective	Andrology clinic	IIEF	Endocrinopathy (297) – 51.9 ± 12.2 No endocrinopathy (951) – 52.3 ± 11.7		Obesity, diabetes, hypertension, ischemic heart disease, dyslipidemia, cerebrovasular stroke	TT, PRL, LH, FSH	morning	>20 ng/ml	4.1–20 ng/ml	ECLA

Study Details[5]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum levels	Test time	Cut-off (PRL)	Normal Range (PRL)	Assay
El-Sakka 2006 (Egypt)	Prospective	Andrology clinic	IIEF	53.9 ± 8.5	26–86	overweight, DM, hypertension, IHD, dyslipidemia, psych. Dis.	TT, PRL	NR	>20 ng/ml	4.1–20 ng/mL	ECLA
Low 2006 (Malaysia)	Prospective	Community	IIEF–5	59.3 ± 7.38		depression	cFT, TT, PRL, LH	before 11 AM	>18.8 mcg/l	NR	direct CMI

Table 6: Prevalence of Hyperprolactinemia in Men with Erectile Dysfunction (serum prolactin levels)

Study Details[6]	Study Design	Setting	T Mean(SD)	Prolactin Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hyperprolactinemia n	N	%	Test time	Cut-off (PRL)	Normal Range	Assay
Studies performed in North America													
Akpunonu 1994 (USA)	Prospective	Primary care clinics	14±5.1	6.3 ± 6.5 mcg/L	10.6±5.8 IU/L	14.7±8.6 IU/L	3	212	*1.42*	–	>20 mcg/l	O–20	NR
Johnson 1992 (USA)	Prospective	Urology clinic	NR	NR	NR	NR	1	7	*14.29*	–	≥18 ng/ml	NR	NR
Studies performed in Europe													
Buvat 1997 (France)	Prospective	Urology clinic	NR	NR	NR	NR	3	451	*0.67*	Morning	20 ng/ml (high 20–35;	NR	RIA

[6]Baseline serum levels: T = total testosterone; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (CMI); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA); automated enzyme immunoassay system (AEIA)
‡ if 1st test elevated, serial measurements in a rested state at 0, 30, 60, and 90 minutes

Study Details[6]	Study Design	Setting	T Mean(SD)	Prolactin Mean(SD)	LH Mean(SD)	FSH Mean(SD)	Hyperprolactinemia n	N	%	Test time	Cut-off (PRL)	Normal Range	Assay
											highest >35)		
Hatzichristou 2002 (Greece)	Prospective	Andrology clinic	NR	NR	NR	NR	8	1276	*0.63*	–	NR	NR	NR
Acar 2004 (Turkey)	Prospective	NR	4.9±1.7	10.6 ± 6.4	5±3.9	6.9±7.7	25	262	*9.54*	Morning	>18ng/ml (2x)	NR	ECLA
Other countries													
Earle 2003 (Australia)	Prospective	Department of endocrinology and diabetes	7.8 (1–10) [101 men with low TT]	48–7800 µg/L [7 men with hith PRL	20 (10–56) U/L [18 men with high LH]	NR	7	1455	*0.48*	Morning‡	NR	NR	RIA
Netto 1993 (Brazil)	Prospective	Primary care	NR	NR	NR	NR	23	600	*3.83*	Morning	20 ng/ml	NR	RIA
Low 2006 (Malaysia)	Prospective	Community	17.4±6.5	8.9±7.99 mcg/L	NR	NR	7	242	*2.89*	Before 11 AM	> 18.8 mcg/l	NR	direct CMI
El-Sakka 2005 (Egypt)	Prospective	Andrology clinic	1.8±0.9	34 ± 13.9 ng/mL	NR	NR	171	1248	*13.7*	NR	>20 ng/ml	4.1–20	ECLA
El-Sakka 2006 (Egypt)	Prospective	Andrology clinic	Baseline – 5.1±1.3 Final visit – 3.5 ±1.3	NS	NR	NR	97	305	*32*	NR	>20 ng/ml	4.1–20	ECLA

Table 7: Prevalence of Hyperprolactinemia in Men with and without Erectile Dysfunction (serum prolactin levels)

Study Details[7]	Study Design	Setting	Hyperprolactinemia n	N	%	Hyperprolactinemia n	N	%	Test time	Cut-off (PRL)	Normal Range	Assay
Acar 2004 (Turkey)	Prospective	NR	25	262	*9.54*	2	53	*3.77*	Morning	>18ng/ml (2x)	NR	ECLA
Low 2006 (Malaysia)	Prospective	Primary care	7	242	*2.89*	1	109	*12.5*	before 11 AM	>18.8 mcg/l	NR	direct CMI

Table 8: Population Characteristics of Studies Measuring Serum LH/FSH Levels in Men with Erectile Dysfunction

Study Details[8]	Study Design	Setting	ED Scale	Age Mean (SD)	Range	Comorbidity	Serum Levels	Test time	Cut-off (LH/FSH)	Normal Range (LH/FSH)	Assay
Jaffe 1996 (Israel)	Prospective	clinic	–	55.3		Hypertension	TT, BT, PRL, LH, FSH	Morning	LH: >15 mIU/mL[9]; FSH: NR	NR	EIA
Earle 2003 (Australia)	Prospective	Department of Endocrinology and Diabetes	NR	54.9	16–82	Prostate cancer, secondary hypogonadism	TT, PRL, LH, FSH	NR	>10U/L	LH: 2–9 U/L	RIA
Bunch 2002 (USA)	Retrospective	outpatients	NR	64.6 ± 10.8	51–85	DM, IHD, hypertension, hyperlipidemia, depression, sleep	TT, LH	NR	LH: <13nIU/ml	NR	RIA

[8]Baseline serum levels: T = total testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (CMI); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA), enzyme immunoassay (EIA)
* calculated free testosterone;[8] the cut for LH > 15mIU/ml was used to define primary hypogonadism
Scales: Sex Health Inventory for Men (SHIM); sexual functioning questionnaire (SFQ);

Study Details[8]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum Levels	Test time	Cut-off (LH/FSH)	Normal Range (LH/FSH)	Assay
						apnea, CVA, AF, hypothyroidism, prostate cancer, CRF, head tumors, compression fractures					
Fahmy 1999 (UK)	Prospective	ED clinic	sexual activity questionneire	NR	NR	NR	TT, FSH, PRL	morning (9–11 am)	NR	NR	NR
Akpunonu 1994 (USA)	Prospective	Primary care clinic	NR	55.4±10	24–76	Renal failure, DM	TT, PRL, LH, FSH	NR	NR	LH: 5–20 IU/L; FSH: 5–20 IU/L	NR
Johnson 1992 (USA)	Prospective	Urology clinic	NR	NR		NR	TT, PRL, LH	NR	NR	NR	NR
El-Sakka 2005 (Egypt)	Prospective	Andrology clinic	IIEF	Endocrinopathy (297) -51.9 ± 12.2 No endocrinopathy (951) -52.3 ± 11.7		Obesity, diabetes, hypertension, ischemic heart disease, dyslipidemia, cerebrovasular stroke	TT, PRL, LH, FSH	NR	LH <1.3 mIU/mL; FSH <0.9 mIU/mL	NR	ECLA
Guay 1991 (USA)	Prospective	Endocrinology clinic	–	53.2 ± 9.1		NR	TT, LH, FSH	Morning	NR	LH: 2–20 mIU/L; FSH: 2–10 mIU/L	RIA
Low 2006 (Malaysia)	Prospective	Community	IIEF–5	59.3 ± 7.38		Depression	cFT, TT, PRL, LH	Morning	>12 IU/l	NR	direct CMI

Study Details[8]	Study Design	Setting	ED Scale	Age Mean (SD) Range		Comorbidity	Serum Levels	Test time	Cut-off (LH/FSH)	Normal Range (LH/FSH)	Assay
								(before 11am)			

Table 9: Prevalence of Primary or Secondary Hypogonadism in Men with Erectile Dysfunction (total serum levels of LH and FSH)

Study details[10]	Study design	Setting	T Mean(SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean (SD)	LH/FSH n	N	%	Test time	Cut–off (TT)	Normal range	Assay
Secondary hypogonadism (Low levels of LH and/or FSH)													
Bunch 2002 (USA)	Retrospective *	Outpatients	177.73 ± 78.36 ng/dL	NR	6.8±9.1 mIU/ml	NR	↓LH: 29[‡]	66	*43.9*	NR	<13 mIU/ml	NR	RIA
El-Sakka 2005 (Egypt)	Prospective	Andrology clinic	1.8±0.9 ng/mL	34 ± 13.9 ng/mL	NR	NR	↓LH/ FSH: 21	1248	*1.68*	morning	NR	NR	ECLA
Primary hypogonadism (High levels of LH and/or FSH)													
Akpunonu 1994 (USA)	Prospective	Primary care clinics	14±5.1 nmol/L	6.3 ± 6.5 mcg/L	10.6±5.8 IU/L	14.7±8.6 IU/L	↑LH: 2	194	*1.03*	NR	NR	5–20 IU/L	-
							↑FSH: 0	194	*0*				

[10]Baseline serum levels: T = total testosterone; Pr = prolactin; LH = luteinizing hormone; FSH = follicle-stimulating hormone
SD = standard deviation; n = number of events; N = total number of participants; % = prevalence
Assay: chemiluminescent microparticle immunoassay (CMI); electrochemiluminescence immunoassay (ECLA), radioimunoassay (RIA)
* All patients in those studies were diagnosed with ED and hypogonadism at baseline; [‡]secondary hypogonadism caused by hypothalamic-pituitary structural abnormalities; [¥]approximately 2/3 of men on this study were using testosterone gel

Study details[10]	Study design	Setting	T Mean(SD)	PRL Mean(SD)	LH Mean(SD)	FSH Mean (SD)	LH/FSH n	N	%	Test time	Cut–off (TT)	Normal range	Assay
Johnson 1992 (USA)	Prospective	Urology clinic	NR	NR	NR	NR	↑LH: 5	330	*1.52*	NR	NR	NR	RIA
Earle 2003 (Australia)	Prospective	Department of Endocrinology and Diabetes	7.8 (1–10) [101 men With ↓TT]	48–7800 µg/L [7 men with ↑PRL]	20 (10–56) U/L [18 men with ↑LH]	NR	↑LH: 18	83 (all ↓TT)	*21.7*	morning	NR	2–9 U/L	RIA
Fahmy 1999 (UK)	Prospective	ED clinic	NR	NR	NR	NR	↓FSH: 1	90	*1.11*	morning	NR	NR	NR
Guay 1991 (USA)	Prospective	Endocrinology	NR	NR	NR	NR	*↓LH: 6*	*21*	*28.6*	NR	Gonadotropin reserve (≥20mIU/mL ↑ in LH, FSH)	NR	RIA
							↓FSH: 1	*21*	*4.76*				
Low 2006 (Malaysia)	Prospective	primary care	17.4±6.5	NR	NR	NR	*↓LH:* 14	242	*5.79*	NR	NR	NR	CMI

Table 10: Serious Adverse Events in Sidenafil vs. Placebo (data from RCTs)

Author year	ED Population Country/Ethnicity	Serious Adverse Events n/N (%)		Active dose	Description of Adverse Events (study arm)
		Sildenafil	Placebo		
Choi (2003)	All causes Asia-NR	0/66	2/67 (3%)	Flexible 25–100 mg	• NR (CG)
Levinson (2003)	All etiologies Men from Egypt and South African	3/128 (2.0%)	0/126	Flexible 25–100 mg	• Myocardial infarction (IG) • Accidental vertebral fracture (IG) • Diverticulitis (IG)
DeBusk (2004)	Stable coronary artery disease UK–NR	1/75 (1.4%)	2/76 (2.6%)	Flexible 25–100 mg	• Atypical chest pain (IG) • Acute UTI (CG) • Severe angina pectoris (CG)
Tan (2000)	All etiologies Men from Malaysia, Singapore and Philippines	1/127 (<1%)	1/127 (<1%)	Flexible 25–100 mg; IG pts on 100 mg	• Severe angina pectoris 4 hr post 100 mg sildenafil (pts with CAD) • Accidental hand injury (CG)
Meuluman (2001)	All causes Europe and US–NR	2/159 (1.3%)	0/156	Flexible 25–100 mg	• Death due to accident (IG) • Death due to cardiac arrest (IG)
Young (2002)	All causes North America, Hispanic	1/98	0/99	Flexible 25–100 mg	• NR (IG)
Eardley (2001)	All causes UK–NR	0/44	1/44 (2.3%)	Flexible dose 25–75 mg	• Myocardial infarction in a pt during 2nd 28 d phase (CG)
Price (1998)	Diabetes type I and II UK–NR	1/21 (4.7%)	0/21	25 mg	• Pneumococcal pneumonia (IG)
Christiansen (2000)	All etiologies Europe-NR	24/205 (11.7%), Group designation not reported		10 or 25 mg	• Death (open label phase, 10 mg) • Other events not described
Olsson (2000)	All etiologies Europe-NR	3/351 (<1%); Group designation not reported		Fixed 25, 50, 100 mg	• Myocardial infarction (NR) • Renal cell carcinoma (NR) • Epileptic crisis (NR)
Chen (2001)	All etiologies Taiwan-Asian	4/119 (3.0%)	4/117 (3.0%)	Flexible 25–100 mg	• No data provided
Fowler (2004)	Multiple sclerosis UK–NR	3/104 (2.7%)	3/113 (2.9%)	Flexible 25–100 mg	• NR (NR) • 12 (6%) of pts experienced SAE (relapse) during open label
Katz (2005)	Stable coronary heart failure Multi-Nation	2/63 (3.0%)	4/74 (5.0%)	Flexible 25–100 mg	• NR
Seibel (2002)	Renal failures Brazil-NR	0/24	2/24 (8.0%)	Fixed 50 mg	• Deaths (CG)
Becher (2002)	All etiologies South America, Chile-Hispanic	2/72 (2.8%)	1/71 (1.4%)	Flexible 25–100 mg	• Death due to myocardial infarction (CG) • Remaining SAEs not

Author year	ED Population Country/Ethnicity	Serious Adverse Events n/N (%)		Active dose	Description of Adverse Events (study arm)
		Sildenafil	Placebo		
					described
Cappelleri (2000)	All etiologies US–NR	3/124 (2.0%)	3/123 (2.0%)	Flexible 25–100 mg	• NR
Albuquerque (2005)	Hypertensive men Brazil	3/61 (5.0%)	1/59 (1.7%)	Flexible 25–100 mg	• Cerebrovascular accident (IG) • Pulmonary edema/heart failure (IG) • Atrial fibrillation/arrhythmia (IG) • polytrauma (CG)
Pickering (2004)	Men with history of atrial hypertension Italy-NR	2/281 (<1%)	2/287 (<1%)	Flexible 25–100 mg	• NR
Glina (2001)	All etiologies Mexico-Brazilian/Mexican	1/124 (<1%)	5/121 (4%)	Flexible 25–100 mg	• NR
McVary (2007)	Men with lower urinary tract syndromes associated with prostatic hyperplasia US: 82% White	2/189 (1.0%)	3/181 (2.0%)	Flexible 25–100 mg	• Worsening of knee arthralgia (100 mg/ IG) • Severe acute cerebrovascular stroke (100 mg/ IG) • Remaining 3 cases were not described
Althof (2006)	All causes Multi-nation: White 55.5%; Black 15%; Asian 5.5%; Other 23.5%	1/274 (<1%)	1/279 (<1%)	NR	• Severe coronary artery disease (IG) • Urinary tract infection (CG)
O'Leary (2006)	All causes (also with low self-esteem) US: 62% White; 25% Black	0/129	1/127 (<1%)	Flexible 25–100 mg	• Death (CG)

NR=not reported; CG=control group; IG=intervention group; pt(s)=patient(s)

Table 11: Efficacy Results of Tadalafil by ED Severity Groups

Study ID	Dose	Mild ED	Moderate ED	Severe ED
Mean change in IIEF–EF scores from baseline				
McMahon (2005)	20 mg	3.0	10.7	11.6
Eardley (2004)	20 mg	6.1	13.2	14.3
Sefte (2004)	20 mg	5.6	10.7	11.0
Carrier (2005)	10 mg	4.5	8.4	8.3
Carrier (2005)	20 mg	5.2	9.0	11.5
Costa, (2006)	On demand	6.2	11.5	14.2
Costa (2006)	3 x week	6.4	11.8	14.6
Saylan (2006)	20 mg	6.3	8.2	14.8
Yip (2006)	20 mg	5.3	9.1	12.5
EF mean end point scores				
McMahon (2005)	20 mg	24.4	23.9	19.0
Rajfer (2007)	2.5 mg	24.3	21.0	13.8
Rajfer (2007)	5 mg	26.2	21.9	15.5
Guo(2006)	10 mg	24.0	22.3	18.1
Guo(2006)	20 mg	23.5	23.0	21.6
Nagao (2006)	5 mg	25.6	22.7	15.8
Nagao (2006)	10 mg	26.0	24.0	20.2
Nagao (2006)	20 mg	25.3	23.0	21.9
Patients with normal EF at end point (%)				
Eardley (2004)	20 mg	80	73	55
Sefte (2004)	20 mg	72.1	52.4	34.3
Saylan (2006)	20 mg	84.4	43.2	40.7
Change from baseline in SEP–3 (% of patients with successful penetration)				
Young (2005)	10 mg*	13.1	46.0	29.2
Young (2005)	20 mg*	38.5	68.9	41.3
Costa, (2006)	On demand	41.7	59.7	55.8
Costa, (2006)	3 x week	44.4	61.3	57.1
Rajfer (2007)	2.5 mg	72.5	56.3	27.4
Rajfer (2007)	5 mg	82.2	61.3	32.6
Nagao (2006)	5 mg	74.2	50.3	31.1
Nagao (2006)	10 mg	80.4	64.5	49.4
Nagao (2006)	20 mg	76.8	67.8	62.1
Change from baseline in SEP–2 (% of patients with successful penetration)				
Rajfer (2007)	2.5 mg	90.0	74.8	38.9
Rajfer (2007)	5 mg	91.9	82.2	44.9
Nagao (2006)	5 mg	89.2	79.2	48.7
Nagao (2006)	10 mg	98.8	84.2	63.4
Nagao (2006)	20 mg	94.2	80.8	73.1

Table 12: Intracavernosal Injection: Sexual Intercourse Success

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Prostaglandins vs. Papaverine				
Earle 1990	Physiologic: 62% Idiopathic: 27% Unclear: 10%	31% (40/129) Over 4 weeks	33% (43/129) Over 4 weeks	0.93 [0.65–1.33]

Table 13: Intracavernosal Injection: Improvement in Erections*

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Prostaglandins (PgE_1) vs. Placebo				
Bechara 1997	NR	50 (30/60)	0 (0/60)	
Colli 1996	Psychogenic: 53% Physiologic: 31% Mixed: 11%	28.9 (39/135) All doses	0 (0/45)	–
Garceau 1996	Psychogenic: 27% Physiologic: 43.8% Mixed: 20.3% Other 8.2%	48.1 (26/54) All doses	NR	–
Linet 1996	Psychogenic: 13% Physiologic: 57% Mixed: 29%	A. Rigiscan 31.6 (75/237) By dose** 2.5 µg: 21% 5 µg: 31% 10 µg: 27% 20 µg: 45%	A. Rigiscan 0 (0/59)	–
		B. Clinical (Full rigidity) 35 (83/237) By dose** 2.5 µg: 17% 5 µg: 27% 10 µg: 45% 20 µg: 50%	B. Clinical (Full rigidity) 0 (0/59)	–
Range of treatment improvement (%)		28.9–66.0	0	NA
PgE_1 vs. Papaverine				

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Earle 1990	Physiologic: 62% Idiopathic: 27% Unclear: 10%	26.4 (34/129)	13.2 (17/129)	2.00 [1.18–3.39]
Kattan 1991	Physiologic: 100%	46 (23/50)	14 (7/50)	3.29 [1.55–6.95]
Kunelius 1998	NR	40 (12/30)	10 (3/30)	4.00 [1.25–12.75]
Mahmoud 1992	Psychogenic: 19% Physiologic: 66% Mixed: 15%	80.8 (42/52)	63.5 (33/52)	1.27 [1.00–1.63]
Range of treatment improvement (%)		26.4–80.8	10.0–63.5	NA
PgE_1 vs. PgE_1 + Papaverine				
Floth 1991	Psychogenic: 10.5% Physiologic: 92%	60.5 (23/38)	73.7 (28/38)	0.82 [0.60–1.13]
PgE_1 vs. Papaverine + Phentolamine				
Bechara 1997	NR	50 (30/60)	56.7 (34/60)	0.88 [0.63–1.23]
PgE_1 vs. Phentolamine+ PgE_1				
Aversa 1996a	Psychogenic: 100%	20.8 (5/24)	54.2 (13/24)	0.38 [0.16–0.91]
Aversa 1996b	Psychogenic:100%	30 (3/10)	60 (6/10)	0.50 [0.17–1.46]
Range of treatment improvement (%)		20.8–30.0	54.2–60.0	NA
PgE_1 vs. Trimix				
Bechara 1996	NR	21.9 (7/32)	50.0 (16/32)	0.44 [0.21–0.92]
Seyam 2005	Psychogenic: 8.9% Physiologic: 53.7% Mixed: 37.4%	67.8 (122/180)	66.7 (120/180)	0.98 [0.85–1.14]
Range of treatment improvement (%)		21.9– 67.8	50.0–66.7	NA
PgE_1 vs. Moxisylate				
Kunelius 1998	NR	40.0 (12/30)	6.7 (2/30)	6.00 [1.47–24.55]
Buvat 1998	Psychogenic: 46% Physiologic: 26%	85.3 (58/68) *At home*	60.7 (37/61) *At home*	1.41 [1.12–1.76]

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
	Mixed: 28%	81.3 (61/75) *Investigator assessment*	45.7 (37/81) *Investigator assessment*	1.78 [1.37–2.31]
PgE_1 vs. Nitroprusside (300 µg or 400 µg)				
Martinez-Piñeiro 1995	NR	20.0 (12/60)	15.0 (9/60) 300 µg	1.33 [0.61–2.93]
		20.0 (7/35)	14.3 (5/35) 400 µg	1.40 [0.49–3.99]
PgE_1 vs. Linsidomine				
Porst 1993	Psychogenic: 60% Physiologic: 40%	65.0 (26/40)	12.5 (5/40)	5.20 [2.22–12.18]
Wegner 1995	NR	40.0 (16/40)	7.5 (3/40)	5.33 [1.68–16.89]
Wegner 1994	NR	30.0 (6/20)	10.0 (4/40)	3.00 [0.95–9.43]
Range of treatment improvement (%)		30.0–65.0	7.5–12.5	NA
PgE_1 vs. Linsidomine + Urapidil				
Wegner 1995	NR	40.0 (16/40)	25.0 (10/40)	1.60 [0.83–3.09]
PgE_1 vs. PgE_1 + Lidocaine				
Kattan 1995	NR DM: 68% Low testosterone: 12%	27.3 (6/22)	63.6 (14/22)	0.43 [0.20–0.91]
PgE_1 vs. PgE_1 + Procaine				
Shramek 1994	Psychogenic: 12.5% Physiologic: 87.5%	66.7 (16/24)	66.7 (16/24)	1.00 [0.67–1.49]
Trimix vs. Trimix + Sodium Bicarbonate				
Moriel 1993	NR	68.4 (13/19)	78.9 (15/19)	0.87 [0.59–1.27]
Trimix vs. Trimix + Atropine				
Sogari 1997	NR Risk factors: DM, hypertension, alcoholism, smoking, Peyronie's disease)	45.6 (52/114)	45.6 (52/114)	–
Papaverine + Phentolamine vs. Placebo				

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Bechara 1997	NR	56.7 (34/60)	0 (0/60)	–
Papaverine + Phentolamine + Sexual counseling vs. Papaverine + Phentolamine				
Van der Windt 2002	Psychogenic: 35.7% Physiologic: 11.4% Mixed: 34.3%	84 (subjective erection score, range 0–100)	79 (subjective erection score, range 0–100)	–
PgE_1 + Papaverine vs. Papaverine + Phentolamine				
Floth 1991	Psychogenic: 12.3% Physiologic: 100% (Patients could have both)	77.6 (38/49)	57.1 (28/49)	1.36 [1.02–1.81]
Papaverine vs. Moxisylate				
Kunelius 1998	NR	10.0 (3/30)	7.0 (2/30)	1.50 [0.27–8.34]
Moxisylate vs. Placebo				
Costa 1993	Psychogenic: 32%	86.9 (53/61)	27.9 (17/61)	3.12 [2.06–4.72]
Vasoactive Intestinal Polypeptide + Phentolamine vs. Placebo				
Sandhu 1999	Physiologic: 47% Mixed: 53% (Dose assessment phase) Results: Phase 1-2 combined. Phase 1 criteria met by 133 patients and phase 2 criteria met by 126 patients (94.7%) ITT population: 172 of 195 of those who received at least one injection of active treatment and placebo	*Erections suitable for intercourse* 25 µg dose: 75.1% (1417/1886 injections) 2 mg dose: 66.5% (257/386 injections) <u>ITT analysis</u> 25 µg dose: 73.7% (1576/2137 injections) 2 mg dose: 69.1% (397/574 injections)	*Erections suitable for intercourse* 25 µg dose: 12.1% (45/373 injections) 2 mg dose: 10.3% (8/78 injections) <u>ITT analysis</u> 25 µg dose: 12.9% (55/426 injections) 2 mg dose: 13.7% (16/116 injections)	p <0.001 p <0.001 p <0.001 p <0.001
Timing of PgE1 and/or use in post-prostatectomy populations PgE_1 (early intervention) vs. PgE_1 (late intervention): post non–nerve-sparing radical prostatectomy				
Gontero 2003	All men had prostate cancer†	72.2 (26/36)	43.2 (16/37)	1.67 [1.10–2.54]

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
PgE_1 vs. No Treatment: post–nerve-sparing radical retropubic prostatectomy				
Montorsi 1997	All men had prostate cancer†	66.7 (8/12)	20 (3/15)	3.33 [1.12–9.90]
PgE_1 + Sexual Counseling vs. PgE_1: post–nerve-sparing radical retropubic prostatectomy or cystectomy				
Titta 2006	Men had either prostate and/or bladder cancer†	*Mean IIEF score* 26.6 (before surgery) 8.4 (before ICI) 23.4 (3 months after surgery) 26.5 (18 months after surgery) 75.8 (22/29) No ED at end of study	*Mean IIEF score* 26.1 (before surgery) 8.4 (before ICI) 21.7 (3 months after surgery) 24.3 (18 months after surgery) 50.0 (14/28) No ED at end of study	 – – p <0.05 1.52 [0.99–2.32]

* Defined as full erection or "positive response," Grade 4/5 erections, or erections sufficient for intercourse or Rigiscan assessment ≥70% rigidity base or tip lasting ≥10 minutes

** Numbers extracted from graph

† All men were potent or had normal International Index of Erectile Dysfunction (IIEF) scores at baseline

†† Percentage of sexual situations producing an erection

Table 14: Intracavernosal Injection: Patients with Adverse Events

Study	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Prostaglandins (PgE_1) vs. Placebo				
Bechara 1997	Pain	35.0 (21/60)	0	–
Linet 1996	Penile pain Priapism	22.7 (54/237) 2.5 (6/237)	NR NR	– –
Vanderschueren 1995	Penile pain	11.7 (74/630)	10.9 (23/210)	1.0 [-4.0, 6.0]
von Heyden 1993	Penile pain/burning sensation	13.3 (18/135)	NR	–
Range of reported pain/discomfort (%)		11.7–35.0	0–10.9	NA
Bechara 1997	Prolonged erection	15.0 (9/60)	0 (0/60)	–
von Heyden 1993	Hematoma	1.5 (2/135)	NR	–
Colli 1996	Treatment-related	2.2 (3/135)	2.2 (1/45)	–
von Heyden 1993	Treatment-related	16.3 (22/135)	NR	–
PgE_1 vs. Papaverine				
Earle 1990	Pain during injection	8.5 (11/129)	4.7 (6/129)	4.0 [-2.0, 10.0]
Kattan 1991	Pain during injection	46.0 (23/50)	44.0 (22/50)	2.0 [-17.0, 21.0]
Mahmoud 1992	Penile pain	11.5 (6/52)	32.7 (17/52)	-21.0 [-37.0, -6.0]
Range of reported pain/discomfort (%)		8.5–46.0	4.7–44.0	NA
Earle 1990	Prolonged erection	0	<1 (1/129)	–
Kattan 1991	Priapism	0	0	–
Kunelius 1998	Prolonged erection	10.0 (3/30)	6.7 (2/30)	3.0 [-11.0, 17.0]
Mahmoud 1992	Priapism	0	0	–
Range of prolonged erection/priapism (%)		0–10.0	0–6.7	NA
Kattan 1991	Dizziness/headache	2.0 (1/50)	4.0 (2/50)	-2.0 [-9.0, 5.0]
PgE_1 vs. Papaverine + PgE_1				
Floth 1991	Pain	34.2 (13/38)	18.4 (7/38)	16.0 [-4.0, 35.0]

Study	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
	Prolonged erection	0	10.5 (4/38)	–
PgE_1 vs. Papaverine + Phentolamine				
Bechara 1997	Pain	35.0 (21/60)	15.0 (9/60)	20.0 [5.0–35.0]
	Prolonged erection	15.0 (9/60)	18.3 (11/60)	-3.0 [-17.0, 10.0]
PgE_1 vs. Phentolamine+ PgE_1				
Aversa 1996a	Prolonged erection	4.2 (1/24)	4.2 (1/24)	–
PgE_1 vs. Trimix				
Bechara 1996	Pain	40.6 (13/32)	12.5 (4/32)	28.0 [8.0–49.0]
Seyam 2005	Pain	17.3 (31/179)	14.4 (26/179)	-3.0 [-11.0, 4.0]
Range of reported pain/discomfort (%)		14.4–40.6	12.5–17.8	NA
Seyam 2005	Priapism	<1.0 (1/179)	5.0 (9/170)	-5.0 [-8.0, -1.0]
PgE_1 vs. Moxisylate				
Buvat 1998	Pain during injection: clinic	13.3 (10/75)	14.8 (12/81)	-1.0 [-12.0, 9.0]
	Pain during injection: home	25.0 (17/68)	14.8 (9/61)	10.0 [-3.0, 24.0]
	Pain during erection: clinic	17.3 (13/75)	2.5 (2/81)	15.0 [6.0–24.0]
	Pain during erection: home	23.5 (16/68)	4.9 (3/61)	19.0 [7.0–30.0]
	Pain after erection: clinic	6.7 (5/75)	0 (0/81)	–
	Pain after erection: home	19.1 (13/68)	4.9 (3/61)	14.0 [3.0–25.0]
	Prolonged erection: clinic	5.3 (4/75)	0 (0/81)	–
	Prolonged erection: home	4.4 (3/68)	1.6 (1/61)	3 .0 [-3.0, 9.0]
	Bleeding: clinic	2.7 (2/75)	2.5 (2/81)	0.0 [-5.0, 5.0]
	Bleeding: home	14.7 (10/68)	4.9 (3/61)	10.0 [0.0–20.0]
	Dizziness/hypotension: home	1.5 (1/68)	8.2 (5/61)	-7.0 [-14.0, 1.0]
Kunelius 1998	Prolonged erection	10.0 (3/30)	3.3 (1/30)	7.0 [-6.0, 19.0]
PgE_1 vs. Nitroprusside (100 µg, 300 µg or 400 µg)				

Study	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Martinez-Piñeiro 1995	Pain during injection Dizziness Hematoma	6.7 (7/105) 3.8 (4/105) 1 subject	0 6.7 (7/105) 1 subject	7.0 [2.0–12 .0] -3.0 [-9.0, 3.0] –
PgE_1 vs. Linsidomine				
Porst 1993	Penile pain	17.5 (7/40)	NR	–
Wegner 1995	Pain during injection	7.5 (3/40)	2.5 (1/40)	5.0 [-4.0, 14.0]
Range of reported pain/discomfort (%)		7.5–17.5	NA	NA
Porst 1993	Moderate/severe headache	NR	7.5 (3/40)	–
PgE_1 vs. Linsidomine + Urapidil				
Wegner 1995	Pain during injection Serve hypotension	7.5 (3/40) 0	7.5 (3/40) 12.5 (5/40)	– –
PgE_1 (fast injection) vs. PgE_1 (slow injection)				
Gherchiu 1996	Pain during injection	54.5 (6/11)	18.2 (2/11)	36.0 [-1.0, 74.0]
PgE_1 vs. PgE_1 + Local Anesthetic				
Kattan 1995	Pain	86.4 (19/22)	45.4 (10/22) Lidocaine	41.0 [16.0–66.0]
Shramek 1994	Pain, moderate to severe	83.3 (20/24) (11 patients with severe ED)	62.5 (15/24) + Procaine (4 patients with severe ED	21.0 [-4.0, 45.0]
Range of reported pain/discomfort (%)		–	–	NA
PgE_1 vs. PgE_1 + Sodium Bicarbonate				
Godschalk 1996	Pain	80.0 (8/10)	70.0 (7/10)	10.0 [-28.0, 48.0]
PgE_1 + Papaverine vs. Papaverine + Phentolamine				
Floth 1991	Pain Prolonged erection	16.3 (8/49) 8.2 (4/49)	0 8.2 (4/49)	– –

Study	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Trimix vs. Trimix + Sodium Bicarbonate				
Moriel 1993	Pain/discomfort	57.9 (11/19)	5.3 (1/19)	53.0 [28.0–77.0]
Trimix vs. Trimix + Atropine				
Sogari 1997	Pain	50.0 (57/114)	55.3 (63/114)	-5.0 [-18.0, 8.0]
Papaverine +Phentolamine vs. Placebo				
Bechara 1997	Pain	15.0 (9/60)	0	–
	Prolonged erection	18.3 (11/60)	0	–
Papaverine + Phentolamine + Sexual Counseling vs. Papaverine + Phentolamine				
Van der Windt 2002	12% discontinued because of prolonged erection Priapism: 3 patients Hematoma: 4 patients Curvature of the penis: 1 patient AE similar between groups			–
Papaverine vs. Moxisylate				
Kunelius 1998	Prolonged erection	6.7 (2/30)	3.3 (1/30)	3.0 [-8.0, 14.0]
Moxisylate vs. Placebo				
Costa 1993	Prolonged erection	1.6 (1/61)	0	–
	Mild pain	3.3 (2/61)	0	–
	Faintness (normal BP)	3.3 (2/61)	0	–
	Hypotension, nausea, or bradycardia	1.6 (1/61)	0	–
	Hot flushes	1.6 (1/61)	0	–
	Vagal shock after sharp pain during injection	0	1.6 (1/61)	–
Vasoactive Intestinal Polypeptide + **Phentolamine vs. Placebo**				
Sandhu 1999	Bruising	43.1 (84/195)	12.3 (24/195)	31.0 [22.0–39.0]
	Bleeding at injection site	20.5 (40/195)	5.1 (10/195)	15.0 [9.0–22.0]

Study	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
	Pain on injection	4.6 (9/195)	8.2 (16/195)	-4.0 [-8.0, 1.0]
	Urethral bleeding	12.3 (24/195)	2.6 (5/195)	10.0 [5.0–15.0]
	Priapism	<1.0 (1/195)	0	–
	Flushing	74.4 (145/195)	13.3 (26/195)	61.0 [53.0–69.0]
	Headache	3.6 (7/195)	1.5 (3/195)	2.0 [-1.0, 5.0]
	Palpitation	7.7 (15/195)	0	–
	Tachycardia	5.1 (10/195)	<1.0 (1/195)	5.0 [1.0–8.0]
Timing of PgE1 PgE_1 (early intervention) vs. PgE_1 (late intervention): post non–nerve-sparing radical prostatectomy				
Gontero 2003	Prolonged erection	8.3 (3/36)	0 (0/37)	–
PgE_1 vs. No Treatment: post–nerve-sparing radical retropubic prostatectomy				
Montorsi 1997)	Prolonged erection	6.7 (1/15)	0 (0/15)	–
	Hematoma	13.3 (2/15)	0 (0/15)	–
PgE_1 + Sexual Counseling vs. PgE_1: post–nerve-sparing radical retropubic prostatectomy or cystectomy				
Titta 2006	Moderate pain	34.5 (10/29)	42.9 (12/28)	-8.0 [-34.0, 17.0]
	Severe pain	13.8 (4/29)	10.7 (3/28)	3.0 [-14.0, 20.0]
	Prolonged erection	17.2 (5/29)	17.8 (5/28)	-1.0 [-20.0, 19.0]
	Hematoma	6.9 (2/29)	10.7 (3/28)	-4.0 [-19.0, 11.0]
	Priapsim	0	0	–
	Nodule	0	0	–
Vasoactive Intestinal Polypeptide + Phentolamine (2 arms) vs. Placebo				
Dinsmore 1999	Bruising	5.5–7.2 (range)	5.1	–
	Bleeding at injection site	4.0–4.6 (range)	3.0	–

Study	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
	Pain on injection	0	7.7	–
	Urethral bleeding	2.2–2.5 (range)	0.4	–
	Priapism	0.1	0	–
	Flushing	47.0–50.0 (range)	9	–
Papaverine followed by Sildenafil vs. Sildenafil followed by Papaverine				
Viswaroop 2005	Priapism	Both arms combined		
	Headache	10.0 (5/50)		–
	Blurred vision	4.0 (2/50)		–
	Dyspepsia	2.0 (1/50)		–
		2.0 (1/50)		–

Table 15: Subcutaneous Injection: Improvement in Erections

Study / Type of Patients	Outcome Definition	Treatment Group% (n/N)	Control Group % (n/N)	Relative risk (RR) [95% CI] or p value
Melanotan II vs. Placebo				
Wessells 2000 Psychogenic: 10 patients	Subject reported "subjectively apparent erections" on at least one of two injections	85.0 (17/20)	NR	–
Physiologic: 10 patients	Subjective erectile activity	69.2 (27/39) Based on number of injections	2.4 (1/41) Based on number of injections	–
Analysis: 10 patients with physiologic ED	Subject reported "subjectively apparent erections" on at least one of two injections	90.0 (9/10)	10.0 (1/10)	9.00 [1.39–58.44]

Study / Type of Patients	Outcome Definition	Treatment Group% (n/N)	Control Group % (n/N)	Relative risk (RR) [95% CI] or p value
	Subjective erectile activity	63.2 (12/19) Based on number of injections	4.8 (1/21) Based on number of injections	–
PT–141 (cyclic heptapeptide melanocortin analog) vs. Placebo				
Rosen 2004 25 patients with moderate-severe ED with inadequate response to sildenafil.		NR NR NR		

Table 16: Subcutaneous Injection: Patients with Adverse Events

Study	Adverse event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute risk difference (%) [95% CI]
Melanotan II vs. Placebo				
Wessells 2000 Psychogenic and physiologic ED subgroups combined		*Number of injections*	*Number of injections*	
	Nausea (any)	38.5 (15/39)	9.8 (4/41)	
	Nausea (severe)	15.4 (6/39)	2.4 (1/41)	
	Yawning/stretching (any)	56.4 (22/39)	12.2 (5/41)	
	Yawning/stretching (severe)	7.7 (3/39)	0 (0/41)	
Analysis of the 10 patients with physiologic ED				NA
	Nausea (any)	42.1 (8/19)	9.5 (2/21)	
	Nausea (severe)	21.1 (4/19)	0 (0/21)	
	Yawning/stretching (any)	42.1 (8/19)	0 (0/21)	
	Yawning/stretching (severe)	15.8 (3/19)	0 (0/21)	
PT–141 (cyclic heptapeptide melanocortin analog) vs. Placebo				

Study	Adverse event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute risk difference (%) [95% CI]
Rosen 2004 AE > 5% in both treatment arms	Nausea	24.0 (6/25) *4 mg* 36.4 (8/22) *6 mg*	0 (0/24)	–
	Headache	36.0 (9/25) *4 mg* 27.3 (6/22) *6 mg*	0 (0/24)	–
	Vomiting	8.0 (2/25) *4 mg* 9.1 (2/22) *6 mg*	0 (0/24)	–
	Diaphoresis	8 (2/25) *4 mg* 9.1 (2/22) *6 mg*	0 (0/24)	–
	Exacerbation of hypertension	9.1 (2/22) *4 mg*	0 (0/24)	–
Apomorphine vs. Placebo				
Segraves 1991	Eight of 12 patients reported adverse events: yawning, drowsiness and nausea. Two patients had severe nausea and hypotension			

Table 17: Intra-urethral Treatment: Sexual Intercourse

Study	ED Etiology	Outcome	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Alprostadil vs. Placebo. Patients randomized included only men who had a maximal penile response (Grade of 4 or 5 on the Erection Assessment Scale) with at least one dose of alprostadil					
Padma-Nathan* 1997	Physiologic: 100%	Total successful attempts (diary self-report) after 3 months	50.4 (2485/4933)	10.4 (454/4346)	4.82 [4.40–28.00]
		Total successful			

Study	ED Etiology	Outcome	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Williams* 1998	Physiologic: 100%	attempts (diary self-report) after 3 months	51.1 (390/763)	7.5 (46/611)	6.79 [5.10–9.04]
I					
Padma-Nathan* 1997	Physiologic: 100%	Total successful attempts for men who had successful intercourse at least once (diary self-report) after 3 months	69.2 (2485/3593)	10.4 (454/4346)	6.62 [6.05–7.24]
Williams* 1998	Physiologic: 100%	Total successful attempts for men who had successful intercourse at least once (diary self-report) after 3 months	61.4 (390/635)	7.5 (46/611)	8.16 [6.14–10.84]
II					
Padma-Nathan* 1997	Physiologic: 100%	Total successful intercourse attempts or orgasm (diary self-report) after 3 months	56.3 (2770/4921)	15.4 (668/4331)	3.65 [3.39–3.93]
Padma-Nathan* 1997	Physiologic: 100%	Patients reporting successful intercourse at least once (diary self-report) after 3 months	61.6 (299/485) *All men randomized*	18.2 (93/511) *All men randomized*	3.39 [2.78–4.12]
Williams* 1998	Physiologic: 100%	Patients reporting successful intercourse at least once (diary self-report) after 3 months	59.0 (46/78) *All men randomized*	9.9 (8/81) *All men randomized*	5.97 [3.01–11.83]
III					
Padma-Nathan* 1997	Physiologic: 100%	Patients reporting successful intercourse at least once (diary self-report) after 3 months	64.9 (299/461) *Men with ≥ 1 administration*	18.6 (93/500) *Men with ≥ 1 administration*	3.49 [2.87–4.24]
Williams* 1998	Physiologic: 100%	Patients reporting successful intercourse at least once (diary self-report) after 3 months	68.7 (46/67) *Men with ≥ 1 administration*	7.5 (8/73) *Men with ≥ 1 administration*	6.26 [3.19–12.29]
Alprostadil (IU) vs. Alprostadil (ICI)					
Shokeir 1999	Physiologic: 100%	Total successful attempts (diary self-report) after 3 months	55.0 (198/360)	85.1 (206/242)	0.65 [0.58–0.72]
Shokeir 1999	Physiologic: 100%	Patients reporting successful intercourse at least once	53.3 (16/30)	86.7 (26/30)	0.62 [0.43–0.88]

Study	ED Etiology	Outcome	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Alprostadil (titrated; starting dose 250 µg),) vs. Alprostadil (titrated; starting dose 500 µg)					
Ekman 2000	NR Vascular: 43%–47% Diabetes: 21% Psychogenic: 7%–12%	Patients reporting successful intercourse at least once	68.1 (113/166)		–

Table 18: Intra-urethral Treatment: Improvement in Erections*

Study	ED etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Alprostadil vs. Placebo				
Padma-Nathan 1997	Physiologic: 100%	65.9 (996/1511)** *Dosing phase*	NA	–
Williams 1998	Physiologic: 100%	63.9 (159/249)** *Dosing phase*	NA	–
Alprostadil vs. Prazosin (IU)				
Peterson 1998	Physiologic: 100%	*Range for % response (dose)* 14.1 (125 mcg) – 31.0 (500 mcg)	*% Response (dose)* 3.0 (2000 mcg)	–
Alprostadil + Prazosin (IU) vs. Placebo				
Peterson 1998	Physiologic: 100%	*Range for % response (Alprostadil dose/Prazosin dose)* 30.4 (125 mcg/500 mcg) – 35.7 (500 mcg/2000 mcg)	0.4	–
Alprostadil (IU) vs. Alprostadil (ICI)				
Shabsigh 2000	NR	21.1 (20/95) *In-office titration phase, Positive buckling test* 61.8 (42/68) *At-home phase, ≥ 1 erection sufficient for intercourse*	61.1 (58/95) *In-office titration phase, Positive buckling test* 92.6 (63/68) *At-home phase, ≥ 1 erection sufficient for intercourse*	0.34 [0.23–0.53] 0.67 [0.55–0.81]

Shokeir 1999	Physiologic: 100%	60.0 (18/30)	90.0 (27/30)	0.67 [0.49–0.91]
Alprostadil (starting dose 250 µg) vs. Alprostadil (starting dose 500 µg)				
Ekman 2000	NR Vascular: 43%–47% Diabetes: 21% Psychogenic: 7%–12%	73.5 (122/166)		–
Prazosin (IU) vs. Placebo				
Peterson 1998	Physiologic: 100%	*% Response (dose)* 3.0 (2000 mcg)	*% Response* 0.4	–

* Defined as full erection or "positive response," Grade 4/5 erections, erections sufficient for intercourse, or Rigiscan assessment ≥ 70% rigidity base or tip lasting ≥ 10 minutes
** Patients achieving an adequate erectile response were then randomized in the double blind placebo controlled home phase

Table 19: Intra-urethral Treatment: Patients with Adverse Events

Study	Adverse Event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Alprostadil vs. Placebo				
Padma-Nathan 1997	Penile pain	32.8 (159/485)	3.3 (17/511)	29.0 [25.0–34.0]
Williams 1998	Penile pain	5.0 (4/78)	1.2 (1/81)	4.0 [-2.0, 9.0]
Padma-Nathan 1997	Minor urethral trauma	5.2 (25/485)	<1.0 (5/511)	4.0 [2.0–6.0]
Williams 1998	Minor urethral trauma	1.3 (1/78)	1.2 (1/81)	0.0 [-2.0, 7.0]
Padma-Nathan 1997	Dizziness	1.9 (9/485)	<1.0 (1/511)	2.0 [0.0–3.0]
Williams 1998	Dizziness	2.6 (2/78)	0 (0/81)	–
Padma-Nathan 1997	Prolonged erection	0	0	–
Williams 1998	Prolonged erection	1.3 (1/78)	0	–
Williams 1998	Urogenital pain/burning	6.4 (5/78)	0	–
Padma-Nathan 1997	Other events: Priapism or fibrosis Urinary tract infection	0 <1 (1/485)	0 <1 (3/511)	– –
Williams 1998	Testicular pain Priapism or fibrosis Urinary tract infection	2.6 (2/78) 0 0	0 0 0	– – –
Alprostadil vs. Prazosin (IU)				

Study	Adverse Event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Peterson 1998		*Dose range 125–1000 mcg*	*Dose range 250-2000 mcg*	
		% Range	*% Range*	
		17.0–23.6	0.7 –5.5	
	Penile pain	1.0–9.1	0–2.1	–
	Urethral pain	2.0–4.4	0–1.4	–
	Testicular pain	0–5.5	0–0.7	–
	Dizziness	1.0–3.6	0–1.8	–
	Hypotension	0	0	–
	Priapism or fibrosis	0	0	–
	There were 12 cases of minor urethral bleeding and 2 cases of prolonged erections (no treatment arms reported).			
Alprostadil + Prazosin (IU) vs. Placebo				
Peterson 1998	Penile pain Urethral pain Testicular pain Dizziness Hypotension Priapism or fibrosis	*Alprostdil (dose range: 125–1000 mcg) + Prazosin (dose range: 250-2000 mcg)*		
		% Range	1.7	–
		17.0–31.6	1.7	–
		1.9–13.5	0.4	–
		1.8–6.8	0	–
		0–11.5	0	–
		0–14.0	0	–
		0		
Alprostadil (IU) vs. Alprostadil (ICI)				
Shabsigh 2000	Patients with ≥ 1 AE	55.8 (53/95) *Office*	30.5 (29/95) *Office*	25.0 [12.0–39.0]
		57.4 (39/68) *Home*	52.9 (36/68) *Home*	4.0 [-12.0, 21.0]
	Penile pain	30.5 (29/95) *Office*	20 (19/95) *Office*	11.0 [-2.0, 23.0]
		25.0 (17/68) *Home*	33.8 (23/68) *Home*	-9.0 [-24.0, 6.0]
	Prolonged erections	0 *Office*	2.1 (2/95) *Office*	–

Study	Adverse Event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
		0 *Home*	2.9 (2/68) *Home*	–
	Local bleeding	4.2 (4/95) *Office*	1.1 (1/95) *Office*	3.0 [-1.0, 8.0]
		2.9 (2/68) *Home*	1.5 (1/68) *Home*	1.0 [-3.0, 6.0]
Shokeir 1999	Urogenital pain	6.7 (2/30)	46.7 (14/30)	-40.0 [-20.0, -60.0]
	Urethral bleeding	3.3 (1/30)	0	–
	Dizziness	6.7 (2/30)	0	–
Alprostadil (starting dose 250 µg) vs. Alprostadil (starting dose 500 µg)				
Ekman 2000	Pain	30.1 (50/166) 2% rated severe		–
Prazosin vs. Placebo				
Peterson 1998		*% Range*		
	Penile pain	0.7–5.5		
	Urethral pain	0–2.1		
	Testicular pain	0–1.0	1.7	–
	Dizziness	0–1.0		
	Hypotension	0–2.0		
	Priapism or fibrosis	0		

Table 20: Alprostadil (Topical Cream) vs. Placebo: Sexual Encounter Profile (SEP)

Study / Duration		Placebo (%)	Alprostadil Topical Cream			
			50 µg (%)	100 µg (%)	200 µg (%)	300 µg (%)
1. Rate of successful vaginal penetration/total attempts (SEP Question): Were you able to insert your penis into your partners' vagina? (yes/no)						
Padma-Nathan 2003 6 weeks Patients with mild-to-moderate ED (Study a)	Number of patients	31	31	29	26	NA
	Baseline	NR	NR	NR	NR	
	End point success rate ± standard deviation	55.3 ± 40.0	69.4 ± 34.2	69.1 ± 39.3	82.9 ± 24.6	
	Mean change	NR	NR	NR	NR	
	p value vs. placebo	NA	NS	NS	0.01	
Padma-Nathan 2003 6 weeks Patients with severe ED (study b)	Number of patients	35	NA	34	29	29
	Baseline success rate	NR		NR	NR	NR
	End point success rate ± standard deviation	15.6 ± 17.2		32.3 ± 18.0	36.2 ± 29.3	38.6 ± 22.8
	Mean change	NR		NR	NR	NR
	p value vs. placebo	NA		NS	NS	NS

Table 21: Topical Treatment: Improvement in Erections*

Study	ED Etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
Alprostadil vs. Placebo				
Goldstein 2001	Vascular: 97%	38.7 (12/31)	6.9 (2/29)	5.61 [1.37–22.96]
Padma-Nathan 2003 6 weeks Patients with	NR	80.2 (69/86) All doses	54.8 (17/31)	1.46 [1.05–2.05]
		81.0 (25/31) 50 µg	54.8 (17/31)	1.47 [1.02–2.11]
		69.0 (20/29) 100 µg	54.8 (17/31)	1.26 [0.84–1.88]

Study	ED Etiology	Treatment Group % (n/N)	Control Group % (n/N)	Relative Risk [95% CI]
mild-to-moderate ED (Study a)		92.0 (24/26) 200 µg	54.8 (17/31)	1.68 [1.20–2.36]
Padma-Nathan 2003 6 weeks Patients with severe ED (study b)	NR	71.7 (66/92) All doses	25.7 (9/35)	2.79 [1.57–4.97]
		58.8 (20/34) 100 µg	25.7 (9/35)	2.29 [1.22–4.29]
		75.9 (22/29) 200 µg	25.7 (9/35)	2.95 [1.62–5.37]
		82.7 (24/29) 300 µg	25.7 (9/35)	3.22 [1.79–5.79]
Aminophylline + Isosorbide dinitrate + Co-dergocrine vs. Placebo,				
Gomaa 1996	Physiologic: 52.3% Psychogenic: 25% Mixed: 22.2%	58.3 (21/36)	8.3 (3/36)	7.00 [2.29–21.41]
Le Roux 1999	Physiologic: 28.6% Psychogenic: 71.4%	3.9 (3/77 applications, 8 patients)	5.3 (4/76 applications, 8 patients)	0.74 [0.17–3.20]
Minoxidil vs. Nitroglycerin				
Cavallini 1994	Physiologic: 100%	44.0 (51/116)	20.7 (24/116)	2.13 [1.41–3.21]
Minoxidil vs. Placebo				
Cavallini 1994	Physiologic: 100%	44.0 (51/116)	1.7 (2/116)	25.5 [6.36–102.29]
Nitroglycerine plasters vs. Placebo plasters				
Gramkow 1999	Physiologic: 27.8% Psychogenic: 66.7% Mixed: 5.6%	16.7 (3/18)	11.1 (2/18)	1.50 [0.28–7.93]
Topical sildenafil + Oral placebo vs. Oral sildenafil + Topical placebo,				
Yonessi 2005	Physiologic: 41.3% Psychogenic: 58.8%	12.5 (5/40)	70.0 (28/40)	0.18 [0.08–0.42]

* Defined as full erection, erections sufficient for intercourse, improved erections based on Global Assessment Questionnaire, or RigiScan assessment ≥ 60% rigidity ("good to excellent effect")

** Intention-to-treat population, defined as patients receiving ≥ one dose of study medication and ≥ one post-baseline efficacy evaluation. Of a total of 1732 patients, 83 patients (4.8%) were not evaluated

† Includes only patients from the cohort for the primary efficacy endpoint analysis, defined as (a) used ≥ three doses of study medication in conjunction with attempts at sexual intercourse between visits 2 and 4, (b) reported both baseline and end of treatment efficacy data (International Index of Erectile Function (IIEF), (c) reported a baseline score for the IIEF EF domain of ≤ 21, and (d) tolerated the test dose at visit 2 †† Based on a difficulties in maintaining an erection during intercourse scale, scored from 1 (always) to 6 (never). A score of 3 indicates difficulties 50% of the time.

Table 22: Topical Treatment: Patients with Adverse Events

Study	Adverse Event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Alprostadil vs. Placebo				
Goldstein 2001	Patients withdrawn from therapy due to adverse events	0/31	0/29	–
	Penile erythema	NR		–
	Mild/minor warmth or burning, tingling, and coolness	Reported by most patients after both alprostadil and placebo application		–
Padma-Nathan 2003 6 weeks Patients with mild-to-moderate ED (Study a)	Urogenital pain	13.2% (16/121) 12%: 50µg 15%: 100µg 13%: 200µg	0 (0/40) NR	–
	Hypotension	5.0% (6/121) 2.0%: 50µg 3.0%: 100µg 1.0%: 200µg	0 (0/40) NR	–
Padma-Nathan 2003 6 weeks Patients with severe ED (Study b)	Urogenital pain	5.5% (6/109) 0%: 100µg 9.0%: 200µg 8.0%: 300µg	0 (0/35) NR	–
	Hypotension	6.4% (7/109) 0%: 100µg 11.0%: 200µg 8.0%: 300µg	0 (0/35) NR	–
Topical PgE1 with or without Calcium Thioglycolate or Methyl Salicylate vs. Placebo				
Foldavi 1998	Patients with ≥ 1 AE	No local AEs were observed during the study		–
Aminophylline + Isosorbide dinitrate + Co-Dergocrine vs. Placebo,				
Gomaa 1996	Patients with ≥ 1 AE	No Patient reported prolonged erection/priapism, clinically significant cardiovascular events or complaints from patients' partners		–
Le Roux 1999	No AE reported	–	–	–
Nitroglycerin vs. Placebo				
Cavallini 1994	Patients with ≥ 1 AE	44.8 (52/116)	0 (0/116)	45.0 [36.0–54.0]
	Burning at application site	12.6 (14/116)	0 (0/116)	12.0 [6.0–18.0]
	Hypotension	10.3 (12/116)	0 (0/116)	10.0 [5.0–16.0]

Study	Adverse Event	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Cavallini 1991	Patients with ≥ 1 AE (burning at application site, headache, hypotension)	45.5 (15/33)	0 (0/33)	–
Nitroglycerin vs. Minoxidil				
Cavallini 1994	Patients with ≥ 1 adverse event	44.8 (52/116)	6.0 (7/116)	39.0 [29.0–49.0]
	Burning at application site	12.6 (14/116)	6.0 (7/116)	6.0 [-1.0, 13.0]
	Hypotension	10.3 (12/116)	0 (0/116)	–
Minoxidil vs. Placebo				
Cavallini 1994	Patients with ≥ 1 AE	6.0 (7/116)	0 (0/116)	–
	Burning at application site	6.0 (7/116)	0 (0/116)	–
	Hypotension	0 (0/116)	0 (0/116)	–
Cavallini 1991	Patients with ≥ 1 adverse event (burning at application site)	6.1 (2/33)	0 (0/33)	–
Nitroglycerine vs. Placebo				
Gramkow 1999	Patients withdrawn from therapy due to adverse events	1/18 due to severe pain from plaster	0/18	–
	Headache (mild)	35.4 (35/99) plasters used	1.1 (1/92) plasters used	34.0 [25.0–44.0]
	Smarting pain	23.2 (23/99) plasters used	1.1 (1/92) plasters used	22.0 [14.0–31.0]
Claes 1992	Patients withdrawn from therapy due to AEs	4 patients due to headache (unclear if due to active treatment)		–
Topical sildenafil + Oral Placebo vs. Oral Sildenafil + Topical Placebo				
Yonessi 2005	Headache	10.0 (4/40)	5.0 (2/40) 1 case each of dyspepsia and visual disturbance	5.0 [-6.0, 16.0]
Intranasal Cyclic Heptapeptide Melanocortin Analog (PT–141) vs. Placebo				
Diamond 2004	Flushing	16.7 (8/48)	4.2 (1/24)	13.0 [-1.0, 26.0]
	Nausea	10.4 (5/48)	0 (0/24)	–
	Feeling hot	4.2 (2/48)	4.2 (1/24)	–

Table 23:Testosterone: Improvement in Sexual Intercourse Outcomes

Study/patient Characteristics		Intervention Group 1	Intervention Group 2	Intervention Group 3	Intervention Group 4
Cavallini 2004 Men >60 with symptoms of androgen decline and depressed mood	Treatment type	**T 160 mg/d oral**	**Placebo**	NA	NA
	Number of patients at baseline	40	45	-	-
	IIEF "Intercourse Satisfaction" (range 0–15): Median score at baseline (range)	4 (3–6)	4 (2–5)	-	-
	IIEF "Intercourse Satisfaction": Median score at end of therapy (6 months)	5 (3–10) p <0.01 vs. baseline	4 (3–5)	-	-
Seftel 2004 Hypogonadal men (secondary to aging and normo-gonadotrophic)	Treatment type	**T gel 50 mg/d**	**T gel 100 mg/d**	**T patch ~25mg/d**	**Placebo**
	Number of patients at baseline	99	106	102	99
	Percentage of patients reporting no intercourse during baseline period	45	47	49	43
	% Improvement in frequency of intercourse from baseline at day 30	+31 *Extracted from graph* p value vs. placebo <0.05 p value vs. T patch NS	+39 p value vs. placebo 0.0096 p value vs. T patch 0.0356	+21 p value vs. placebo NS	+24 p value vs. T gel (50mg/d or 100mg/d) < 0.05 p value vs. T patch NS
Schiavi 1997 Men with ED and hypoactive sexual desire	Treatment type	**T (IM) 200 mg**	**Placebo**	NA	NA
	Number of patients at baseline	18 Crossover study (Washout period: 4 weeks)	18 Crossover study (Washout period: 4 weeks)	-	-

Study/patient Characteristics		Intervention Group 1	Intervention Group 2	Intervention Group 3	Intervention Group 4
	Frequency of intercourse at baseline	NR	NR	-	-
	Median frequency of "sex with partner" per week at week 6	1.25 (0–2) vs. Placebo: p value (NS)	0.54 (0–2.7) vs. T (IM): p value (NS)	-	-
	p value vs. placebo	NS	–	-	-
Gooma 2006 89 men with low testosterone levels and psychogenic and organic ED	Treatment type	**T 0.8% + Isosorbide Dinitrate + Co-dergocrine Cream**	**Placebo**	NA	NA
	Number of patients at baseline	45	44	**-**	-
	Number of patients having full erections with successful intercourse at study end	40% (18/45)	0/44	-	-
Gomaa 2001 Aged men with ED and hypoactive sexual desire	Treatment type	**T 0.8% + Isosorbide Dinitrate + Co-Dergocrine Cream**	**T 0.8% cream**	NA	NA
	Number of patients at baseline	42 Crossover study (washout period: 1 week)	42 Crossover study (washout period: 1 week)	-	-
	Frequency of intercourse at baseline	NR	NR	-	-
	Mean number of full erections with satisfactory intercourse at 1 month (standard deviation)	6.46 (2.7)	4.05 (1.8)	-	-

Study/patient Characteristics		Intervention Group 1	Intervention Group 2	Intervention Group 3	Intervention Group 4
	Number of patients with full erections and satisfactory intercourse at 1 month	66.7% (28/42) All patients 84.2% (16/19) Psychogenic 55.6% (10/18) Vascular 40% (2/5) Neurogenic	31% (13/42) All patients 57.9% (11/19) Psychogenic 11.1% (2/18) Vascular 0% (0/5) Neurogenic	-	-
Cavallini 2004 Men >60 with symptoms of androgen decline	Treatment type	**T (oral) 160 mg/d**	**Propionyl-L Carnitine + Acetyl-L Carnitine 2 g/d**	NA	NA
	Number of patients at baseline	40	45	-	-
	IIEF Intercourse satisfaction): Median score at baseline	4 (3–6)	4 (3–7)	-	-
	IIEF Intercourse satisfaction: Median score at end of therapy (6 months)	5 (3–10) p <0.01 vs. baseline	6 (3–10) p <0.01 vs. baseline	-	-

Table 24: Testosterone (T) Combined with PDE–5 inhibitors: Improvement in Sexual Intercourse Outcomes

Study/patient Characteristics		Testosterone Group	Control Group	Relative risk (RR) or weighted mean difference (WMD) [95% CI]
Shabsigh 2004 Hypogonadal men, non-responders to sildenafil therapy	Treatment type	**T 1% gel + Sildenafil 100mg**	**Placebo gel + Sildenafil 100mg**	
	Number of patients at baseline	39	36	
	Mean number of successful sexual attempts per week	1.7–2.1	1.5–2.4	–

	Proportion (%) of successful sexual attempts per week	49–59	43–50	–
Aversa 2003 Men with arteriogenic ED	Treatment type	**T 5 mg/d patch + Sildenafil 100mg**	**Placebo patch + Sildenafil 100mg**	
	Number of patients at baseline	10	10	
	Mean frequency of intercourse at baseline (SD)	1.4 (0.6)	NR	NA
	Mean frequency of intercourse at 1 month	2.8 (0.9)	1.5 (0.5)	WMD = 1.30 [0.66–1.94]
	IIEF** Intercourse satisfaction (range 0–15): mean score at baseline	7.1 (1.4)	7.8 (1.8)	WMD = -0.70 [-2.11, 0.71]
	IIEF Intercourse satisfaction: mean score at 1 month	12.1 (1.6)	7.7 (1.2)	WMD = 4.40 [3.16–5.64]
Yassin 2006 Hypogonadal men, non-responders to tadalafil therapy	Treatment type	**T 50 mg/d gel + Tadalafil 20 mg**	**T 50 mg/d gel**	
	Number of patients at baseline	34	35	NA
	IIEF Intercourse satisfaction (range 0–15): mean score at baseline	8.9 (2.8)		NA
	IIEF Intercourse satisfaction: mean score at 10 weeks	13.1 (0.8)	12.8 (0.9)	WMD = 0.30 [-0.10, 0.70]

* International Index of Erectile Dysfunction

Table 25: Testosterone Treatment: Improvement in Erections

Study/patient Characteristics	Outcome	Treatment Group	Control Group	Relative risk (RR) or weighted mean difference (WMD) [95% CI] or p value
Testosterone (IM) vs. Placebo				
Seidman 2006 32 hyogonadal men with major depressive disorder	Full erection during phases of a normal sexual response cycle (foreplay through intercourse and orgasm) at baseline (standard deviation). Based on DSPS (range 0–8)*	1.54 (1.94)	1.18 (1.78)	NR
	Full erection during phases of a normal sexual response cycle (foreplay through intercourse and orgasm) at study end.	1.77 (2.17) Mean change = 0.23	1.53 (1.62) Mean change = 0.35	p value (NS)
	A satisfying orgasm at baseline. Based on DSPS (range 0–8)*	1.92 (1.44)	1.82 (1.81)	NR
	A satisfying orgasm at end of study period	2.31 (2.06) Mean change = 0.23	2.06 (1.44) Mean change = 0.35	p value (NS)
Rabkin 2000 74 HIV positive men with hypo-gonadal symptoms	Completers who experienced ED rated as much to very much improved based on the Clinical Global Impression Scale	62.5% (20/32)	20.0% (4/20)	RR = 3.12 [1.25–7.82]
Clopper 1993 9 gonadotropin-deificent hypopituitary men	Self-reported weekly frequency of erection	7.9 (6.1)	4.9 (3.3)	p value (NS)
Testosterone (IM) vs. Human Chorionic Gonadotropin (IM)				

Study/patient Characteristics	Outcome	Treatment Group	Control Group	Relative risk (RR) or weighted mean difference (WMD) [95% CI] or p value
Clopper 1993 9 gonadotropin-deificent hypopituitary men	Self-reported weekly frequency of erection	7.9 (6.1)	8.2 (7.1)	p value (NS)
Testosterone (oral) vs. Placebo				
Haran 2005	"Are your erections less strong?" % reporting yes after 12 months	86%	93%	p = 0.059
Cavallini 2004 95 men > 60 with symptoms of androgen decline	IIEF Erectile function (range 1–30): Median score at baseline (range)	8 (5–19)	8 (5–21)	NR
	IIEF Erectile function: Median score at end of therapy (6 months)	16 (6–29)	8 (5-21)	Testosterone p <0.01 vs. baseline
Testosterone (oral) vs. No Treatment				
Boyanov 2003 48 middle-aged men, with type 2 diabetes, obesity, and symptoms of androgen deficiency	IIEF–5 to assess erectile function, score at baseline (absent-1 to severe-5)	2.25 (0.68)	2.50 (0.75)	NR
	IIEF–5 score after treatment (3 months)	1.062 (0.90)	2.25 (0.88)	p <0.05
Dihydrotestosterone Gel vs. Placebo Gel				
Kunelius 2002 120 men with andropause symptoms	Based on difficulties in maintaining an erection during intercourse scale, scored from 1 (always) to 6 (never). A score of 3 indicates difficulties 50% of the time.	3.24 (1.35)	2.81 (1.56)	NA
Testosterone 50 mg Gel (T 50) vs. Testosterone 100 mg Gel (T 100) vs. Andropatch				

Study/patient Characteristics	Outcome	Treatment Group	Control Group	Relative risk (RR) or weighted mean difference (WMD) [95% CI] or p value
McNicholas 2002 208 aging, hypogonadal men	Mean number of spontaneous erections/week at baseline	T 50: 0.8 T 100: 0.8	Andropatch 0.9	
	Mean change in spontaneous erections/week after therapy (90 days)	T 50: +0.6 T 100: +0.5	Andropatch +0.3	T 50: p <0.05 vs. baseline T 100: p <0.05 vs. baseline
Wang 2000 227 hypogonadal men	% of full erections at baseline (estimated from graph)	T 50: 53 T 100: 60	Andropatch 57%	NR
	% of full erections at day 90 (estimated from graph)	T 50: 67 T 100: 68	Andropatch 65%	p = 0.0001 for all groups vs. baseline
Testosterone 0.8% + Isosorbide Dinitrate + Co-Dergocrine Cream vs. Placebo				
Gooma 2006 89 men with low testosterone levels	Full erection after treatment (2 months)	40.0% (18/45) *All patients* 68.8% (11/16) *Psychogenic* 11.1% (1/9) *Vascular* 37.5% (3/8) Neurogenic 25% (3/12) *Mixed*	0/44	–
Testosterone 0.8% + Isosorbide Dinitrate + Co-Dergocrine Cream vs. Testosterone 0.8% cream				
Gomaa 2001 42 aged men with ED and hypoactive sexual desire	Mean number of full erections with satisfactory intercourse at 1 month.	6.46 (2.7)	4.05 (1.8)	WMD = 2.41 [1.43–3.39]

Study/patient Characteristics	Outcome	Treatment Group	Control Group	Relative risk (RR) or weighted mean difference (WMD) [95% CI] or p value
	Number of patients with full erections and satisfactory intercourse at 1 month	66.7% (28/42) *All patients* 84.2% (16/19) *Psychogenic* 55.6% (10/18) *Vascular* 40.0% (2/5) *Neurogenic*	31.0% (13/42) *All patients* 57.9% (11/19) *Psychogenic* 11.1% (2/18) *Vascular* 0% (0/5) *Neurogenic*	RR = 2.15 [1.31–3.55] RR = 1.45 [0.95–2.24] RR = 5.00 [1.27–19.68] –
Testosterone (oral) vs. Propionyl-L carnitine + Acetyl-L carnitine				
Cavallini 2004 95 men > 60 with symptoms of androgen decline and depressed mood	IIEF Erectile function (range 1–30): Median score at baseline	8 (5–19)	8 (5–22)	NR
	IIEF Intercourse satisfaction: Median score at end of therapy (6 months)	16 (6–29)	24 (8–29)	Testosterone p <0.01 vs. baseline Carnitines p <0.01 vs. baseline
Testosterone 5 mg/d Patch + Sildenafil 100mg vs. Placebo Patch + Sildenafil 100mg				
Aversa 2003 20 men with arteriogenic ED	Global Assessment Questionnaire: "has treatment improved erections"	80% (8/10)	10% (1/10)	RR = 8.00 [1.21–52.69]
	IIEF** Intercourse satisfaction (range 1–30): mean score at baseline	14.4 (1.4)	13.2 (1.1)	WMD = 1.20 [0.10–2.30]
	IIEF Intercourse satisfaction: mean score at 1 month	21.8 (2.1)	14.2 (0.7)	WMD = 7.60 [6.23–8.97]
Testosterone 1% Gel + Sildenafil 100mg vs. Placebo Gel + Sildenafil 100mg				

Study/patient Characteristics	Outcome	Treatment Group	Control Group	Relative risk (RR) or weighted mean difference (WMD) [95% CI] or p value
Shabsigh 2004 75 hypo-gonadal men, non-responders to sildenafil therapy	Patients with IIEF-Q3/Q4: 4-5 ** at study end	51.4% (19/37)	39.4% (13/33)	RR = 1.30 [0.77–2.21]
	Patients who increased functioning by at least 1 category over baseline for either IIEF Q3 or Q4 at week 12	78.8% (26/33)	71.0% (13/31)	RR = 1.11 [0.83–1.48]
Testosterone (oral) + Sildenafil (50 or 100mg) vs. Testosterone (oral): sildenafil non-responder men				
Shamloul 2005 Study a 20 men with ED associated with PADAM (partial androgen deficiency in aging men)	IIEF–5 to assess erectile function, score at baseline	10.1 (1.3) *Baseline*	9.9 (1.4) *Baseline*	
	IIEF–5 score after treatment	15.0 (1.4) p <0.01 vs. baseline	11.1 (1.5) p = 0.27 vs. baseline	WMD = 3.90 [2.63–5.17]
Testosterone (oral) + Sildenafil (50 or 100mg) vs. Sildenafil (50 or 100mg): men partially responding to sildenafil				
Shamloul 2005 Study b 20 men with ED associated with PADAM (partial androgen deficiency in aging men)	IIEF–5 to assess erectile function, score at baseline	15.3 (1.6) *Baseline*	15.4 (1.2) *Baseline*	–
	IIEF–5 score after treatment	17.5 (1.8) p <0.01 vs. baseline	15.9 (1.3) p = 0.24 vs. baseline	WMD = 1.60 [0.22–2.98]

* Derogatis Sexual performance Scale. Range 0 (not at all) to 8 (4 or more times/day)

** Question 3: "Over the past 4 weeks, when you attempted sexual intercourse, how often were you able to penetrate your partner?" and Question 4: Over the past 4 weeks, during sexual intercourse, how often were you able to maintain your erection after you penetrated your partner?"

Table 26: Testosterone Treatment: Patients with Adverse Events

Study/patient Characteristics	Adverse Events	Treatment Group % (n/N)	Control Group % (n/N)	Absolute Risk Difference [95% CI]
Testosterone (IM) vs. Placebo				
Seidman 2006	No adverse events occurred except one placebo subject had a myocardial infarction.			
Rabkin 2000	Patients with ≥ 1	41 (16/39)	20 (7/35)	21.0 [1.0–41.0]
	Irritability	17.9 (7/39)	17.1 (6/35)	1.0 [-17.0, 18.0]
	Acne	20.5 (8/39)	0/35	21.0 [7.0–34.0]
	Testicular atrophy	5.1 (2/39)	0/35	–
	Decreased ejaculate	2.6 (1/39)	2.9 (1/35)	-0.3 [-8.0, 7.0]
		Hair loss (n=1) Bossiness (n=1)	0 0	–
Testosterone (oral) vs. Placebo				
Cavallini 2004	Mild epigastralgia	2.5 (1/40)	2.2 (1/45)	0.3 [-6.0, 7.0]
Testosterone (oral) vs. No Treatment				
Boyanov 2003	No AE were reported during the study			
Testosterone (Cream) vs. Placebo				
Gooma 2006	Headaches (transient)	11.1 (5/45)	0 (0/44)	–
	Skin irritation	2.2 (1/45)	0 (0/44)	–
	Prolonged erections/priarism	0	0	–
Testosterone (Gel) vs. Placebo				
Seftel 2004	Treatment-related (application site reactions, BPH, increases in blood pressure and hematocrit/hemoglobin, gyencomastia, headache, hot flashes, insomnia, mood swings, spontaneous erections)	29.3 (29/99) T 50 36.8 (39/106) T 100	40.4 (40/99)	-11.0 [-24.0, 2.0] -4.0 [-17 to 10]
	Skin reaction leading to	0	0	

	study withdrawal			
Dihydrotestosterone Gel vs. Placebo Gel				
Kunelius 2002	Mild headache Mild depression Hair growth	5.0 (3/60) 3.3 (2/60) 1 patient	3.3 (2/60) 3.3 (2/60)	2.0 [-5.0, 9.0] –
Testosterone 0.8% + Isosorbide Dinitrate + Co-Dergocrine Cream vs. Testosterone 0.8% Cream				
Gomaa 2001	Mild transient headache PSA values: no significant increase of reported	N = 5 (phase 1 and 2)	0	–
T**estosterone (patch) vs. Placebo**				
Merza 2005	Increase in hematocrit	15 (3/20) n = 2 withdrawals in phase 2	5.3 (1/19)	10 [-9 to 28]
	Significant difference in the percentage change of hemoglobin between the two groups of 4% during phase 1 (p = 0.036). PSA: 25% increase testosterone vs. 6% for placebo (difference between the two means: NS)		n =1 (angina)	
Seftel 2004	Treatment-related Skin reaction leading to study withdrawal	62.7 (64/102) n = 15	40.4 (40/99) 0	22.0 [9.0–36.0] –
Testosterone 5 mg/d Patch + Sildenafil 100mg vs. Placebo Patch + Sildenafil 100mg				
Aversa 2003	No clinically significant adverse events were observed with both treatments			
Testosterone 50 mg Gel (T 50) vs. Testosterone 100 mg Gel (T 100) vs. Andropatch				

McNicholas 2002	Patients reporting ≥ 1 treatment-emergent (erythema, irritation and reactions at application site)	35.3 (24/68) **T 50** 29.2 (21/72) **T 100**	 63.2 (43/68) **Patch**	-28.0 [-44.0, -12.0] -34.0 [-50.0, –19.0]
	Skin irritation	"Very low Incidence" – both groups	47% at day 30 and 53% after 90 days	–
Wang 2000	Skin irritation	5.7 (3/53) **T 50** 5.3 (3/57) **T 100**	 65.8 (50/76) **Patch**	-60.0 [-72.0, –48.0] -61.0 [-73.0, –48.0]
	Urogential events	9.6 (7/73) **T 50** 5.1 (4/78) **T 100**	 0 (0/76) **Patch**	 – –
	Serum PSA levels elevated to above the normal range	1.4 (1/73) **T 50** 5.1 (4/78) **T 100**	 0 (0/76) **Patch**	 – –
	Gynecomastia (2 of the patients had preexisting gynecomastia)	1.4 (1/73) **T 50** 3.8 (3/78) **T 100**	 0 (0/76) **Patch**	 – –
	One patient in T 50 group had depression (discontinued); one patient in T 100 group had high blood pressure (discontinued), and one patient had memory loss/sadness (discontinued); One patient in Patch group discontinued due to elevated hematocrit and hemoglobin			
Testosterone (oral) vs. Propionyl-L Carnitine + Acetyl-L Carnitine				
Cavallini 2004	Mild headache	0 (0/40)	2.2 (1/45)	–

Testosterone 1% Gel + Sildenafil 100mg vs. Placebo Gel + Sildenafil 100mg				
Shabsigh 2004	One patient on testosterone withdrew from the study because of an AE. No further details were provided.			
Testosterone (oral) + Sildenafil (50 or 100mg) vs. Testosterone alone or Sildenafil (50 or 100mg) alone				
Shamloul 2005	No significant adverse events observed (mild headache in three patients on sildenafil 100mg) Slight increase in serum PSA (NS)			
Testosterone 50 mg/d Gel + Tadalafil 20 mg vs. Testosterone 50 mg Gel				
Yassin 2006	No adverse events observed			

* Derogatis Sexual Performance Scale. Range 0 (not at all) to 8 (4 or more times/day)

Table 27: Miscellaneous Treatments: Efficacy and Adverse Events

Author (year) Country	Study Population	Interventions (Dose and duration)	Outcomes		• Any Event • Serious Event • Withdrawals Due to Adverse Event n (%)
			Self rated Erection End Points	RigiScan Measures	
Mann (2001) Germany	13 (6/7) men diagnosed with psychogenic ED	• Oral moclobemide, 450 –600 mg/wk; 8 wks • Placebo	• Clinical Global Impression (GCI), NS between groups	Nocturnal penile response: improvement NS between groups	• 3 (50) vs. 3 (43) • 0 • NR
Piha (2003) Finland	11 hypertensive men 41–58 years old	• Oral moxonidine, 0. 4–0.6 mg/d; 8 wks • Oral metoprolol, 100–200 mg/d; 8 wks	• IIEF–5: positive changes in 9/11 (82%) vs. 0, p<0.0002	NR	NR
Reiter (1998) Austria	40 (20/20) men with low serum DHEAS (<1.5 µmol/L), and ED unrelated to any other known organic cause	• Oral dehydro-epiandrosterone (DHEA) • Placebo	• IIEF, mean scores in all 5 domains improved in DHAE vs. placebo	NR	• 0 • 0 • 0
Safarinejad (2001) Iran	44 men 28–55 years old with vasculogenic ED	• Oral isoxsuprine hydrochloride, 60 mg/d; 30 d • Placebo	• Complete erectile response 8.3% vs. 8.3% (NS)	NR	• 70% vs. 15% • 1 (2.3) vs. 0 • NR
Sommer (2006) Germany	18 (NR) men with ED (no etiology reported)	• Oral (BH4) + VSS, 200 or 500 mg; once • Placebo; once	• NR	Improved duration of >60%: at base 33.1 and 36.1 min; at tip by 29.4 and 33.7 min (200 and 500 mg respectively)	• 3 (17) vs. 1 (5.6) • NR • NR
Sommer (2006) Italy	176 (NR) men with DM type II and ED of longer than	• Oral myoinositol + folic acid Combination, 4g + 400µg; 12 wks • Placebo; 12 wks	• Mean IIEF–5 change: 8 vs. -1	NR	• NR

Author (year) Country	Study Population	Interventions (Dose and duration)	Outcomes		• Any Event • Serious Event • Withdrawals Due to Adverse Event n (%)
			Self rated Erection End Points	RigiScan Measures	
	6 mo of organic cause				
Sommer (2006) Canada	68 men > 18 years old diagnosed with depressive disorder and ED for longer than 6 mo	• Oral tianeptine, NR; 8 wks • Placebo; 8 wks	• Patients with full response to treatment: 72.7% vs. 27.9% • Patients with successful sexual intercourse: 89.4% vs. 50.0%	NR	• 5 (7.4) vs. 1 (1.5) • NR • NR
Speel (2005) the Netherlands	59 men with mean age of 60 years old, and atherosclerosis ED	• Oral angiotensin-converting enzyme (ACE), 20 mg/d; 26–46 wks • Placebo	• IIEF–EF: severity of ED improved in both groups (NS between groups)	NR	• 11 (37) vs. 4 (14) • NR • NR
Van Ahlen (1995) Germany	20 men with mean age of 46 y, and idiopathic ED	• Oral Naltrexone (NTX), 25 or 50 mg/d; 3 mo • Placebo; 3 mo	• Early morning erections change from baseline 1.39 vs. 0.22 ($p<0.05$)	NR	• NR

Table 28: Nonarteritic Anterior Ischemic Optic Neuropathy (NAION)

Study	Study Design	Subject(s) (number, age, co-morbidities, medical history)	Treatment (type, dose)	Visual Complaint (or diagnosis)	Relative Risk (RR) 95% CI
Akash (2002)	Case report	n = 1 54 years Caucasian None	100 mg 2–3/week; one time overdose: 200 mg	Blindness in left eye hours post overdose Left combined NAION w+ cilioretinal artery occlusion	NA
Cunningham (2001)	Case report	n = 1 42 years Depression	50 mg/d; 3 doses	Blurred vision post 2nd and 3rd dosing NAION	NA
Dheer (2002)	Case report	n = 1 48 years None	100 mg/d; two doses	Blue flashes and blurring vision in both eyes NAION	NA
Egan (2000)	Case report	n = 1 52 years Transurethral resection for prostate cancer	50 mg; single dose	Bilateral blue lightning bolts and blurry vision within 1 hr post dosing NAION	NA
Gedik (2006)	Case report	n = 1 36 years NR	100 mg; two separate dosing 4 months apart	Blurred vision deteriorated to light perception in both dosing cases NAION	NA
Grugn (2004)	Case report	n = 1 69 years (only case reported to date in Scandinavia)	50 mg (single dose)	Abnormal vision in right eye NAION	NA
Margo (2007)	Retrospective cohort	n = 479,489 Veterans ≥50 years; documented PDE–5 inhibitor use	100 mg in 99.4% of pts	NR Diagnosed NAION: n = 442 (<1%) Possible NAION: n = 228 (<1%)	RR for diagnosed NAION = 1.02 (95% CI 0.92–1.12)* RR for possible NAION = 1.34 (95% CI: 1.17–1.55)

Pomeranz (2002)	Case series	n = 5 42–69 years, elevated lipids, smoking, diabetes, coronary artery disease, diagnosis of NAION (n = 1)	50–100 mg	Loss of vision in the affected eye within min to hrs post dosing NAION	NA
Pomeranz (2005)	Case series	n = 7 50–69 years, hypertension, diabetes, elevated cholesterol, or hyperlipidemia	25–50 mg (dosing regiment ranged from single dose to sporadic use over several years)	Vision loss [unilateral (n=6), bilateral (n=1)] NAION	NA
Sinha (2004)	Case report	n = 1 61 years, smoking	200 mg at once (usual dose of 100 mg)	Loss of vision in right eye Possible NAION	NA

* Relative risk was calculated as ratio of risks in men exposed to PDE–5 inhibitors those unexposed.

Table 29: Penile Fibrosis in Studies of Intracavernosal Injection (Non-randomized)

Study	Study Design	Patients	Treatment(s)	Treatment Duration	Fibrosis % (n/N) by Treatment Group
Perimenis 2006	Clinical trial	38 Greek men Mean age 56.4 (range 42–62) years With diabetes mellitus (DM) (type I and II)	1. Prostaglandin (PGE_1) 5–20 µg 2. Papaverine (PAP) ≥8 mg 3. PGE_1 + PAP 20 µg/ 8 mg	10 years	13.2% (5/38)
Althof 1991	Clinical trial	42 American men, mean age 54.4 years	PAP + phentolamine, NR	12 months	26%
Canale 1996	Clinical trial	68 Italian men, mean age 50.5 (22-70) years	PGE_1, 20 µg/ml /wk (20-60 µg/2-3 d in one case)	> 12 months	4.4% (3/68)
Porst 1998	Clinical trial	162 European men, mean age 54 (22-70) years	PGE_1, NR	1- 4 y	11.7% (19/162) 1st y: 6.8% 2nd y: 2.5% 3rd y: 7.3% 4th y: 1.7%
Claro 2001	Retrospective cohort	168 Brazilian men, median age 61 (43–78) years, had undergone prostatectomy for localized prostate cancer	1. PAP + Phentolamine (PHEN) + PGE_1 22.6 mg / 1.34 mg/ 13.4 mg	NR	0%
Lepore 2001	Clinical trial	52 Italian men, mean age 56.7 (range 35–74) years With diabetes	1. PGE_1 NR 2. Sildenafil	3 months	0%
Perimenis 2001	Clinical trial	40 Greek men 18 diabetic and 22 non–diabetic controls Mean age 55.6 (48–64)	1. PGE_1 5–20 µg 2. PAP 8–16 mg 3. PGE_1 + PAP 20 µg/ 8–16 mg	7 years	17.5% (7/40) One non-diabetic control developed early Peyronie's plaque leading to study withdrawal
Wespes 2000	Clinical trial	10 Belgian men, mean age 56.5 (46–69) years	1. PGE_1 6–20 ug	NR	0%
Shmueli 1999	Clinical trial	452 Israeli men, mean age 59.5 (26–85) years	Protocol I: PAP + PHEN 6–25 mg/ 0.05–1.5 mg.	6 months	0% Small nodules

Study	Study Design	Patients	Treatment(s)	Treatment Duration	Fibrosis % (n/N) by Treatment Group
			Patients who failed received Protocol II: PGE_1 10–25 µg. Patients who failed received Protocol III: PAP + Phentolamine + PGE1 Patients who failed received Protocol VI: PAP + Phentolamine + PGE1+ atropine 0.02–0.06 mg		Protocol I: 0.6% (3/452) Protocol II: 2% (3/147) Protocol III: 3.5% (3/86) Protocol IV: 9.7% (3/31)
Chew 1997	Retrospective cohort	245 Australian men, mean age 62 (21–79) years, hypertension (22.8%), DM (8.5%)	1. PGE_1 2–60 µg (mean 13 µg)	2.1 years (up to 86 months)	23.3% (57/245)
Sundaram 1997	Retrospective cohort	160 American men Age not reported	1. PAP 30 mg 2. PAP + PHEN 25 mg + 0.83 mg 3. PGE_1 NR (alternative therapy)	1–5 years	<1% (1 patient)
Gupta 1997	Retrospective cohort	1089 American men, mean age 62 (21–94) years	1. PGE_1 5–10 µg 2. TRIMIX 4.41 mg/ 0.5 mg/ 1.47 µg 3. PGE_1 + PAP 5–10 µg/ 30 mg 4. PAP + PHEN 30 mg/ 0.5 mg	Up to 80 months	Penile scarring /nodules in patients discontinuing therapy 1. PGE_1 10.7% (8/75) 2. TRIMIX 23.1% (6/26) 3. PAP + PHEN 11.1% (4/36)
Flynn 1996	Retrospective cohort	126 British men, mean age 57 (27–77) years, 40% had co-morbidities	1. PAP NR 2. PAP + PHEN NR	3.9 years	<1% (1 subject)
Chen 1996	Retrospective cohort	92 American men, mean age 58.6 (32–78) years, 67% had co-morbidities	1. PGE_1 initial dose <10 µg/ml in most cases	1–56 months	16.3% (15/92)
Bolayir 1994	Clinical trial	40 Cypriot men,	1. PAP +	1 year	2.5% (1/40)

Study	Study Design	Patients	Treatment(s)	Treatment Duration	Fibrosis % (n/N) by Treatment Group
		age range 40–75 years	Verapamil 20–35 mg/5 mg		
Hattat 1994	Clinical trial	69 Turkish men, mean age 52.6 (31–71) years	1. PGE_1 NR 2. PAP NR	13.6 months	3.6% (2/56) PAP 0 (0/13) PGE_1
Betts 1994	Clinical trial	46 British men, mean age 39 (26–58) with multiple sclerosis	1. PAP 10–80 mg	NR	2.2% (1/46)
Chiang 1992	Clinical trial	51Taiwanese men, mean age 58.3 (29–79) years	1. PGE_1 5–40 µg 2. PAP 15–60 mg	1 year	3.9% (2/51)
Kerfoot 1991	Retrospective cohort	119 American men Group 1 (n = 65): Geriatric (>65), mean age 70 years Group 2 (n = 54): younger, mean age 47	1. PAP + PHEN 30 mg / 1.0 mg (titrated up to 1.5 if no response)	> 6 months	2.5% (3/119)
Schramek 1990	Clinical trial	149 Austrian men, Mean age 56.5 (25–76) years	1. PGE1 10–40 µg	NR	0%

Figures

Note: Figure 1 (Analytic Framework) and Figure 2 (Quorum Flow Chart) are found in Chapter 2.

Figure 3. The mean IIEF "EF domain" score

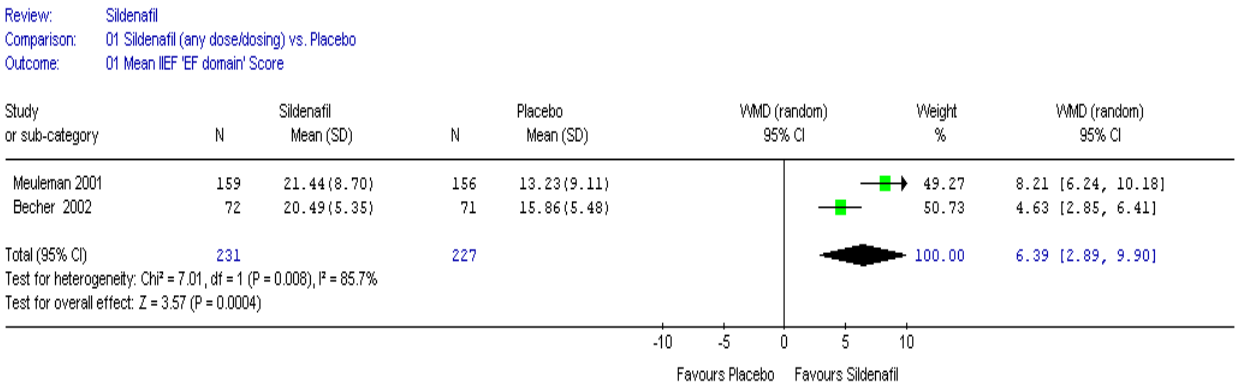


Figure 4. The mean IIEF–Q3 score

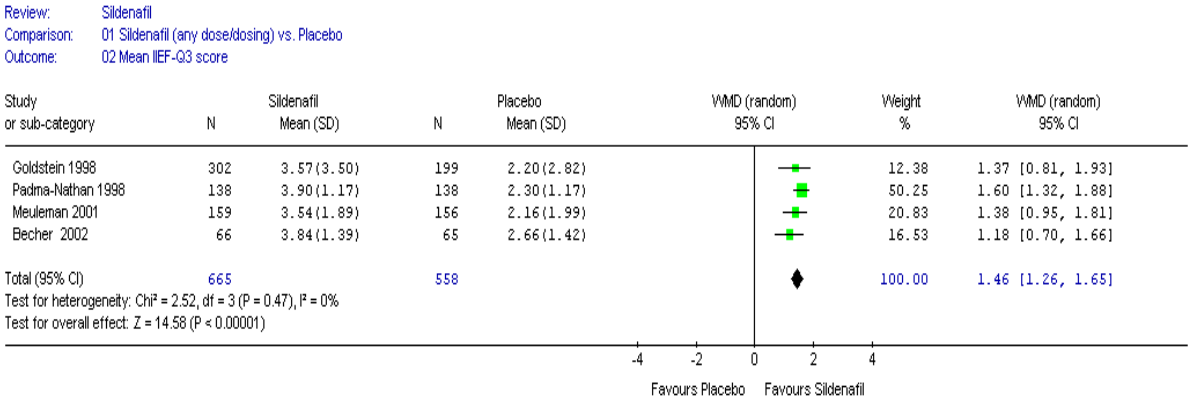


Figure 5. The mean IIEF–Q4 score

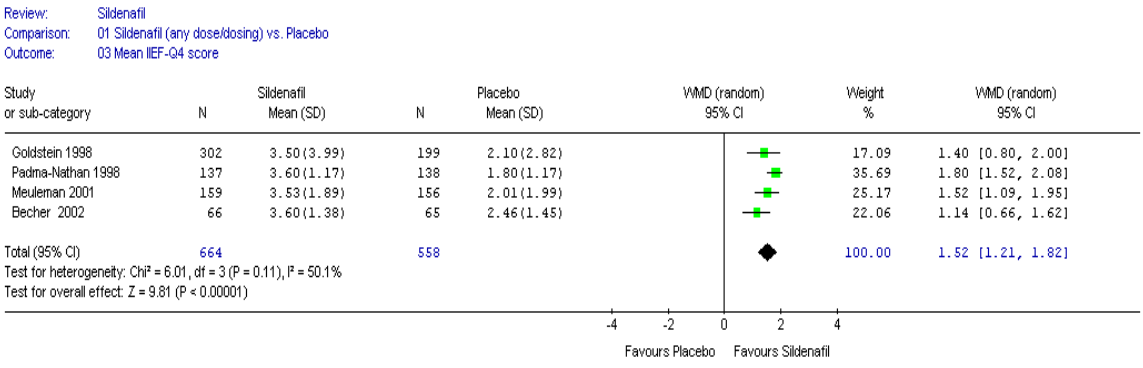


Figure 6. Improved erection (GEQ–Q1)

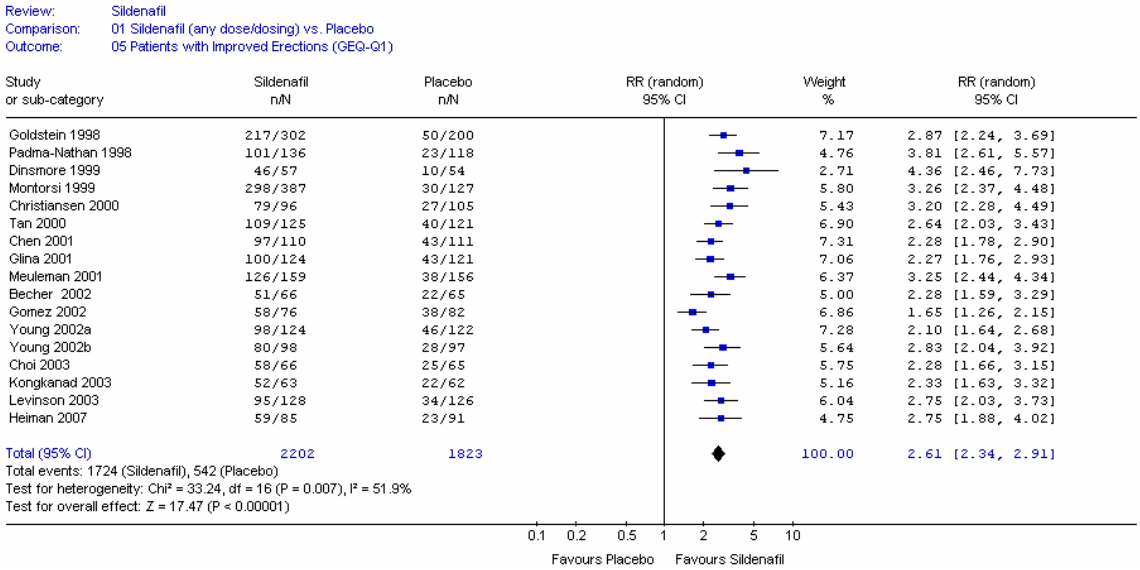


Figure 7. Any adverse events (all cause)

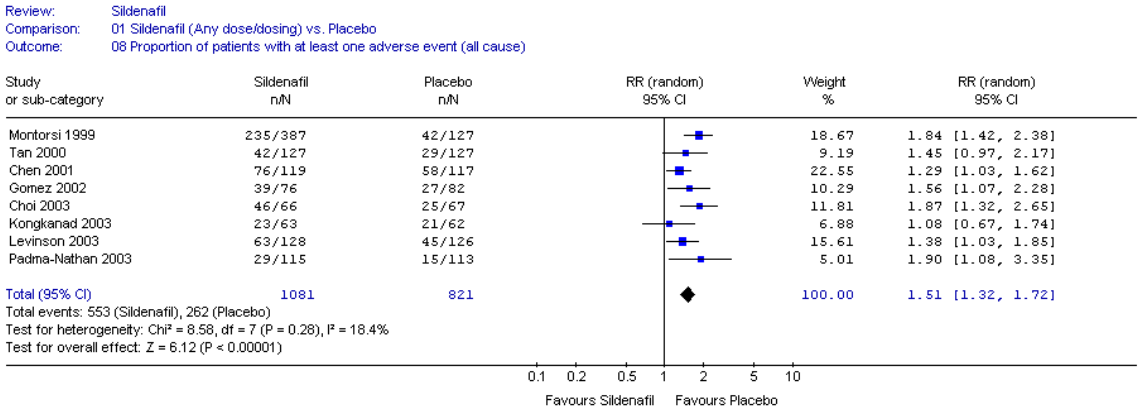


Figure 8. Any adverse events (treatment-related)

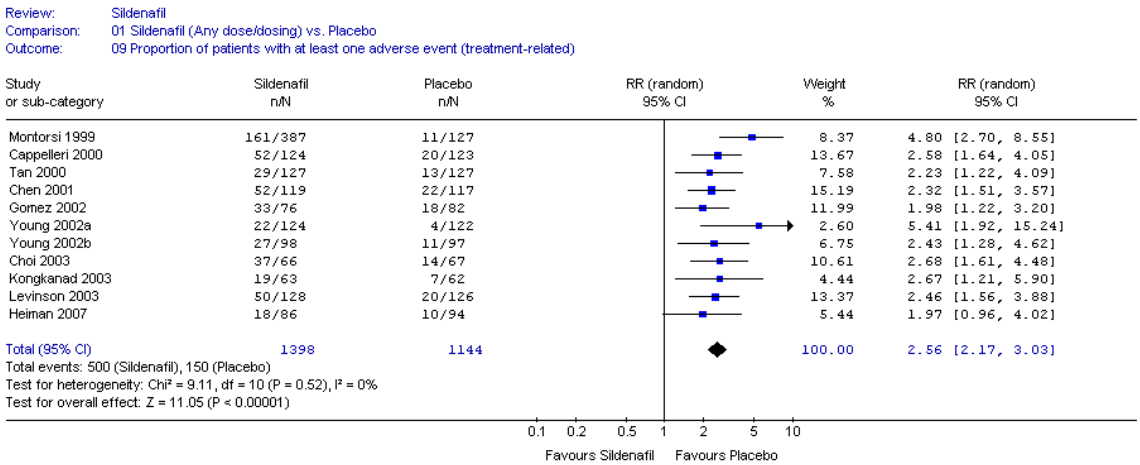


Figure 9. Headache (all cause)

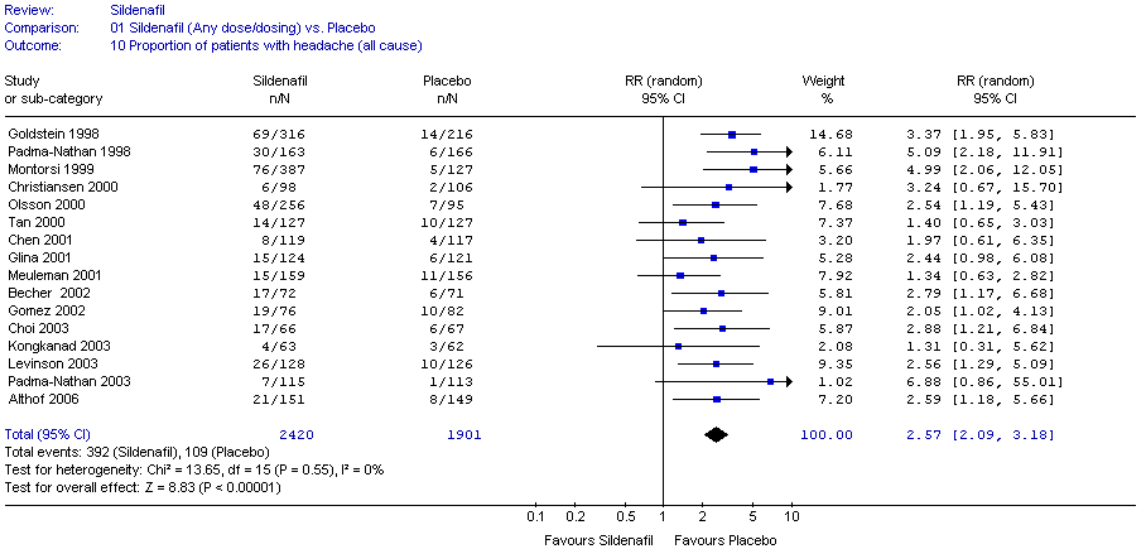


Figure 10. Flushing (all cause)

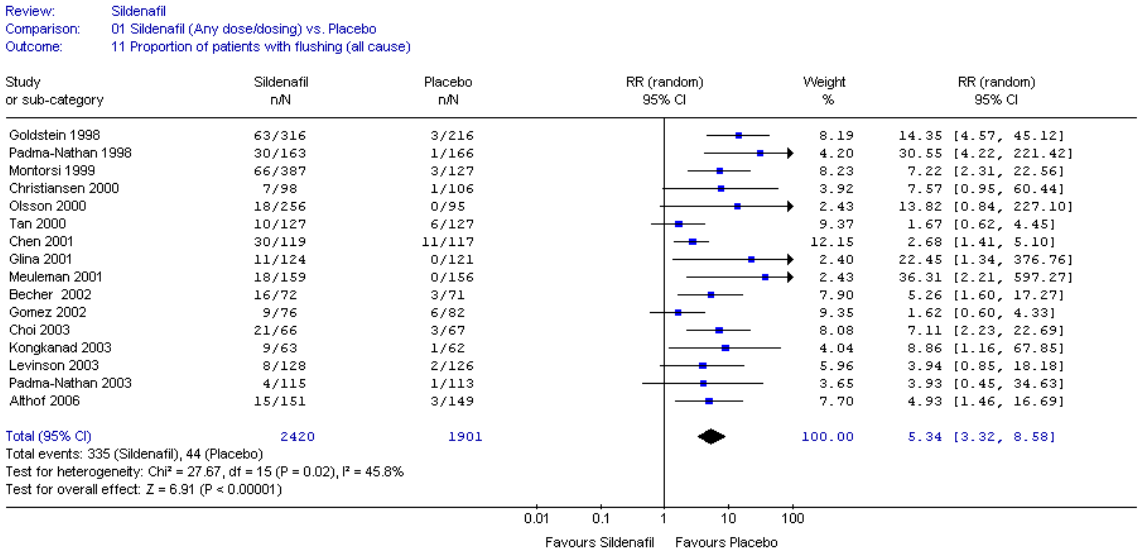


Figure 11. Visual disturbances (all cause)

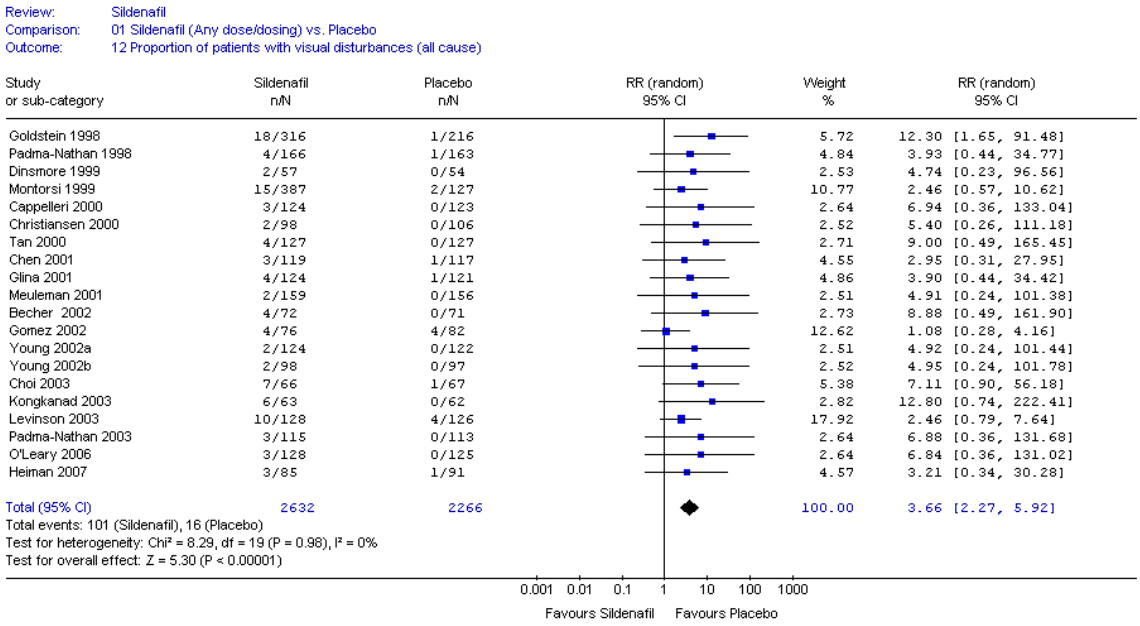


Figure 12. Improved erection (GEQ–Q1): Type I-II diabetes

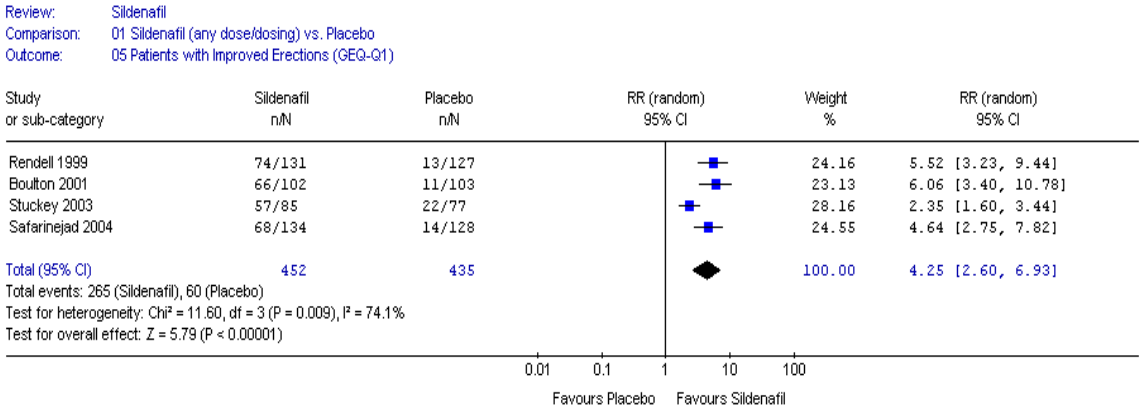


Figure 13. Improved erection (GEQ–Q1): Type II diabetes

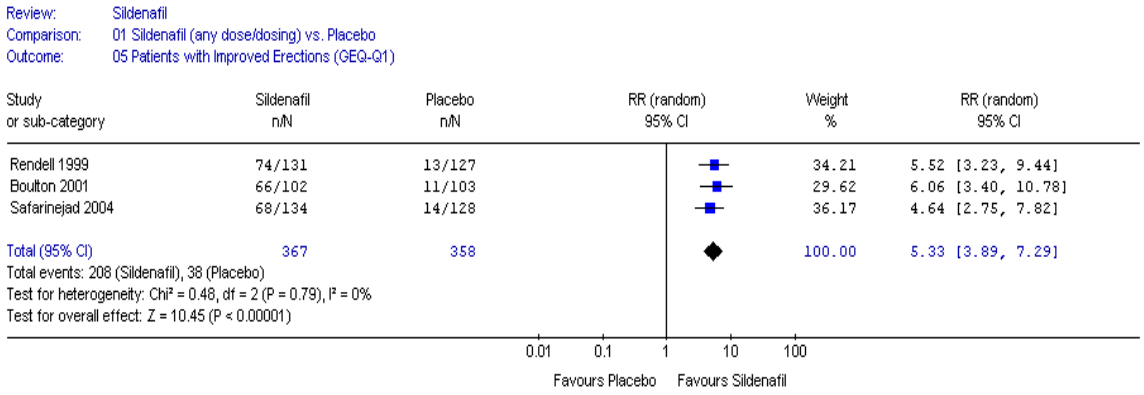


Figure 14. The mean IIEF–Q3 score: Type I-II diabetes

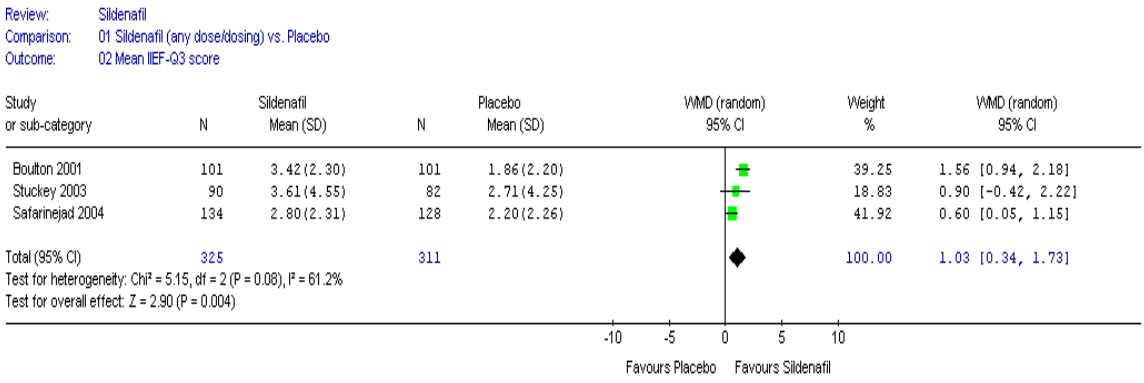


Figure 15. The mean IIEF–Q4 score: Type I-II diabetes

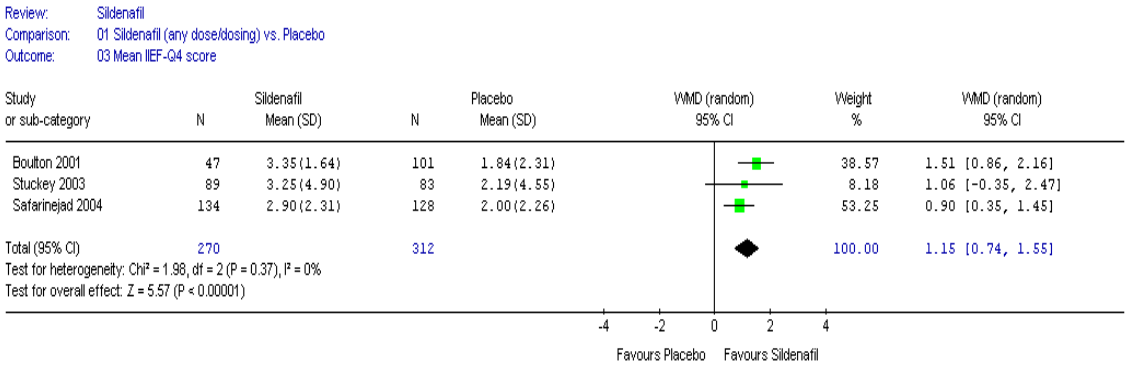


Figure 16. Any adverse events (treatment-related): Type I-II diabetes

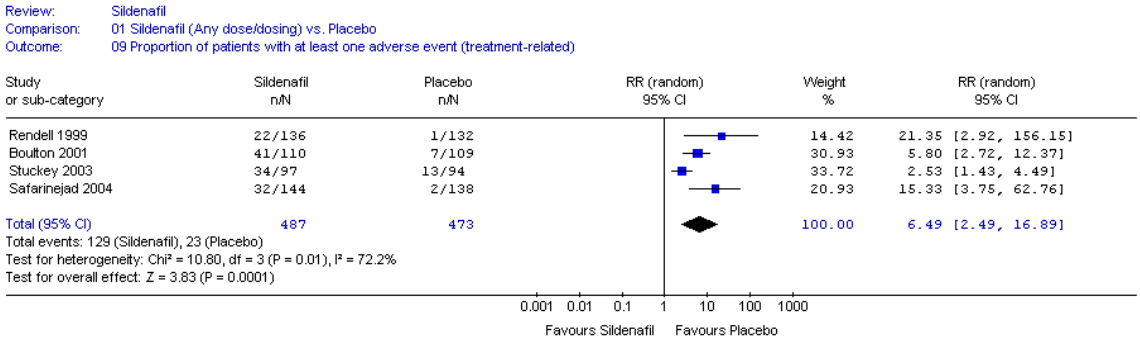


Figure 17. Any adverse events (treatment-related): Type II diabetes

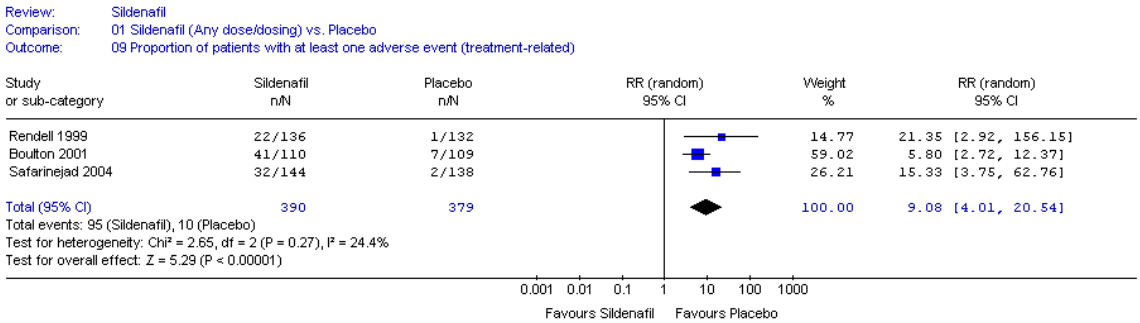


Figure 18. Successful intercourse attempts: major depressive disorder in remission

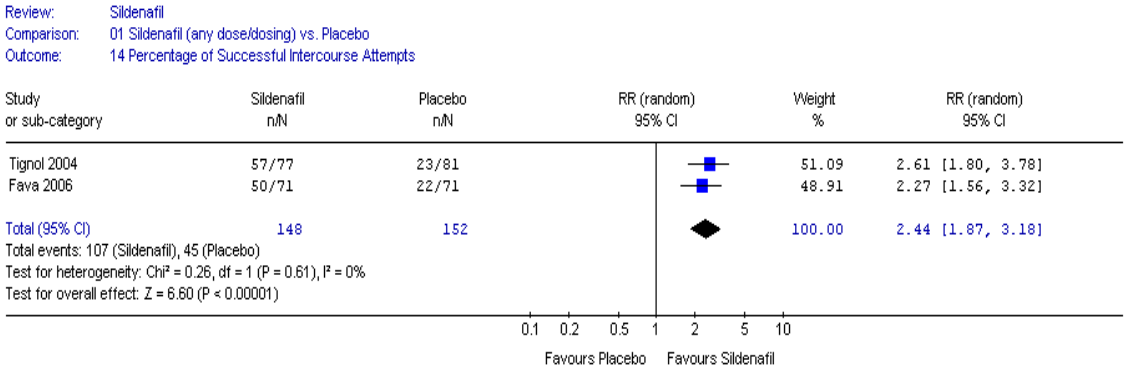


Figure 19. Improved erection (GEQ–Q1): major depressive disorder in remission

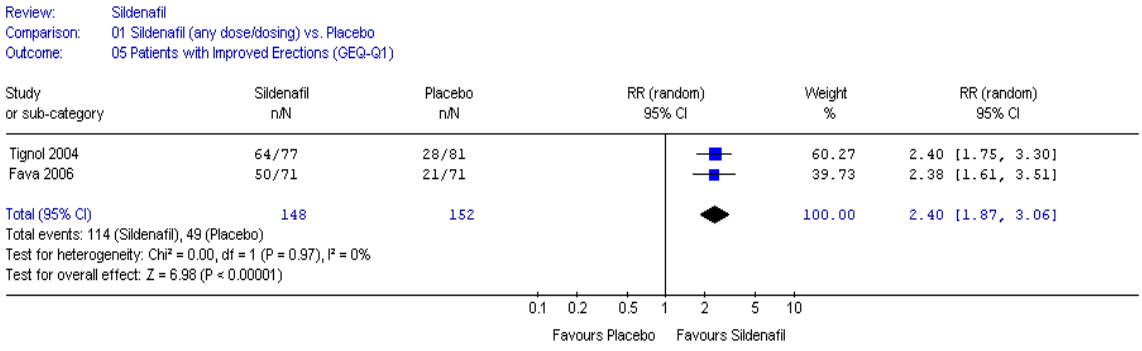


Figure 1. The mean IIEF–Q3 score: major depressive disorder in remission

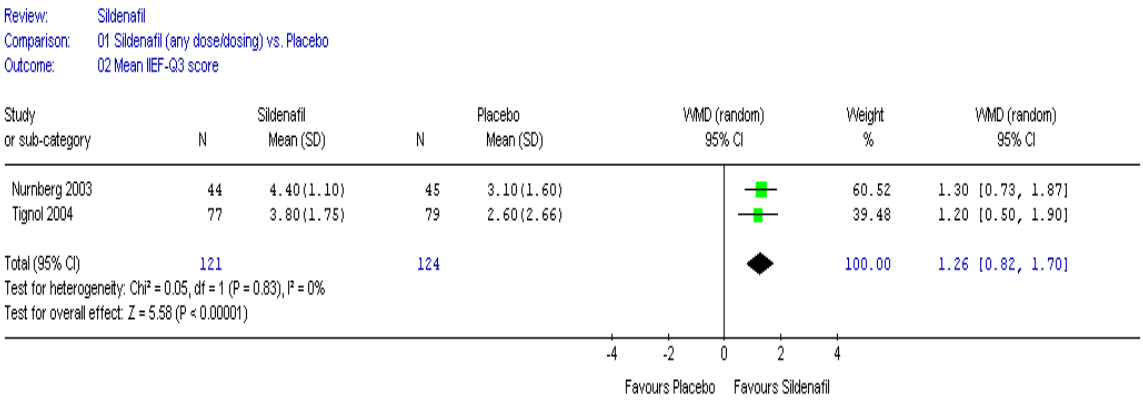


Figure 212. The mean IIEF–Q4 score: major depressive disorder in remission

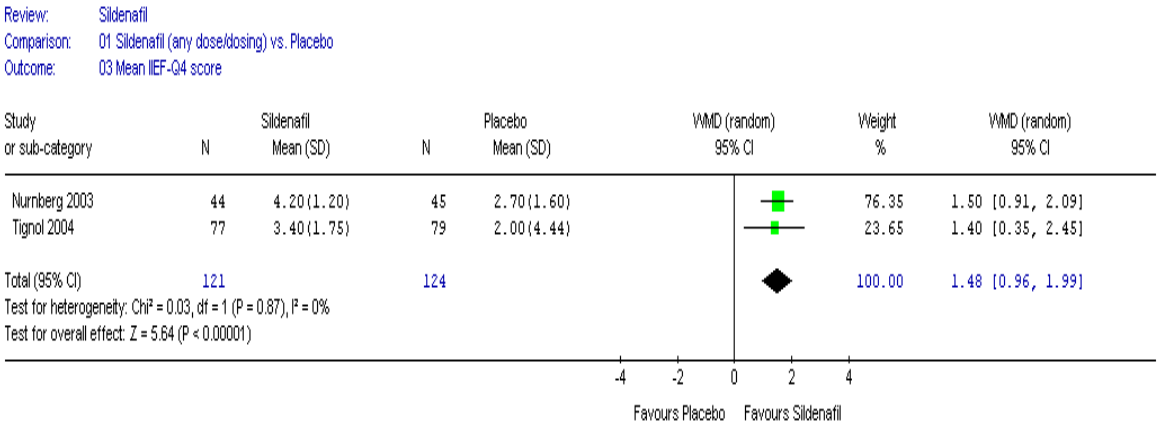


Figure 22. The mean IIEF–Q3 score: patients with hypertension taking anti-hypertensive drugs

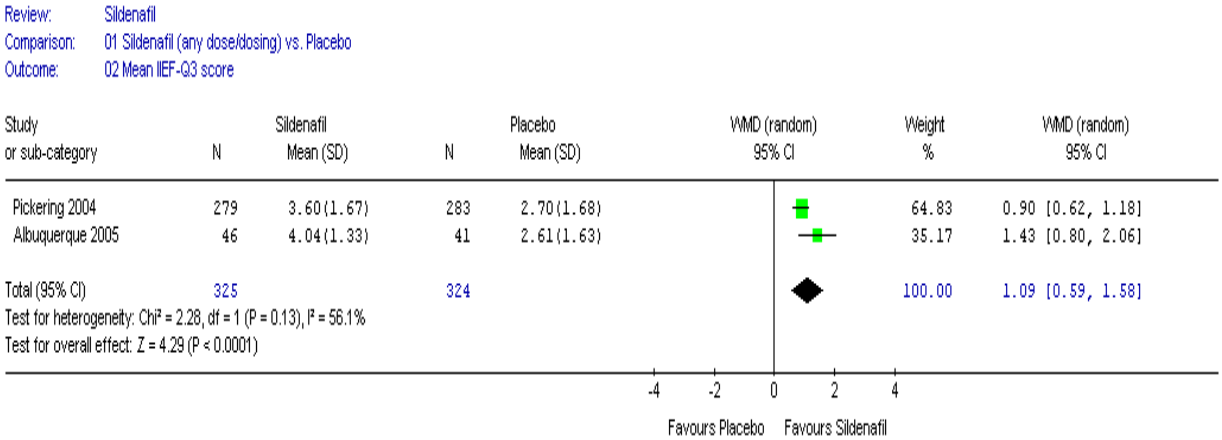


Figure 23. The mean IIEF–Q4 score: patients with hypertension taking anti-hypertensive drugs

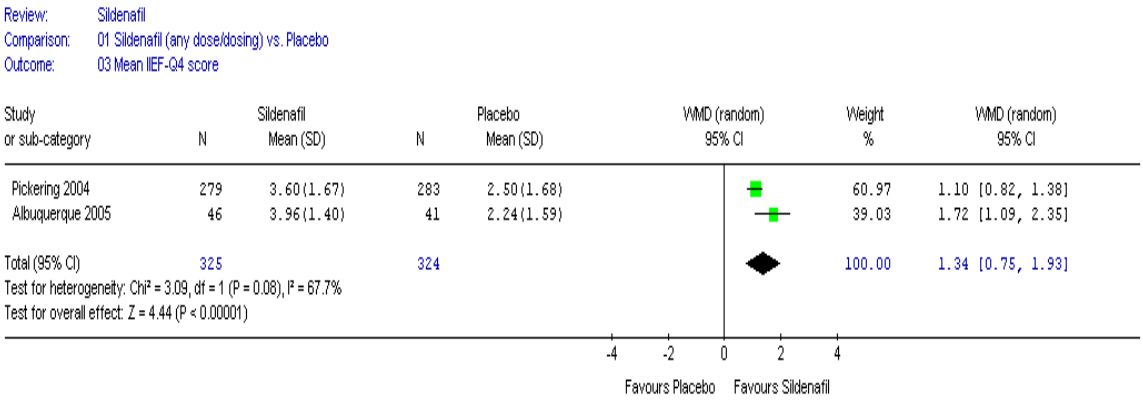


Figure 24. Improved erection (GEQ–Q1): patients with hypertension taking anti-hypertensive drugs

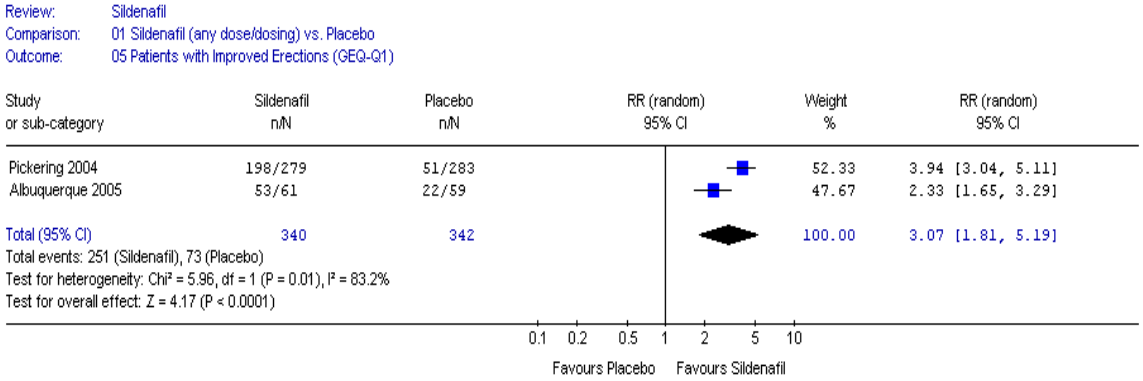


Figure 25. Successful intercourse attempts: patients with hypertension taking anti-hypertensive drug*s*

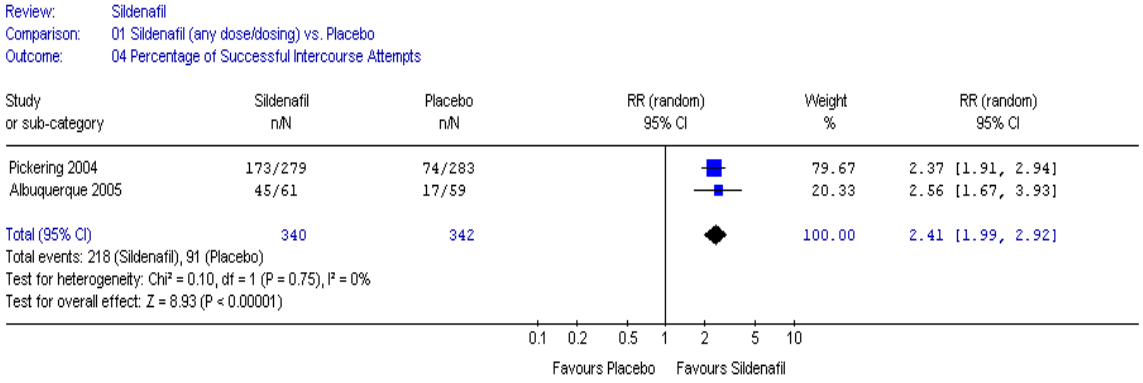


Figure 26. Any adverse event (all cause): patients with hypertension taking anti-hypertensive drugs

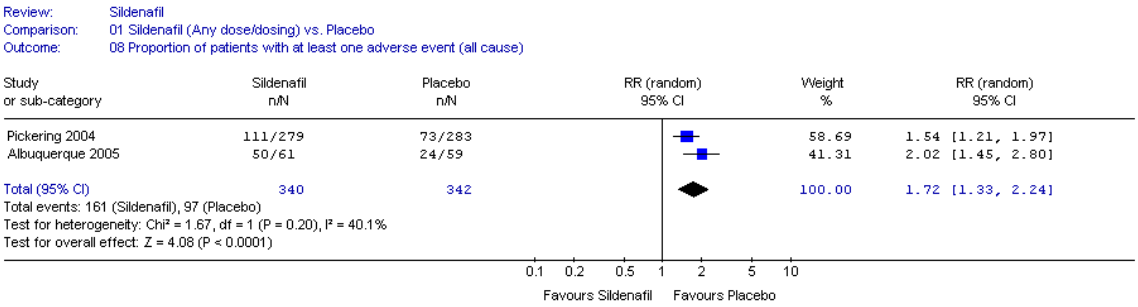


Figure 27. Headache (treatment-related): patients with hypertension taking anti-hypertensive drugs

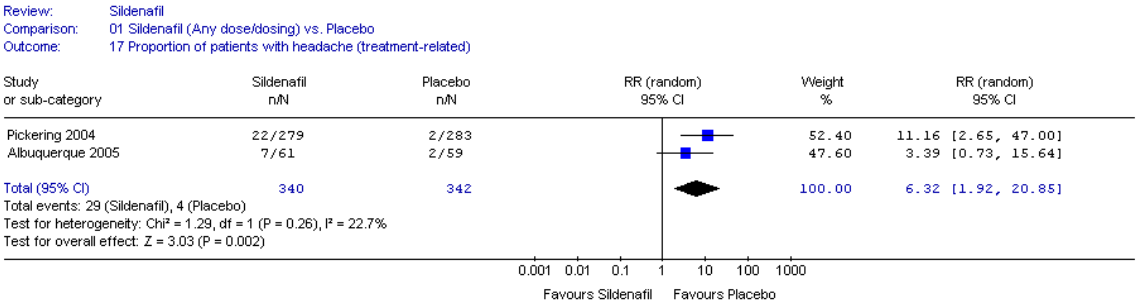


Figure 28. Dyspepsia (treatment-related): patients with hypertension taking anti-hypertensive drugs

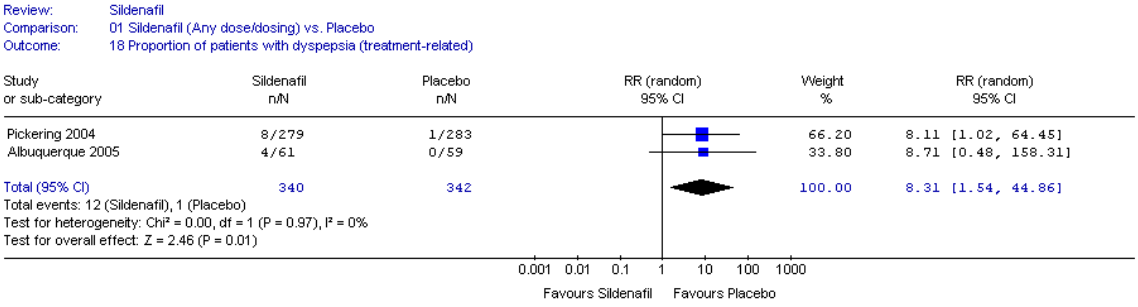


Figure 29. Flushing (treatment-related): patients with hypertension taking anti-hypertensive drugs

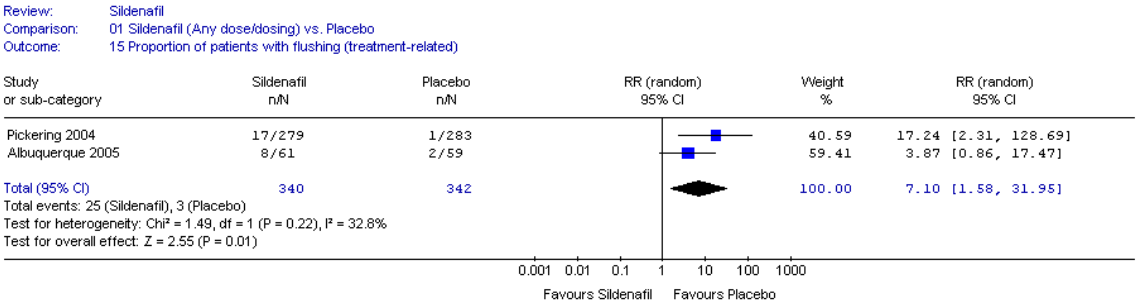


Figure 30. Improved erection (GEQ–Q1)

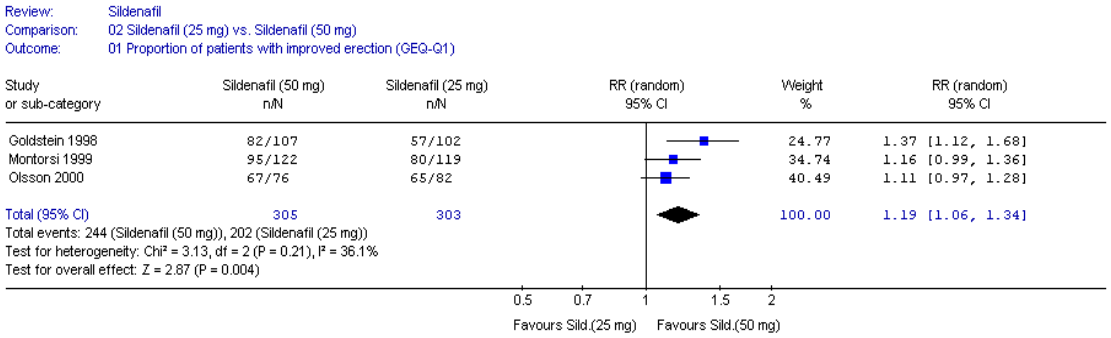


Figure 31. Headache (all cause)

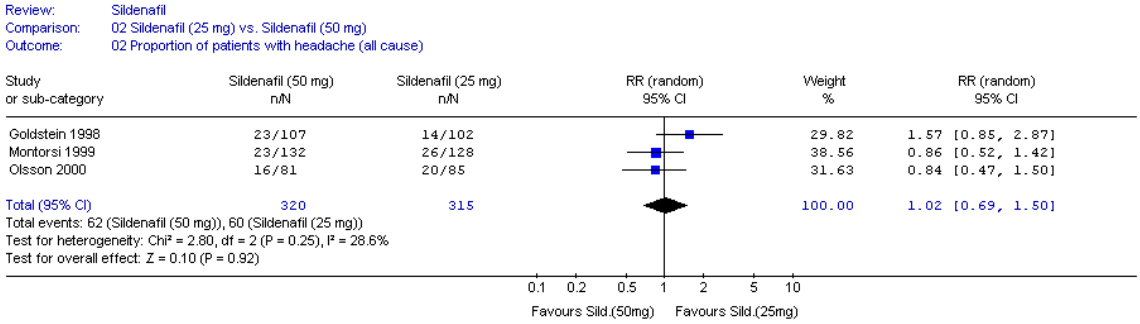


Figure 32. Flushing (all cause)

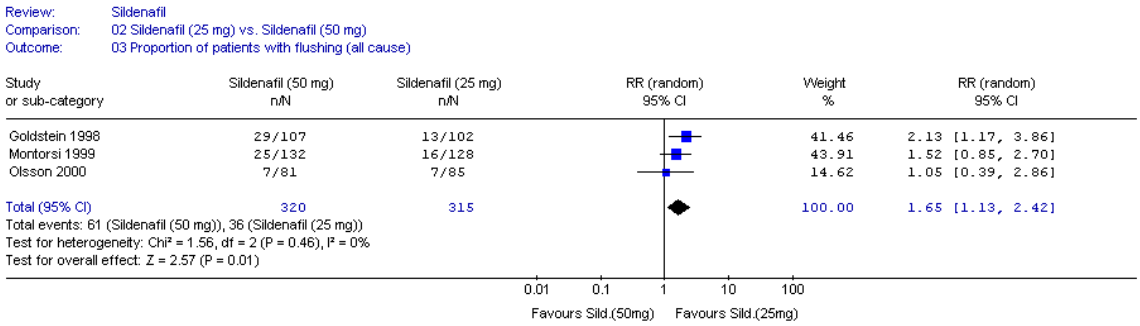


Figure 33. Visual disturbances (all cause)

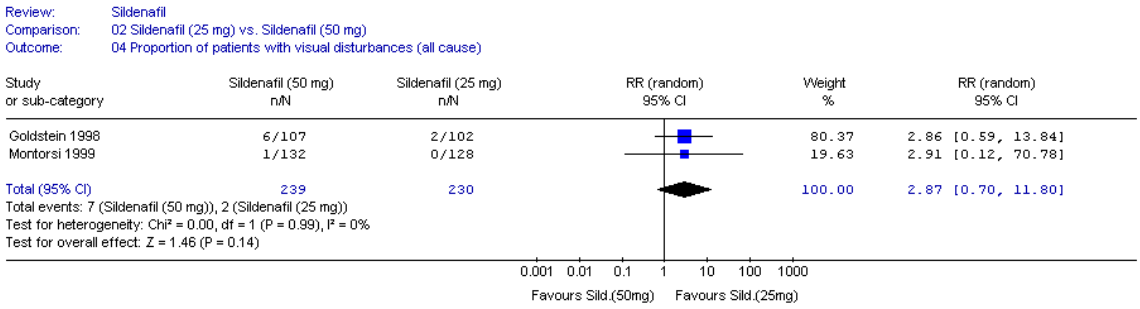


Figure 34. Improved erection (GEQ–Q1)

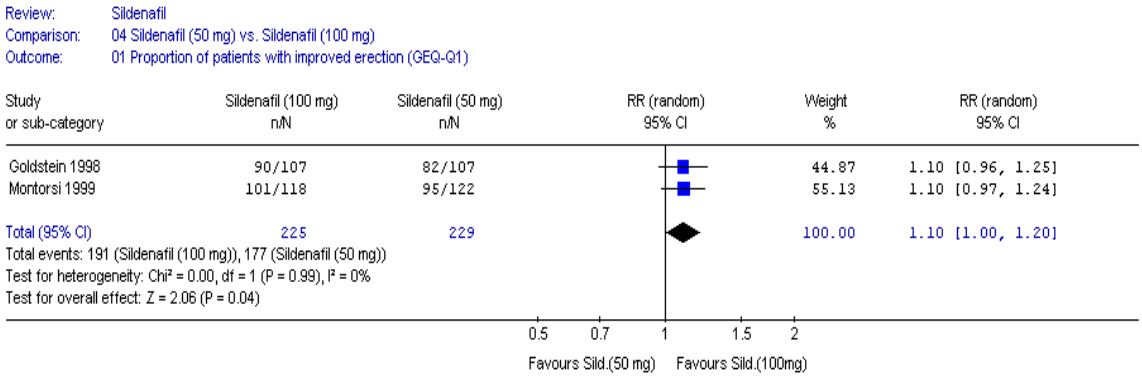


Figure 35. Headache (all cause)

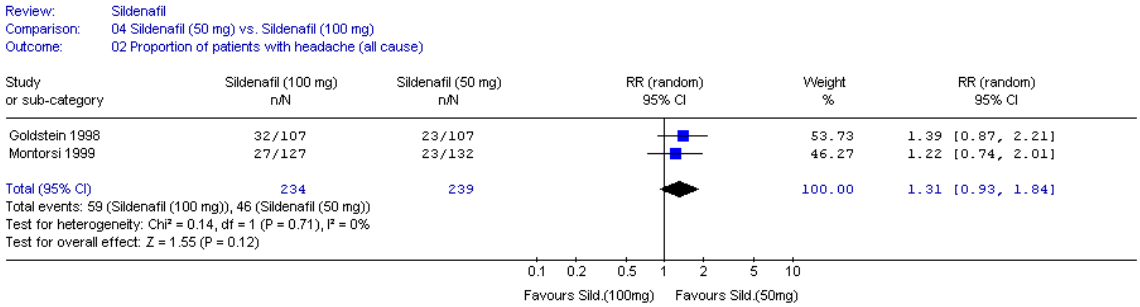


Figure 36. Flushing (all cause)

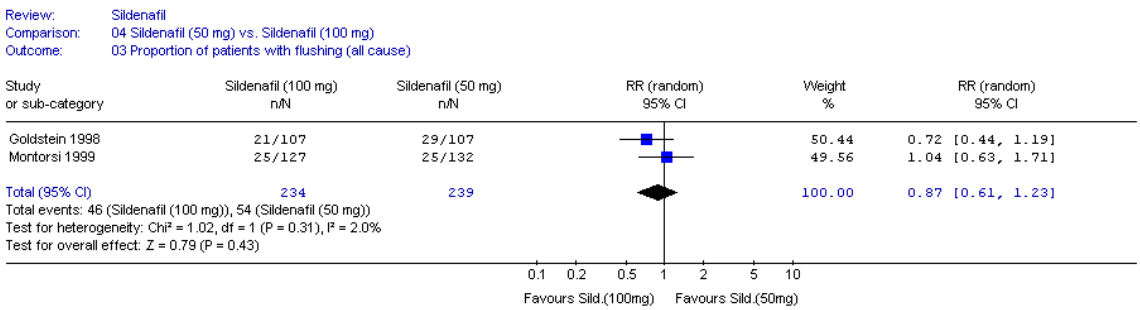


Figure 37. Visual disturbances (all cause)

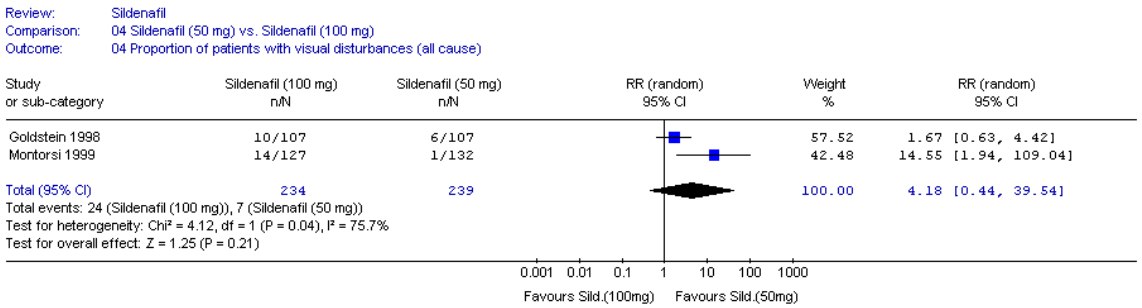


Figure 38. The mean IIEF "EF domain" score

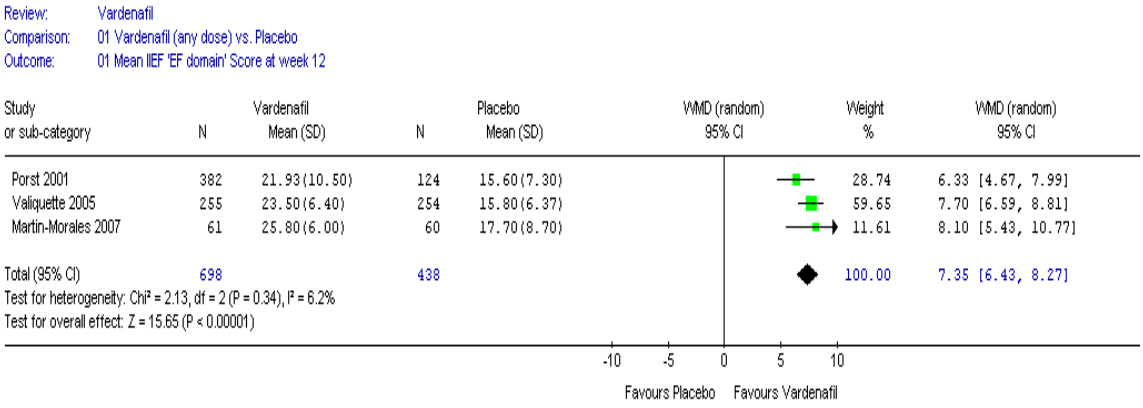


Figure 39. Successful intercourse attempts (SEP–Q2)

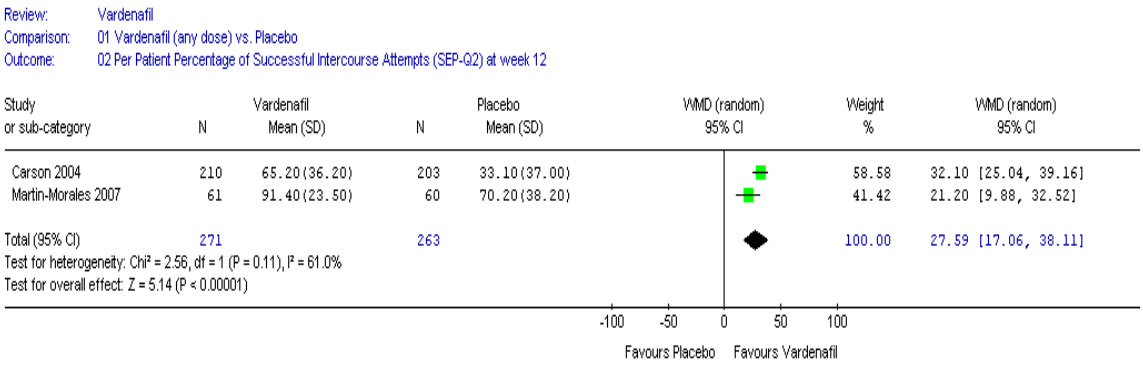


Figure 40. Successful intercourse attempts (SEP–Q3)

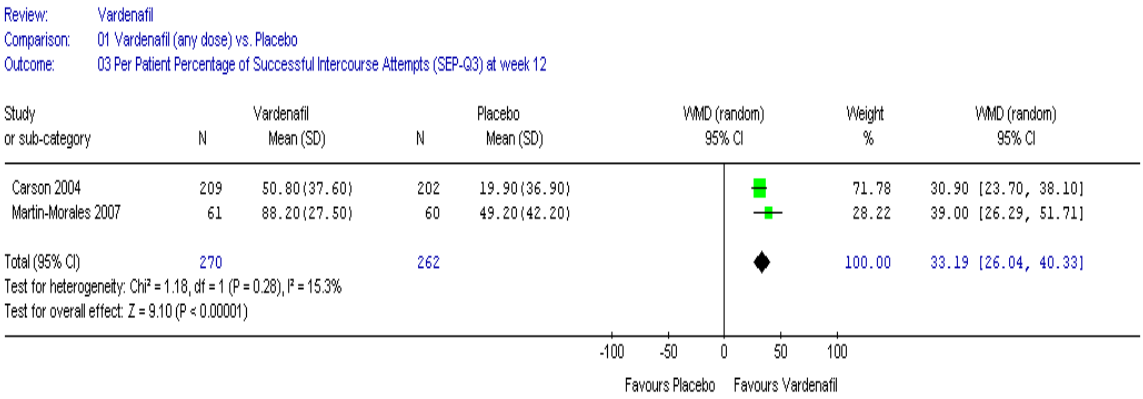


Figure 41. Improved erection (GAQ–Q1)

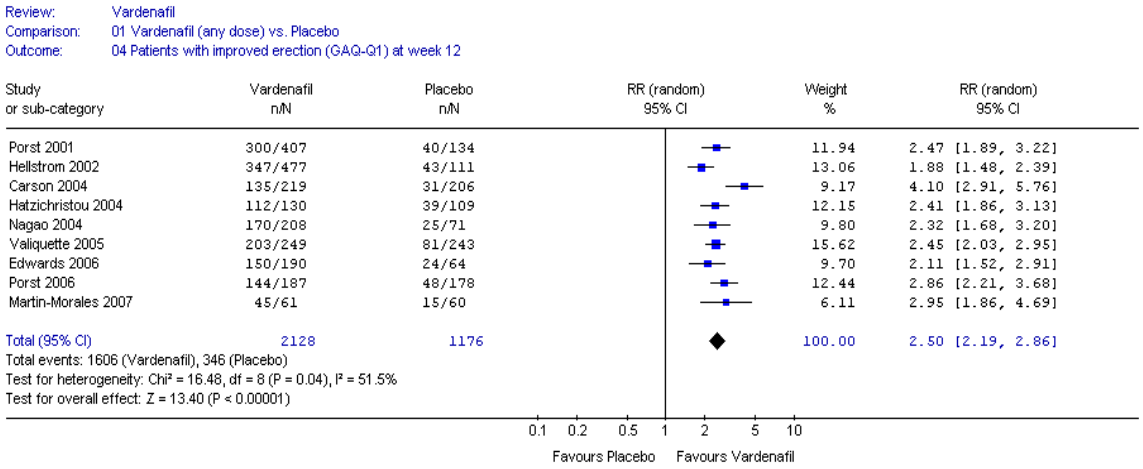


Figure 42. Improved erection without Carson 2004 (GAQ–Q1)

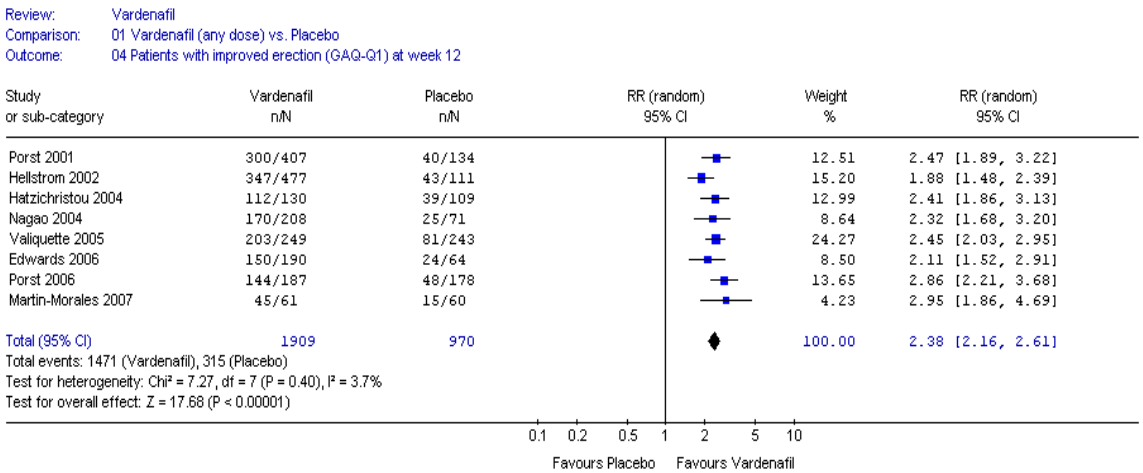


Figure 43. IIEF-EF ≥ 26 at follow up (weeks 10–12)

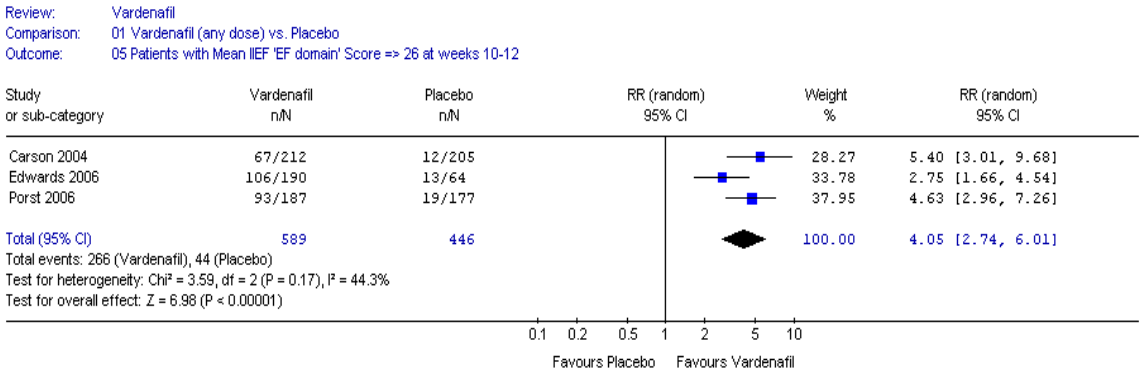


Figure 44. Any adverse events (all cause)

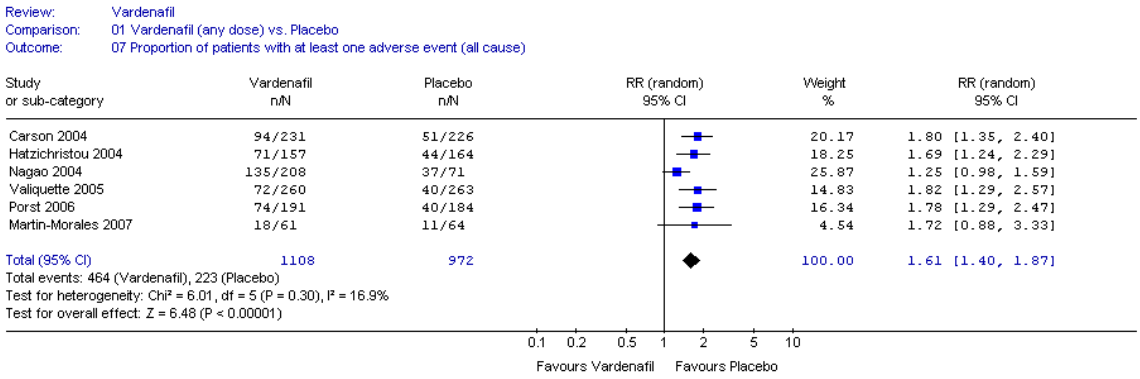


Figure 45. Withdrawals due to adverse events

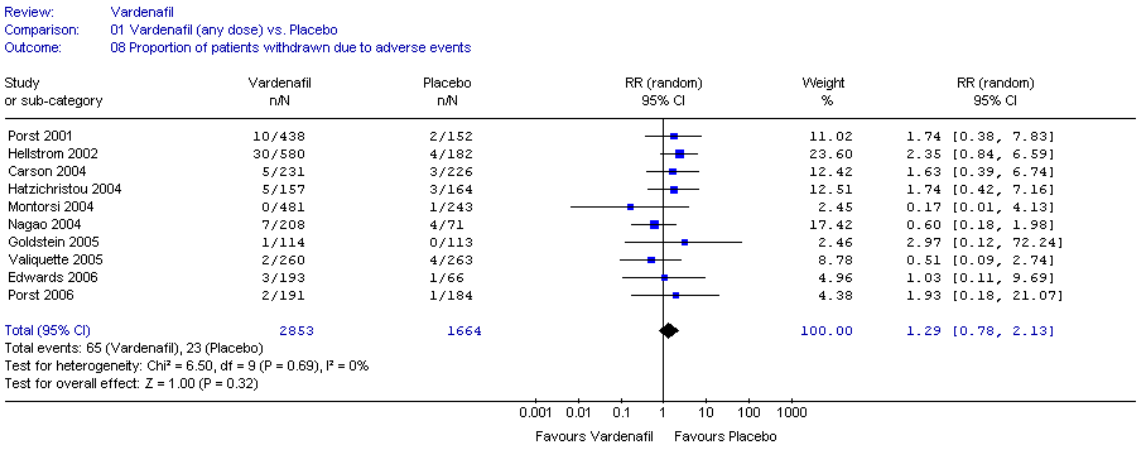


Figure 46. Serious adverse events

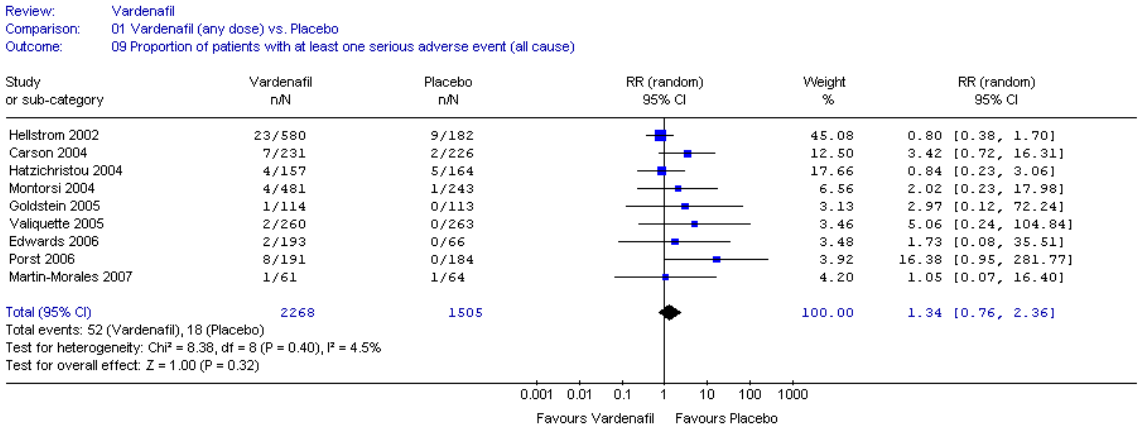


Figure 47. Headache (all cause)

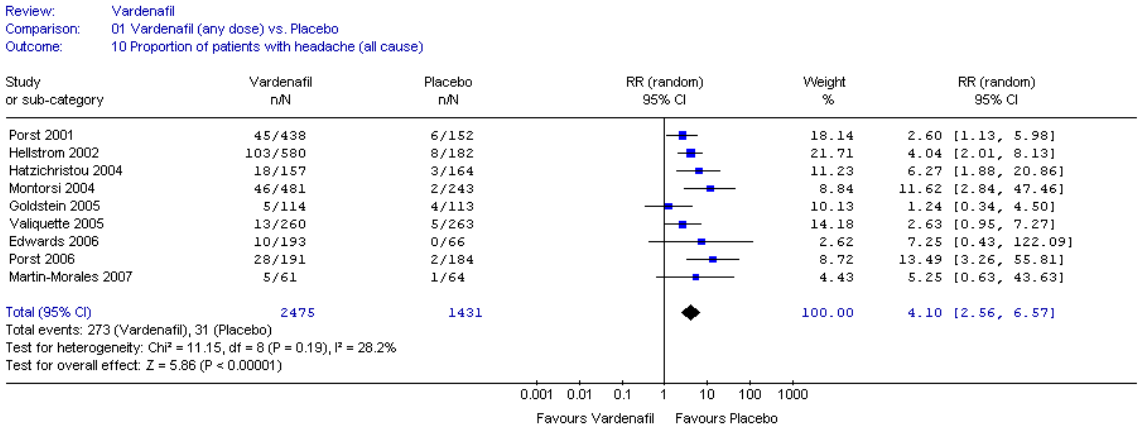


Figure 48. Flushing (all cause)

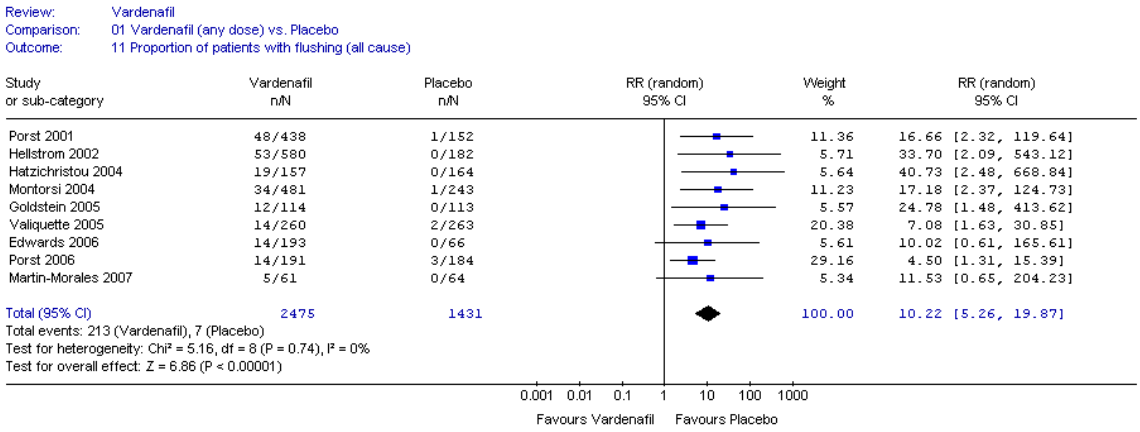


Figure 49. Dyspepsia (all cause)

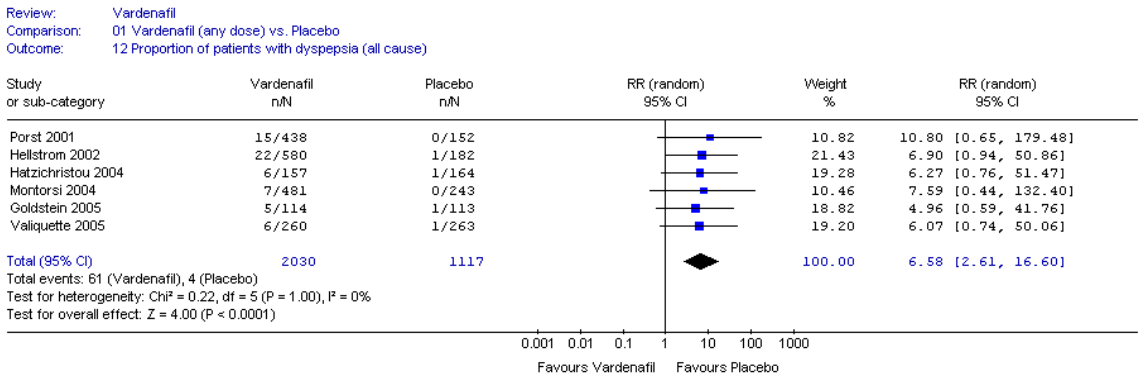


Figure 50. Serious adverse events: patients with diabetes

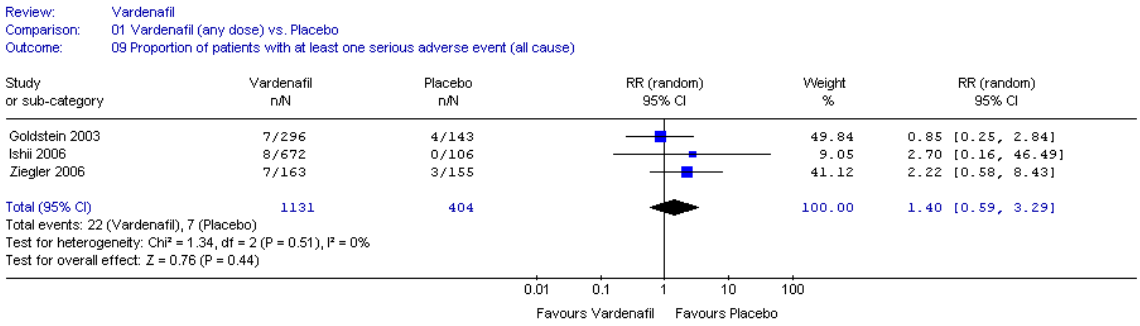


Figure 51. Withdrawals due to adverse events: patients with diabetes

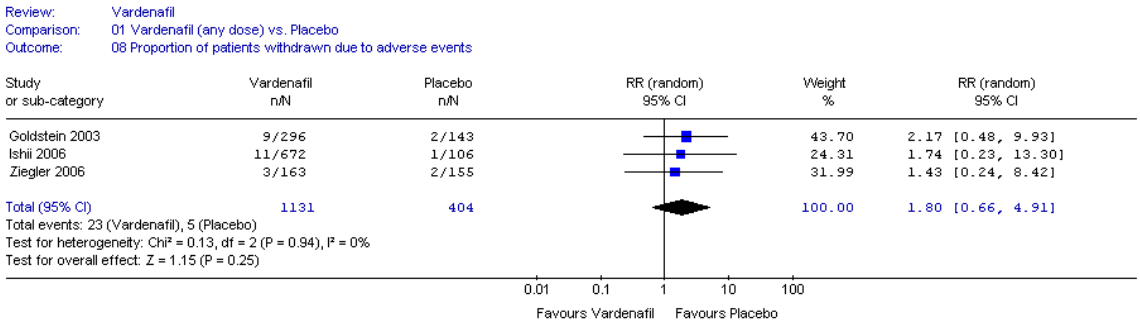


Figure 52. The mean IIEF "EF domain" score (at week 12–104)

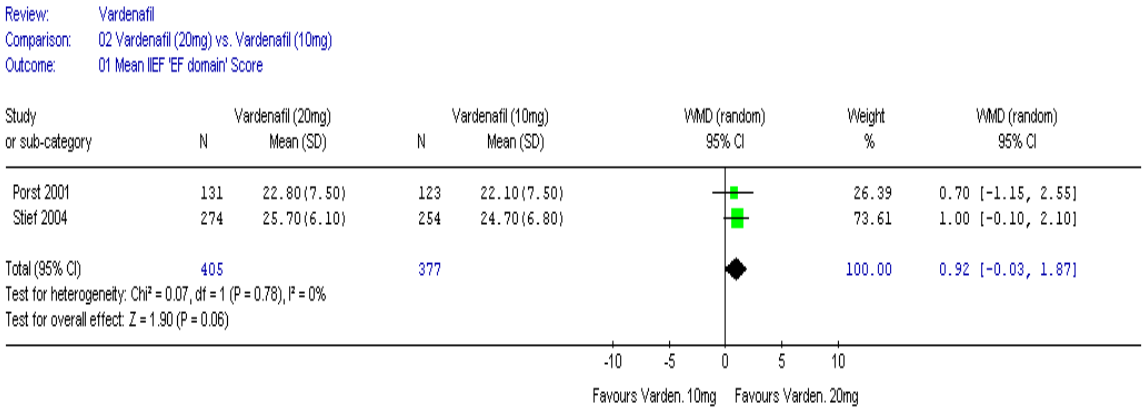


Figure 53. Improved erection (GAQ–Q1) (at week 12)

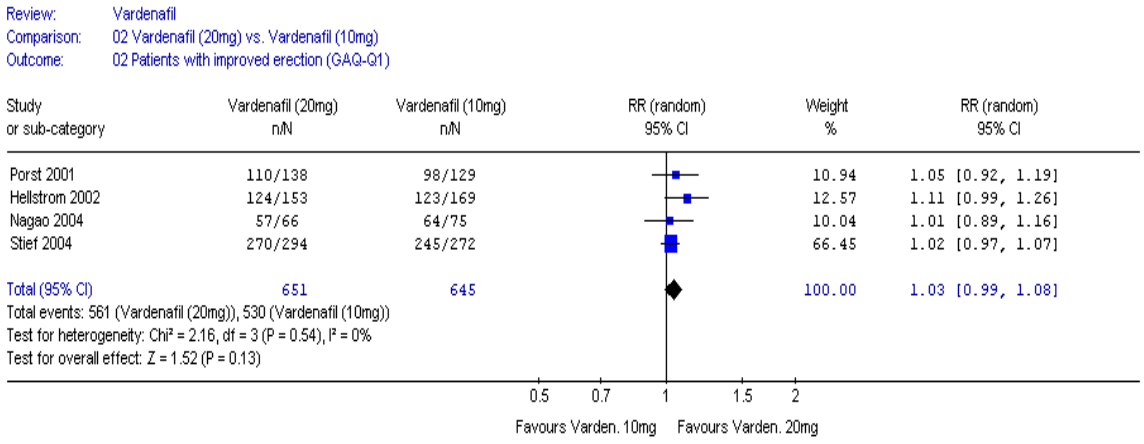


Figure 54. Any adverse events (all cause)

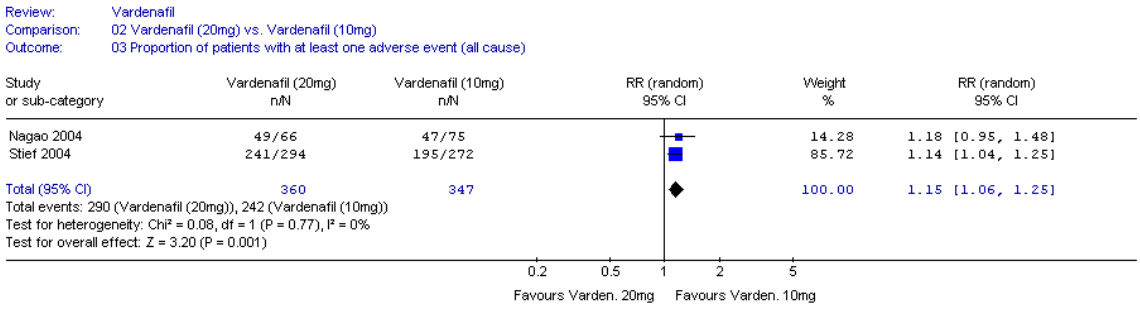


Figure 55. Serious adverse events (all cause)

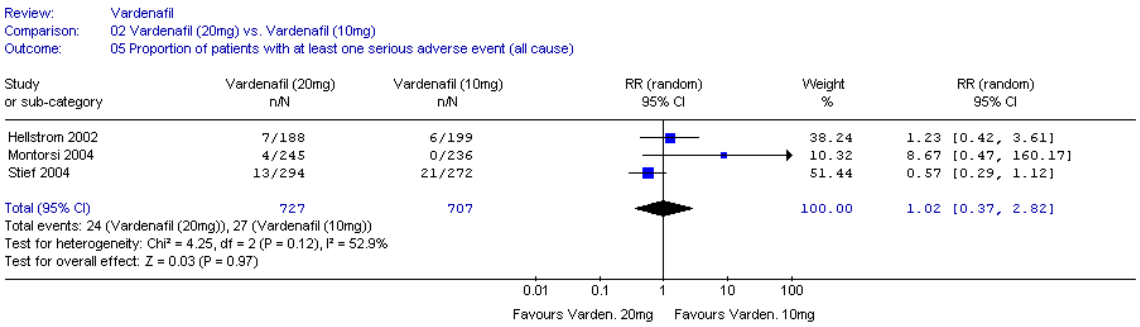


Figure 56. Withdrawals due to adverse events

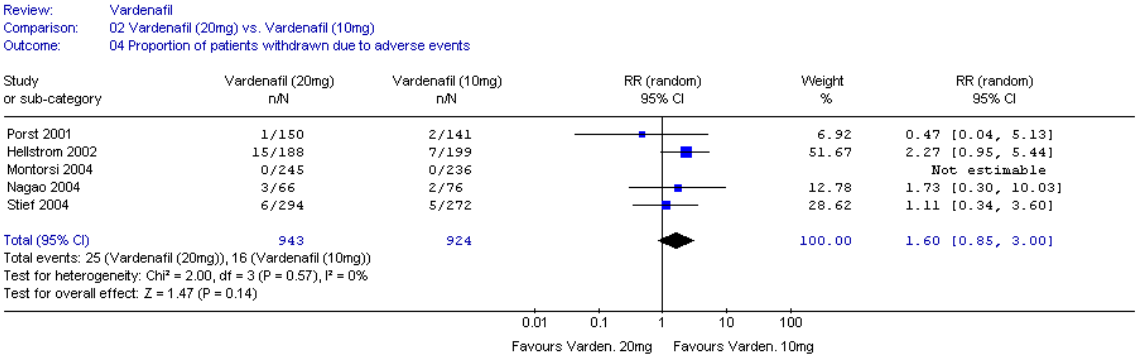


Figure 57. Headache (all cause)

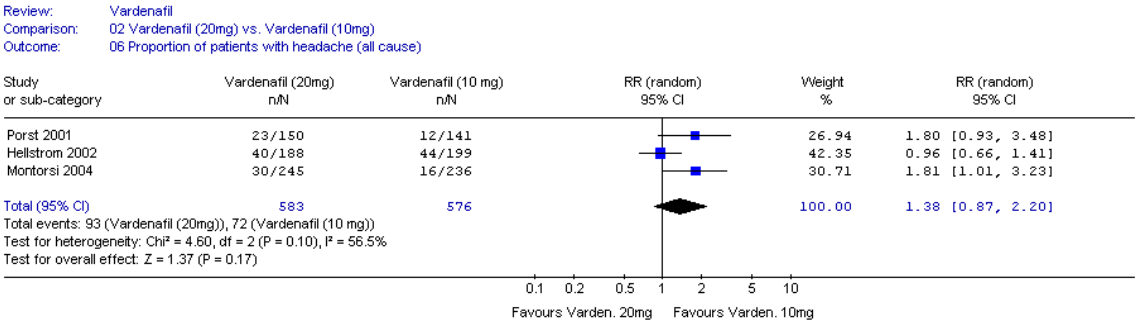


Figure 58. Flushing (all cause)

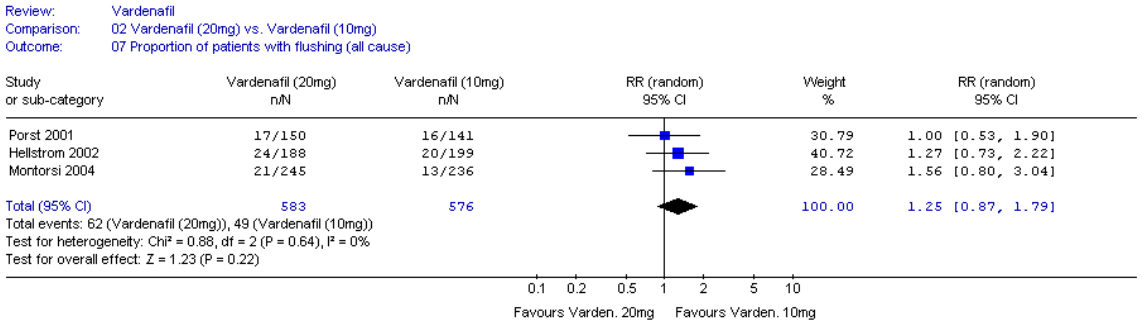


Figure 59. Dyspepsia (all cause)

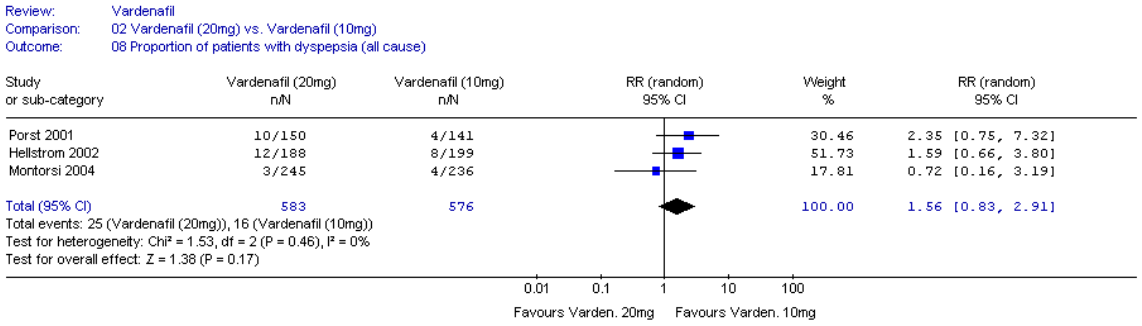


Figure 60. Absolute mean change in IIEF–EF score

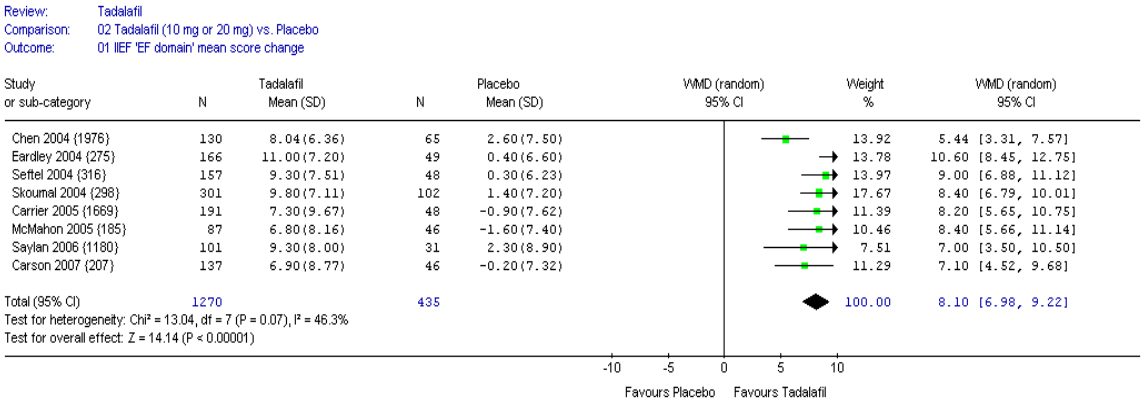


Figure 61. Mean per-patient percent absolute change from baseline in SEP–Q2

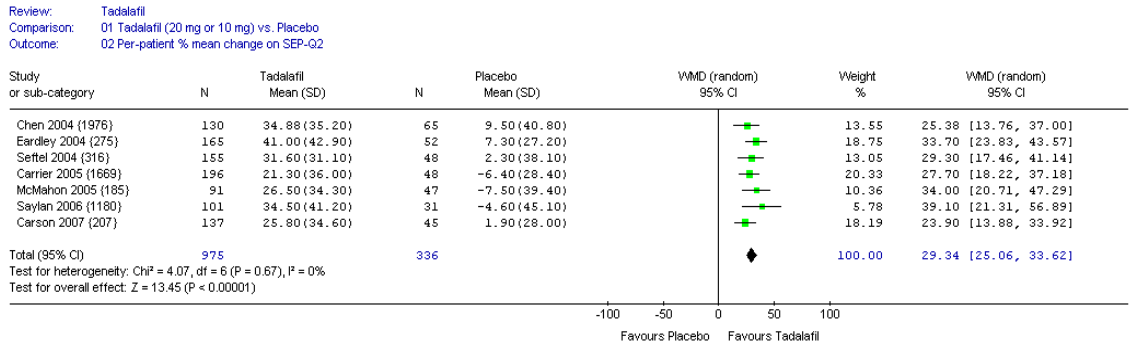


Figure 62. Improved erection (GAQ–Q1)

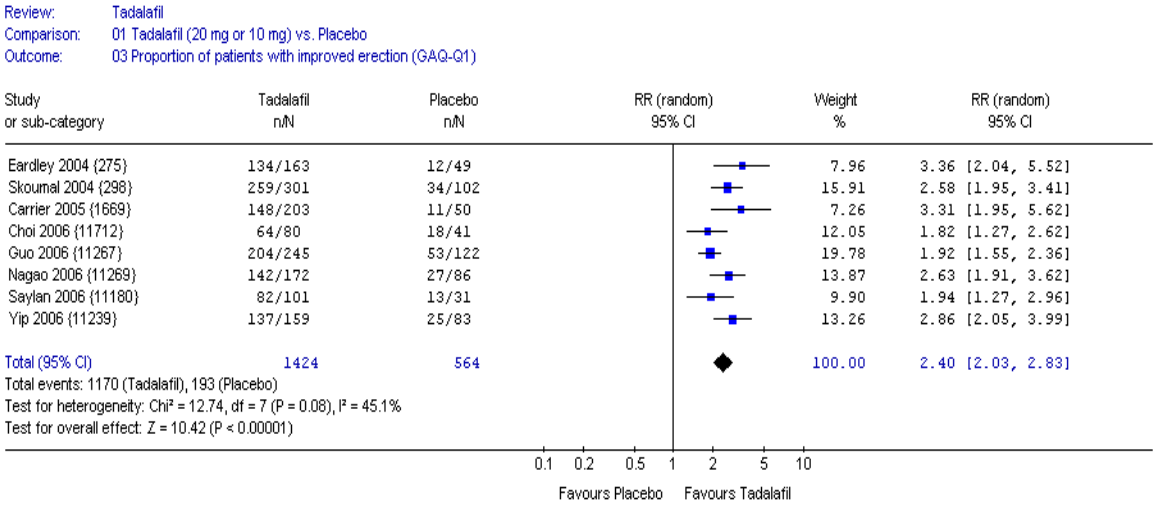


Figure 63. Absolute mean change from baseline in IIEF–EF score

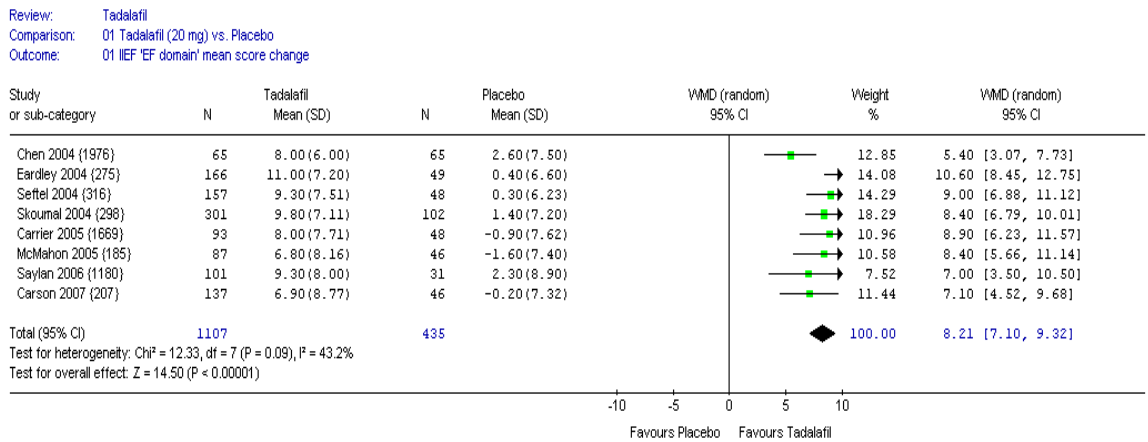


Figure 64. Mean per-patient percent absolute change from baseline in SEP–Q2

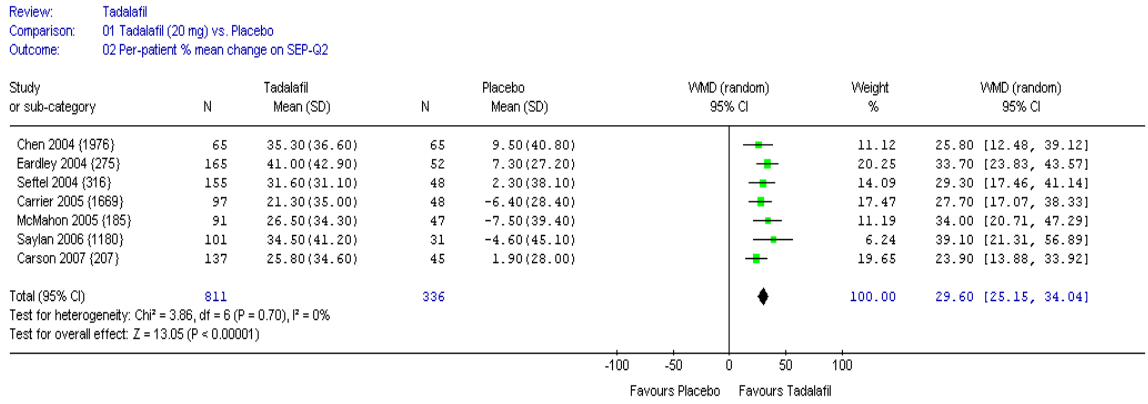


Figure 65. Improved erection (GAQ–Q)

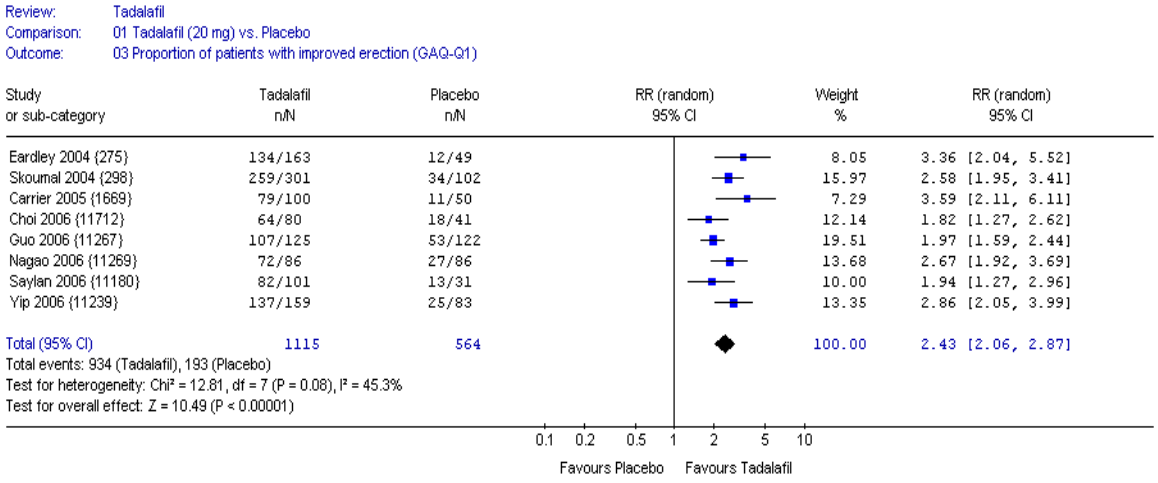


Figure 66. Any adverse events (all-cause)

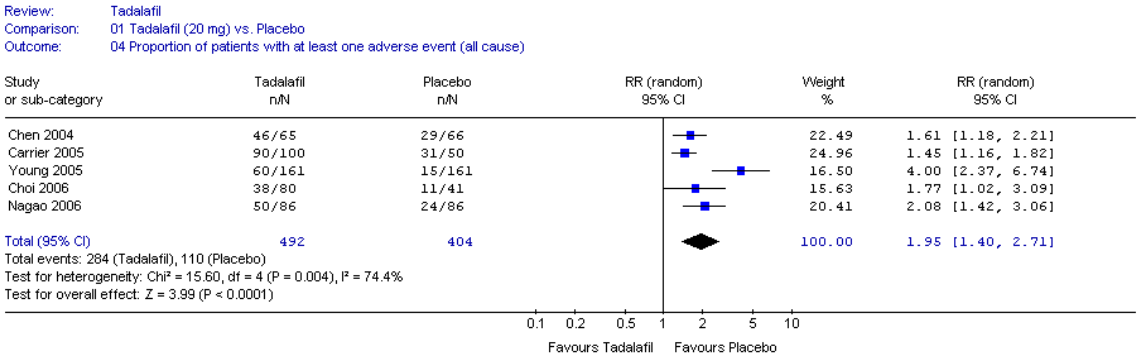


Figure 67. Any adverse events (all-cause)

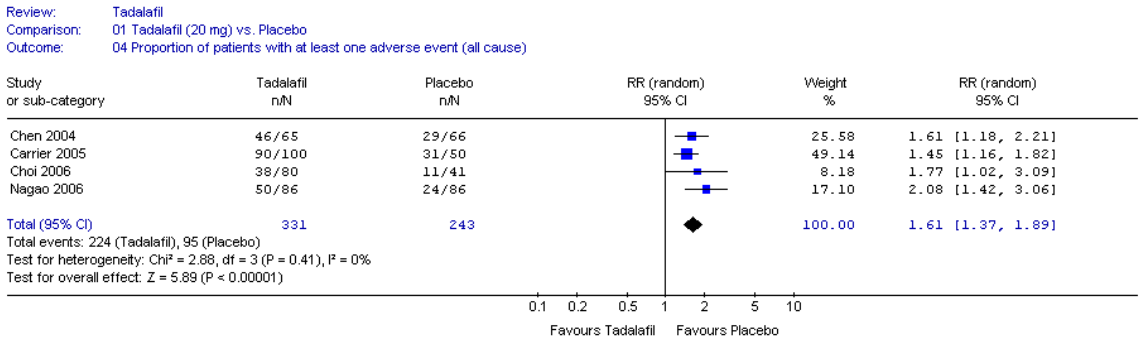


Figure 68. Mean change from baseline in IIEF–EF score

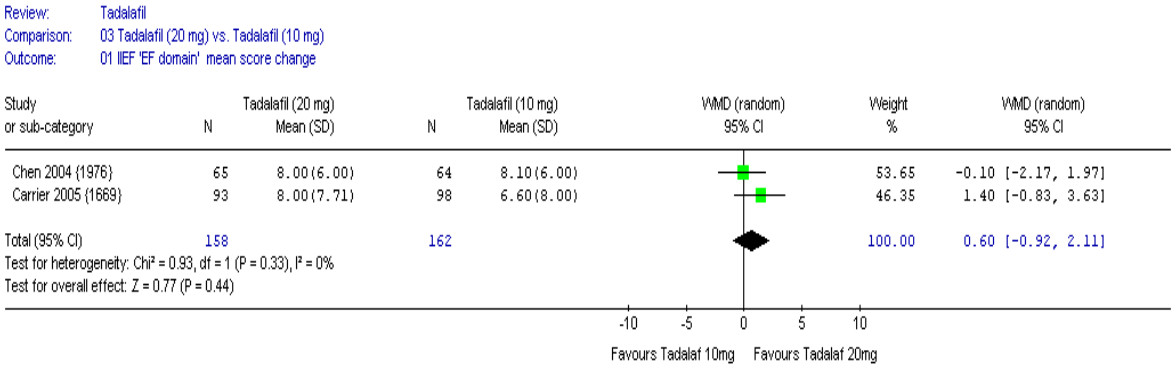


Figure 69. Mean per-patient percent absolute change from baseline in SEP–Q2

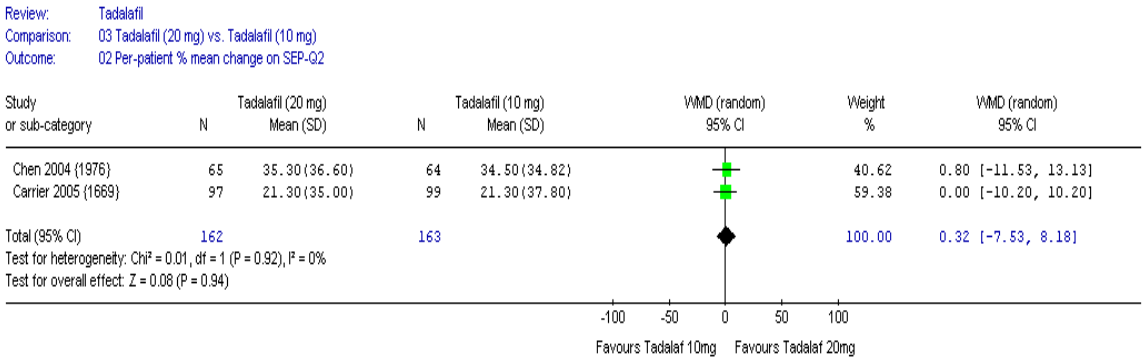


Figure 70. Improved erection (GAQ–Q1)

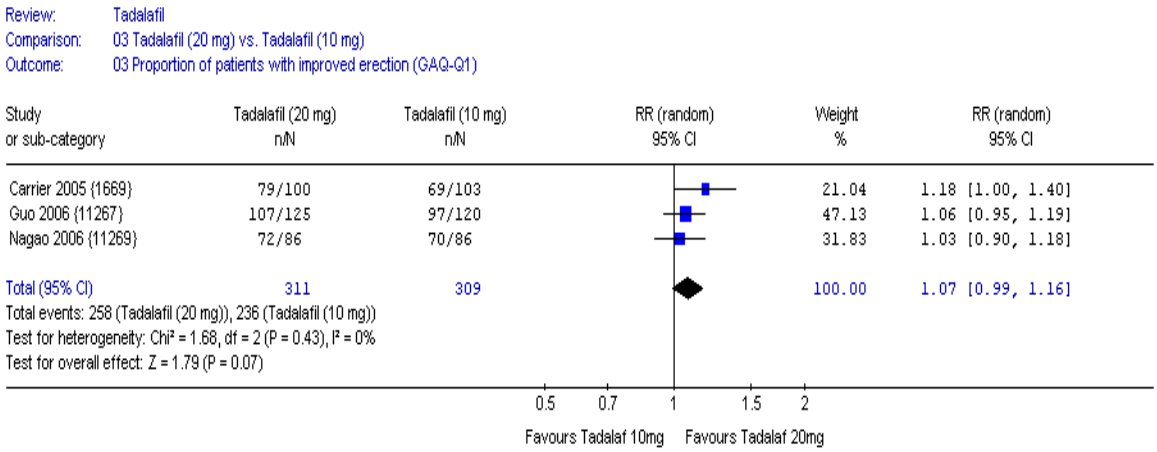


Figure 71. Any adverse events (all-cause)

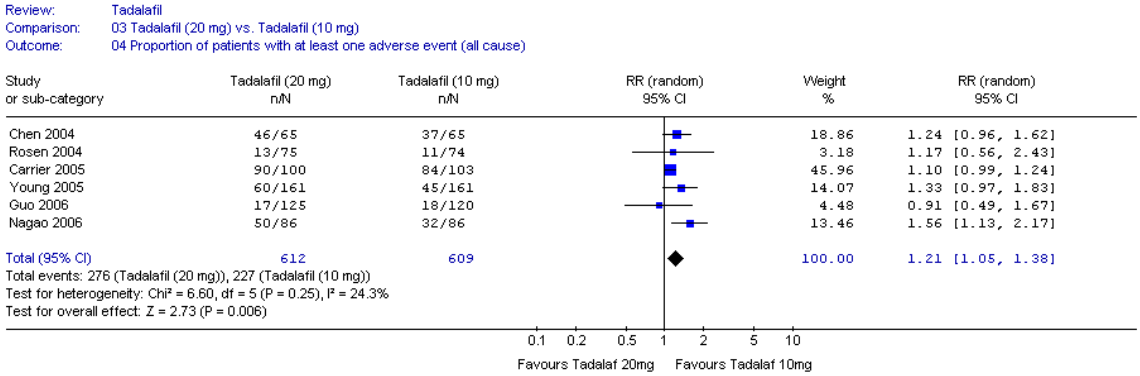


Figure 72. Any adverse events (all-cause)

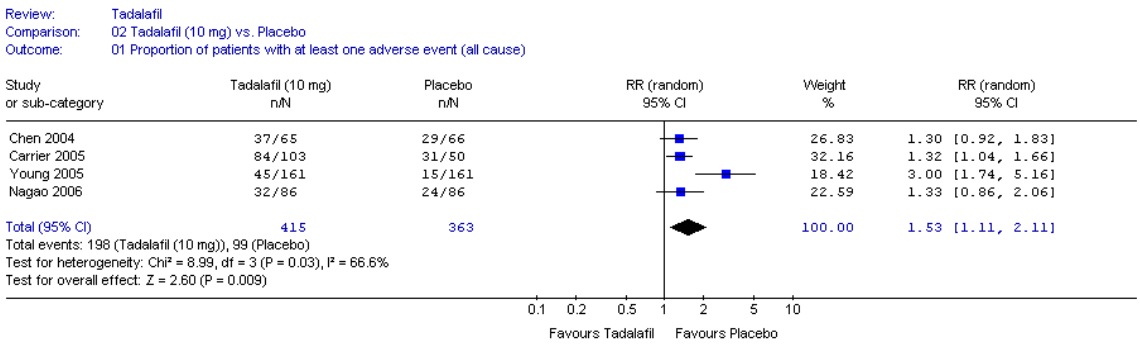
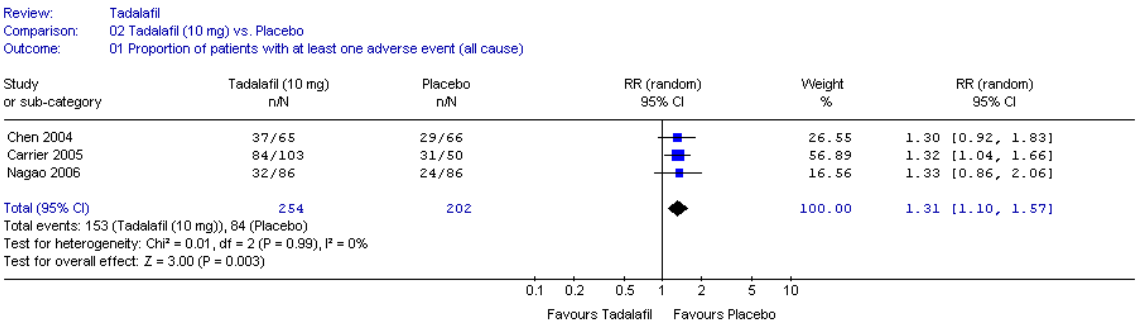


Figure 73. Any adverse events (all-cause)



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List of Acronyms/Abbreviations

CLINICAL	
3DCRT	three-dimensional conformal external-beam radiotherapy
AMI	acute myocardial infarction
BMI	body mass index
BPH	benign prostatic hyperplasia
CAD	coronary artery disease
CHF	congestive heart failure
cGMP	cyclic guanosine monophosphate
CI	confidence interval
CRP	C-reactive protein
CT	computer tomography
CVD	cardiovascular disease
DBP	diastolic blood pressure
DM	diabetes mellitus
ECG	electrocardiogram
ED	erectile dysfunction
EDV	end-diastolic velocity
EID	endothelium-independent dilatation
FMD	flow mediated dilation
FSH	follicle-stimulating hormone (pituitary gland)
GnRH	gonadotropin-releasing hormone
HbA1C	hemoglobin,
HDL-c	high-density lipoprotein cholesterol
IC/I	intracavernosal/ injection
IIEF	International Index of Erectile Function
IM/I	intramuscular/ injection
IU	Intraurethral
LDL-c	low-density lipoprotein cholesterol
LH	luteinizing hormone (pituitary gland)
LUTS	lower urinary tract symptoms
MI	myocardial infarction
MuSE	Multiple Streaming Engine (intraurethral pellets of PGE1)
MRI	magnetic resonance imaging
NAION	nonarteritic ischemic optic neuropathy
NO	nitric oxide
nNOS	neuronal nitric oxide synthase
PADAM	partial androgen deficiency of the aging male
PC	prostate cancer
PDE–5/i	phosphodiesterase type 5/ inhibitor
PGE_1	prostaglandin E_1
PH	prostatic hyperplasia
PKG	protein kinase G
PRL	prolactin
PSA	prostate-specific antigen

PSV	peak systolic velocity
RCT	randomized controlled trial
RI	resistance index
RIA	Radioimmunoassay
SBP	systolic blood pressure
SC	Subcutaneous
SD	standard deviation
SE	standard error
T	Testosterone
TG	Triglycerides
TRT	testosterone replacement treatment
WMD	weighted mean difference

Specific Scales (subscales)

AMS	Aging Males Symptoms
CES-D	Center for Epidemiologic Studies Depression Scale
EDITS	Erectile Dysfunction Inventory of Treatment Satisfaction
GAQ	global assessment question
GEQ	global efficacy question
HARS	Hamilton Anxiety Rating Scale
HDRS	Hamilton Depression Rating Scale
IcS	intercourse satisfaction
IIEF	International Index of Erectile Function,
- EF	erectile function
- OF	orgasmic function
- OS	overall satisfaction
- SD	sexual desire
IIEF–5	modified 5-item IIEF
RAU	rigidity activity unit
SFP	sexual function profile
SHIM	Sexual Health Inventory for Men
TAU	tumescence activity unit
TICS	Trier Inventory for the Assessment of Chronic Stress

UNITS	
µg	Micrograms
µg /L	micrograms per liter
µg /mL	micrograms per milliliter
µg/dL	micrograms per deciliter
µm	micromolar
µmol/L	micromoles per liter
cm	centimeters
cm/s	centimeters/second
Ibs	pounds
IU/L	international units per liter

IU/L	international units per liter
kg	kilograms
kg/m2	kilograms per meter squared
m	meters
mg	milligrams
mg/d	milligrams per day
mL	milliliter
mmol/L	millimoles per liter
N	sample size
ng/dL	nanogram per deciliter
ng/L	nanogram per liter
ng/mL	nanograms per milliliter
nmol/L	nanomoles per liter
pg/mL	picograms per milliliter
pmol/L	picomoles per liter

STATISTICS

ANCOVA	analysis of covariance
ANOVA	analysis of variance
ARD	absolute risk difference
CCT	controlled clinical trial
CI	confidence interval
CV	coefficient of variation
HR	hazard ratio
IQR	interquartile range
ITT	intention to treat
LOCF	last observation carried forward
LS	Least square
NS	not significant
RCT	randomized controlled trial
S/sign.	significant
SD	standard deviation
SE/SEM	standard error
WMD	weighted mean difference

COMMONLY USED ABBREVIATIONS

#	Number
%	Percent
>	greater than
< or </=+	less than or equal to and
<	less than
> or >/=	greater than or equal to
▲/↑ or ▼/↓	increased, or decreased,
CG	control group
grp	group/s
ctrls	Controls

d	Day
Deg	Degrees
Dept.	department
F	Female
f/u	followup
FHx	family history
hr	Hour
Hx	History
IG	intervention group
M	Male
max	maximum
min	minimum
mo	Month
NA	not applicable
NIH	National Institute of Health
NR	not reported
prn	*pro re nata* (as required)
Q	Question
Tx	treatment
versus	Versus
wks	Weeks
y	Year

Appendix A. Search Strategies

Medline strategy: [variations of these strategies exist for a) Embase, b) CENTRAL CINAHL AMED, c) Biological abstracts]

Main Search

OVID MEDLINE Preliminary search
1. Impotence/
2. erectile dysfunction$.mp.
3. 1 or 2
4. limit 3 to ebm reviews
5. limit 3 to systematic reviews
6. limit 3 to guideline
7. or/4-6

Diagnostic Questions – Ovid MEDLINE
1. Impotence/
2. erecti$.tw.
3. 1 or 2
4. limit 3 to "diagnosis (sensitivity)"
5. routin$.ti.
6. 3 and 5
7. or/4,6
8. follicle stimulating hormone/
9. (follicle stimulating hormone or fsh).tw.
10. Luteinizing Hormone/
11. (luteini?ing hormone or lh).tw.
12. Prolactin/
13. prolactin.tw.
14. Testosterone/
15. testosterone.tw.
16. or/8-15
17. 7 and 16
18. limit 17 to (yr="1990 - 2006" and male and english language)
19. limit 18 to (case reports or editorial or letter)
20. 18 not 19
21. Impotence/
22. erecti$.tw.
23. 21 or 22
24. RANDOMIZED CONTROLLED TRIAL.pt.
25. CONTROLLED CLINICAL TRIAL.pt.
26. RANDOMIZED CONTROLLED TRIALS.sh.
27. RANDOM ALLOCATION.sh.
28. DOUBLE BLIND METHOD.sh.
29. SINGLE-BLIND METHOD.sh.

30. or/24-29
31. (ANIMALS not HUMAN).sh.
32. 30 not 31
33. CLINICAL TRIAL.pt.
34. exp CLINICAL TRIALS/
35. (clin$ adj25 trial$).ti,ab.
36. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
37. PLACEBOS.sh.
38. placebo$.ti,ab.
39. random$.ti,ab.
40. versus.tw.
41. RESEARCH DESIGN.sh.
42. or/33-41
43. 42 not 31
44. 43 not 32
45. 32 or 44
46. 23 and 45
47. limit 46 to yr="1990 - 2008"
48. limit 47 to female
49. limit 47 to male
50. 47 not (48 not 49)
51. 20 not 50
52. limit 51 to english language

OVID EMBASE Diagnostic Questions
1. Erectile Dysfunction/
2. erecti$.tw.
3. 1 or 2
4. limit 3 to "diagnosis (sensitivity)"
5. routin$.ti.
6. 3 and 5
7. or/4,6
8. follicle stimulating hormone/
9. (follicle stimulating hormone or fsh).tw.
10. Luteinizing Hormone/
11. (luteini?ing hormone or lh).tw.
12. Prolactin/
13. prolactin.tw.
14. Testosterone/
15. testosterone.tw.
16. or/8-15
17. 7 and 16
18. limit 17 to (yr="1990 - 2008" and male and english language)
19. limit 18 to (editorial or letter)
20. 18 not 19
21. Erectile Dysfunction/

22. erecti$.tw.
23. 21 or 22
24. CLINICAL TRIAL.pt.
25. exp CLINICAL TRIALS/
26. (clin$ adj25 trial$).ti,ab.
27. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
28. PLACEBO.sh.
29. placebo$.ti,ab.
30. random$.ti,ab.
31. versus.tw.
32. METHODOLOGY.sh.
33. or/24-32
34. 23 and 33
35. limit 34 to yr="1990 - 2008"
36. limit 35 to female
37. limit 35 to male
38. 35 not (36 not 37)
39. 20 not 38

OVID MEDLINE – Intervention questions
1. Impotence/
2. erecti$.tw.
3. 1 or 2
4. RANDOMIZED CONTROLLED TRIAL.pt.
5. CONTROLLED CLINICAL TRIAL.pt.
6. RANDOMIZED CONTROLLED TRIALS.sh.
7. RANDOM ALLOCATION.sh.
8. DOUBLE BLIND METHOD.sh.
9. SINGLE-BLIND METHOD.sh.
10. or/4-9
11. (ANIMALS not HUMAN).sh.
12. 10 not 11
13. CLINICAL TRIAL.pt.
14. exp CLINICAL TRIALS/
15. (clin$ adj25 trial$).ti,ab.
16. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
17. PLACEBOS.sh.
18. placebo$.ti,ab.
19. random$.ti,ab.
20. versus.tw.
21. RESEARCH DESIGN.sh.
22. or/13-21
23. 22 not 11
24. 23 not 12
25. 12 or 24
26. 3 and 25

27. limit 26 to yr="1990 - 2008"
28. limit 27 to female
29. limit 27 to male
30. 27 not (28 not 29)
31. limit 30 to english language

OVID MEDLINE – Intervention questions, Injectable medications
1. Injections/
2. inject$.tw.
3. 1 or 2
4. Penis/
5. (peni$ or intercav$).tw.
6. or/4-5
7. 3 and 6
8. Papaverine/
9. Phentolamine/
10. Phenoxybenzamine/
11. Alprostadil/
12. Moxisylyte/
13. (papaverine or prostaglandin E1 or PgE1 or phentolamine or phenoxybenzamine or alprostadil or moxisylyte or thymoxamine or Opilon or Icavex or Trimix).tw.
14. or/8-13
15. 3 and 14
16. or/7,15
17. Impotence/
18. erectile dysfunction.tw.
19. or/17-18
20. 16 and 19
21. limit 20 to (yr="1990 - 2008" and male and english language)
22. limit 21 to (case reports or comment or editorial)
23. 21 not 22

OVID EMBASE – Intervention questions
1. Erectile Dysfunction/
2. erecti$.tw.
3. 1 or 2
4. CLINICAL TRIAL.pt.
5. exp CLINICAL TRIALS/
6. (clin$ adj25 trial$).ti,ab.
7. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
8. PLACEBO.sh.
9. placebo$.ti,ab.
10. random$.ti,ab.
11. versus.tw.
12. METHODOLOGY.sh.
13. or/4-12

14. 3 and 13
15. limit 14 to yr="1990 - 2008"
16. limit 15 to female
17. limit 15 to male
18. 15 not (16 not 17)
19. limit 18 to english language

OVID EMBASE – Intervention questions – Injectable medications
1. Injection/
2. inject$.tw.
3. 1 or 2
4. Penis/
5. (peni$ or intercav$).tw.
6. or/4-5
7. 3 and 6
8. Papaverine/
9. Phentolamine/
10. Phenoxybenzamine/
11. Prostaglandin E1/
12. Moxisylyte/
13. (papaverine or prostaglandin E1 or PgE1 or phentolamine or phenoxybenzamine or alprostadil or moxisylyte or thymoxamine or Opilon or Icavex or Trimix).tw.
14. or/8-13
15. 3 and 14
16. or/7,15
17. Erectile Dysfunction/
18. erectile dysfunction.tw.
19. or/17-18
20. 16 and 19
21. Phenoxybenzamine/ca [Intracavernous Drug Administration]
22. Papaverine/ca
23. Phentolamine/ca
24. Moxisylyte/ca
25. Prostaglandin E1/ca
26. or/21-25
27. 26 and 19
28. or/20,27
29. limit 28 to (yr="1990 - 2008" and male and english language)
30. limit 29 to (editorial or letter or note or short survey)
31. 29 not 30

OVID AMED Intervention questions
1. erecti$.mp.
2. impoten$.mp.
3. exp sex disorders male/
4. or/1-3

5. exp clinical trials/
6. random$.mp.
7. or/5-6
8. 4 and 7
9. limit 8 to yr="1990 - 2008"
10. limit 9 to english language

OVID CENTRAL Intervention questions
1. erecti$.mp.
2. impoten$.mp.
3. or/1-2
4. limit 2 to yr="1990 - 2008"

OVID PsycINFO Intervention questions
1. erecti$.mp.
2. impoten$.mp.
3. impotence/
4. or/1-3
5. exp treatment/
6. random$.tw.
7. control$.tw.
8. placebo$.tw.
9. or/5-8
10. 4 and 9
11. limit 10 to yr="1990 - 2008"
12. limit 11 to female
13. limit 11 to male
14. 11 not (12 not 13)
15. limit 14 to english language

Scopus – Intervention questions
(((TITLE-ABS-KEY(placebo) or TITLE-ABS-KEY(clin* W/25 trial*))) OR ((TITLE-ABS-KEY(random*) OR TITLE-ABS-KEY(doubl* w/25 blind*))) OR (TITLE-ABS-KEY(versus))) AND (TITLE-ABS-KEY(erecti*)) AND (LIMIT-TO(PUBYEAR,2006) OR LIMIT-TO(PUBYEAR,1990) OR LIMIT-TO(PUBYEAR,1994) OR LIMIT-TO(PUBYEAR,1998) OR LIMIT-TO(PUBYEAR,1995) OR LIMIT-TO(PUBYEAR,2000) OR LIMIT-TO(PUBYEAR,1992) OR LIMIT-TO(PUBYEAR,2005) OR LIMIT-TO(PUBYEAR,1999) OR LIMIT-TO(PUBYEAR,2001) OR LIMIT-TO(PUBYEAR,1996) OR LIMIT-TO(PUBYEAR,2004) OR LIMIT-TO(PUBYEAR,1991) OR LIMIT-TO(PUBYEAR,1993) OR LIMIT-TO(PUBYEAR,2002) OR LIMIT-TO(PUBYEAR,1997) OR LIMIT-TO(PUBYEAR,2003))

Vision loss or sleep apnea

Ovid MEDLINE

1. exp Sleep Apnea Syndromes/
2. Optic Neuropathy, Ischemic/
3. exp Vision Disorders/
4. or/1-3
5. (139755-83-2 or 224785-90-4).rn.
6. phosphodiesterase type 5 inhib$.mp.
7. (PDE-5$ or PDE inhibit$).mp.
8. (sildenafil or vardenafil or tadalafil).mp.
9. or/5-8
10. 4 and 9

Embase
1. (139755-83-2 or 224785-90-4).rn.
2. phosphodiesterase type 5 inhib$.mp.
3. (PDE-5$ or PDE inhibit$).mp.
4. (sildenafil or vardenafil or tadalafil).mp.
5. or/1-4
6. central sleep apnea syndrome/ or sleep apnea syndrome/
7. ischemic optic neuropathy/ or optic nerve infarction/
8. exp Visual Impairment/
9. or/6-8
10. 5 and 9

Fibrosis secondary to injectable medications

Ovid MEDLINE
1. Injections/
2. inject$.tw.
3. 1 or 2
4. Penis/
5. (peni$ or intercav$).tw.
6. or/4-5
7. 3 and 6
8. Papaverine/
9. Phentolamine/
10. Phenoxybenzamine/
11. Alprostadil/
12. Moxisylyte/
13. (papaverine or prostaglandin E1 or PgE1 or phentolamine or phenoxybenzamine or alprostadil or moxisylyte or thymoxamine or Opilon or Icavex or Trimix).tw.
14. or/8-13
15. 3 and 14
16. or/7,15
17. Penile Induration/
18. Fibrosis/
19. fibro$.tw.

20. or/17-19
21. 16 and 20
22. limit 21 to (yr="1980 - 2006" and english language)

Embase
1. Injections/
2. inject$.tw.
3. 1 or 2
4. Penis/
5. (peni$ or intercav$).tw.
6. or/4-5
7. 3 and 6
8. Papaverine/
9. Phentolamine/
10. Phenoxybenzamine/
11. Alprostadil/
12. Moxisylyte/
13. (papaverine or prostaglandin E1 or PgE1 or phentolamine or phenoxybenzamine or alprostadil or moxisylyte or thymoxamine or Opilon or Icavex or Trimix).tw.
14. or/8-13
15. 3 and 14
16. or/7,15
17. Fibrosis/
18. Peyronie Disease/
19. fibro$.tw.
20. or/17-19
21. 16 and 20
22. limit 21 to (yr="1980 - 2006" and english language)

Appendix B. Data Assessment, Data Abstraction and Quality Assessment Forms

Screening Forms

Level 1: Title and Abstract Screening

1. Is this a potentially relevant record addressing 1. the benefits or harms (note:only SRs examining Viagara studies for harms data to be included; all other drugs include original studie for harms) of a pharmaceutical treatment (oral, topical, intraurethral, injectable, or intracavernosal) for male erectile dysfunction? OR 2. the sensitivity or specificity of testosterone/LH/FSH/prolactin in identifying a glandular disorder as a cause of ED OR 3. the prevalence of a hormonal (testosterone/LH/FSH/prolactin) disorder in association with male erectile dysfunction?
    - Yes
    - No
    - Can't tell

2. Please indicate which of the following best describes the current record –
    - Original study
    - Narrative review
    - Systematic review/meta-analysis
    - Guideline
    - Comment/Opinion piece
    - Letter to the editor
    - Can't tell

3. Is this an English Language Record? (this question is optional)
    - Yes
    - No
    - Can't tell

Level 2: Full Text Relevance Screening

1. **Which of the following best describes the attached record: *(please check all that apply)***
    - ❑ A study examining the measurement of testosterone and/or other androgen hormone, FSH, LH, Prolactin (but not GnRH, Inhibin, Activin, or Follistin) OR the sensitivity or specificity of hormones in ED screening/diagnosing OR prevalence of reversible hormonal disorders in males with erectile dysfunction

    - ❑ A study examining an oral medication in the treatment of [efficacy/effectiveness (for all drugs) and/or harm outcomes] in male erectile dysfunction in relevant a population (if yes; please indicate in the text box if this is a viagra monotherapy study)

- ❑ A systematic review of harms associated with Viagra
- ❑ A study examining an intramuscular injectable medication in the treatment of male erectile dysfunction
- ❑ A study of an injectable medication into the penis (intracavernosal) OR intraurethral pellet (alprostadil/MUSE, misoprostol, enprostil, arbabprostil, unoprostone) in the treatment of male erectile dysfunction
- ❑ A study examining a topical (patch or cream) or intranasal medication in the treatment of male erectile dysfunction
- ❑ None of the above (e.g., not relevant, animal study, etc.)
- ❑ Can't tell
- ❑ A study that examines any harm(s) (e.g., priapism; penile fibrosis/corporal fibrosis only) for injectable medications in males with ED (Note: treatment and/or f/u must be of >=6 months in duration)
- ❑ A study that examines any harm(s) (e.g., priapism; penile fibrosis/corporal fibrosis only) for injectable medications in males with ED - treatment and/or f/u of less than 6 months in duration
- ❑ A study with treatment and/or f/u >= 6 months in duration that DOES NOT examine harm(s) for injectable medications in males with ED

2. Level of Evidence for this report:

- ❑ Systematic Review
- ❑ RCT parallel design, RCT cross-over, or RCT factorial design
- ❑ Controlled clinical trial (non-RCT)
- ❑ Multiple prospective cohort(s)
- ❑ Case-control
- ❑ Cross-sectional
- ❑ Before-and-after
- ❑ Single prospective cohort
- ❑ Single retrospective cohort
- ❑ Case series (non-comparative)
- ❑ Case study

- ❑ Cross-national ecological analysis
- ❑ Other (describe)
- ❑ Can't tell
- ❑ Not applicable (the study is considered to be not relevant)

3. This study meets relevancy requirements and is considered an included study:
Oral medication – only RCTs (Viagra systematic reviews including harms INCLUDED; Viagra RCT effectiveness/efficacy included – EXCEPT in spinal cord population)

- ❑ Yes
- ❑ No
- ❑ Can't tell
- ❑ Not applicable (the study is deemed not relevant in Q#1)

4. This article should be retrieved to supplement introduction/background information for the report:

- ❑ Yes (indicate specific disorder etc.)

5. Additional Notes/Comments

Data Extraction Form

Summary Table- Randomized Controlled Trials

Author, (year)/ Funding source/ QA	Study design characteristics	Participant characteristics	Patient diagnosis details	Intervention	Outcome & measures
Author (year) {REF ID} Funding source:	N screened = N randomized = IG1, n = IG2, n = CG, n = ITT analysis used for primary outcome: Inclusion: Exclusion:	Age, mean (): Race: Co-morbidities, n (%): Previous ED treatment: Smoking status: Body weight: Other:	Concomitant medications, n (%): Duration of ED: Underlying disease, n (%): Psychogenic ED, n (%): Physiologic ED, n (%): Mixed ED, n (%): Other:	IG1: IG2: CG: IG1: Dose: Duration: Frequency: Compliance: IG2: Dose: Duration: Frequency: Compliance: CG: Dose: Duration: Frequency: Compliance: Run In period: Wash out period: Follow up duration:	Primary outcome (erectile function): Other outcomes assessed: Withdrawals/drop-outs/loss to followup, n (%): WDAE, n (%): TAE, n (%): SAE, n (%): Ascertainment of outcomes assessed: Other:

List of abbreviations: RCT=randomized control trial, CC=controlled clinical trials, ED=erectile dysfunction, NA=not applicable, IG=intervention group, CG=comparator/control group, HbA1C= haemoglobin, BMI=body mass index, wk=week(s), mo=month(s), yr=year(s), hr=hour (s), f/u=follow-up, M=male, IIEF= international index of erectile function, GAQ=global assessment question, ECG=electrocardiograms, ▲=increased, ▼=decreased, sign. =significant; vs.=versus, %=percent, max=maximum, kg=kilograms, lbs=pounds, ITT=intent-to-treat (Y = yes, N = no, NR = not reported), AE=adverse event, SAE=serious adverse event, TAE=total adverse event, grp=group, Hx: history, PgE_1; Prostagladin E_1 IC= intracavernosal injection

Quality Assessment Forms

Randomized Controlled Trials (Jadad Scale)

1. Was the study described as randomized (including the use of words such as randomly, random, and randomization)?
    - Yes =1
    - No = 0

2. The method used to generate the sequence of randomization was described and it was appropriate (table of random numbers, computer generated, etc)
    - Appropriate
    - Not appropriate

3. Was the study described as double blind?
    - Yes = 1
    - No = 0

4. The method of double blinding was described and was appropriate (identical placebo, active placebo, dummy, etc)?
    - Yes = 1
    - No = 0

5. Was there a description of withdrawals and dropouts, by treatment group?
    - Yes = 1
    - No = 0

Total Jadad Score: (i.e = 0 - 5)

Allocation Concealment:
1 = yes, 0 = no

A: Adequate
- Sequentially numbered, opaque, sealed envelopes (SNOSE)
- Pharmacy controlled
- Numbered or ordered containers
- Central randomization – e.g. by telephone to a trials office or other method which described elements convincing of concealment – e.g. a secure computer assisted method.

I: Inadequate
- Alternation
- Reference to case record numbers or to dates of birth

U: Unclear
- No mention of an allocation concealment approach at all
- An approach that does not fall into either adequate or inadequate allocation concealment

The Quality Assessment of Studies of Diagnostic Accuracy Included in Systematic Reviews (QUADAS)

Q1: Was the spectrum of patients representative of the patients who will receive the test in practice? Yes/no

Q2. Were selection criteria clearly described? Yes/no

Q3. Is the reference standard likely to correctly classify the target condition? Yes/no

Q4. Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests? Yes/no

Q5. Did the whole sample or a random selection of the sample, receive verification using a reference standard? Yes/no

Q6. Did patients receive the same reference standard regardless of the index test result? Yes/no

Q7. Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)? Yes/no

Q8. Was the execution of the index test described in sufficient detail to permit replication of the test? Yes/no

Q9. Was the execution of the reference standard described in sufficient detail to permit its replication? Yes/no

Q10. Were the index test results interpreted without knowledge of the results of the reference standard? Yes/no

Q11. Were the reference standard results interpreted without knowledge of the results of the index test? Yes/no

Q12. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice? Yes/no

Q13. Were uninterpretable/ intermediate test results reported? Yes/no

Q14. Were withdrawals from the study explained? Yes/no

Appendix C. Evidence Tables

C1-Oral Sildenafil

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Abdel-Naser (2004) [1] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 30 **IG1, n =** 15 **IG2, n =** 15 **CG, n =** 12 (normal men) **Intention to treat (ITT) analysis:** NR **Inclusion:** men with psychogenic ED (no response to sildenafil citrate of up to 100 mg in more than one occasion within a one mo); also non-sildenafil treated pts with ED served as control **Exclusion:** penile anatomical defects, active peptic ulcer, bleeding dx, retinitis pigmentosa, major haematological renal or hepatic abnormalities; hx of stroke or recent MI; loss of libido; use of anihypertensives, nitrates, tranquilizers or drugs known to interfere with sildenafil citrate metabolism (e.g. cimetadine & ketoconazol)	**Age, mean (sd):** 42.5 (6.7) y, range 34-58 y **Race (%):** NR **Co-morbidities:** NR **Previous ED treatment:** 100% with Sidenafil, 100 mg **Smoking status**: NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** 100% **Physiologic ED:** 0 **Mixed ED:** 0	**IG1:** sildenafil citrate (night 3) & placebo (nights 1,2 & 4) **IG2:** sildenafil citrate (night 4) & placebo (nights 1, 2, & 3) **CG:** placebo (all nights) **IG1:** Dose: 50 mg Duration: 4 nights Frequency: once, 1 hr before bedtime/ night Compliance (%): NR **IG2:** Dose: as IG Duration: 4 nights Frequency: as IG Compliance (%): NR **CG:** Dose: NA Duration: 4 nights Frequency: once/night Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** NPTR for basal condition, mean (sd) placebo nights vs. sildenafil night Number of events IG1 4.7 (1.4) vs. 6.7 (1.6) IG2: 3.8 (1.2) vs. 7 (1.2) Total event duration, hr: IG: 1.4 (0.2) vs. 2.1 (0.4) IG2: 1.3 (0.2) vs. 2.4 (0.2) Tip rigidity IG1: 39.7 (9.5) vs. 47.8 (10.4) IG2: 44.3 (10.3) vs. 57.6 (10.7) Base rigidity: IG1: 45.1 (8.8) vs. 57.3 (10.5) IG2: 49.4 (10.5) vs. 60.8 (11) **Other outcomes assessed:** base, tip RAU, and TAU (result suggestive of possible performance anxiety effect in this population); no result reported for CG **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE, n (%):** 3 (10), headache in 2 pts (6.7%), GI upset in 1 (3.3%) **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan nocturnal penile tumescence and rigidity (NPTR); RAU and TAU

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Albuquerque (2005) [2] **Funding source:** Pfizer	**N screened =** 153 **N randomized =** 120 **IG, n =** 61 **CG, n =** 59 **ITT analysis used for primary outcome:** yes (n=120) **Inclusion**: men 18 y or older, with established ED of at least 6 mo duration, in a stable sexual relationship for 6 mo, and with hypertension that is being treated with at lest 2 drugs. (Diuretics, alpha-blocker, beta blockers, ACE inhibitors or calcium blockers); baseline IIEF score of 25 or less **Exclusion**: Concurrent tx with nitrates, presence of genital deformity or sexual disturbance that precluded sexual intercourse, use of any form of ED tx within 4 wks, alcohol or drug abuse, presence of retinitis pigmentosa, major medical condition or inability to fill out log or comply with study	**Age, mean (range):** 30-81y **Race:** Brazilian **Co-morbidities:** None **Previous ED treatment**: None **Smoking status n (%):** 13 (21.3) vs. 15 (25.4) **Body weight**: NR	**Concomitant medications:** None **Duration of ED, median (range):** 2.0 (0.6 – 24) vs. 2.3 (0.6 –30) **Underlying disease:** hypertension (duration 0.6 -30 y) **Psychogenic ED**, **n (%):** 9 (14.8) vs. 7 (11.9) **Physiologic ED, n (%):** 11 (18) vs. 11 (18.6) **Mixed ED, n (%):** 41 (67.2) vs. 41 (69.5) **Other, n (%):** alcohol use 30 (49.2) vs. 30 (50.2)	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50mg (adjusted to 25 or 100mg) Duration: 8wks Frequency: 1 hr before sexual intercourse Compliance n (%): 46 (75.4) **CG:** Dose: NA Duration: 8 wks Frequency: 1 hr before sexual intercourse Compliance n (%): 41 (69.5) **Run In period:** None **Wash out period:** 4 wks **F/u duration:** 2, 4 and 8 wks **Other:** % pts taking 25 mg: 6.6 vs. 5.1 50 mg: 39.3 vs. 74.6 100 mg: 54.1 vs. 20.3	**Primary outcome results:** IIFE, mean (sd): (mean baseline/Q=2) Q1: 4.2 (1.3) vs. 2.6 (1.5) Q3: 4 (1.3) vs. 2.6 (1.6) Q4: 4 (1.4) vs. 2.2 (1.6) Q5: 4.2 (1.2) vs. 2.6 (1.5) Q15: 3.6 (1.0) vs. 2.4 (1.1) Q6: 4.2 (1.3) vs. 3.4 (1.4) Q7: 4.2 (1.2) vs. 2.3 (1.4) GEQ, % improved: (87) vs. (37) Successful intercourse attempts wks 2, 4 and 8 (%): 54, 61, 73 vs. 13, 20, 29 **Other outcomes assessed:** EDITS **Withdrawals/drop-outs/loss to f/u, n (%):** 22 (18.3) **WDAE:** tx interrupted 1 (1.4) vs. 2 (3.4) **TAE, n (%):** in 2% or more 35 (57.3) vs. 16 (27.1); including facial flushing 8 (13) vs. 2 (3.4); headache 7 (11.4) vs. 2 (3.4); rhinitis 6 (9.8) vs. 1 (1.7); dyspepsia 4 (6.5) vs. 0; dizziness= abdominal pain 2 (3.2) vs. 1 (1.7); paresthesia 1 (1.6) vs. 0; hypertension 1 (1.6) vs. 3 (5.1); chest pain 1 (1.6) vs. 2 (3.4); flue like syndrome= diarrhea 1 (1.6) vs. 2 (3.); AE in 82% vs. 40% of pts **SAE:** 3 (5) vs. 1 (1.7); CVA, pulmonary edema/heart failure, atrial fibrillation/arrhythmia, and one polytrauma due to MVA leading to death) **Ascertainment of outcomes assessed:** IIEF, patient logs, EDITIS, GEQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Althof (2006) [3] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 553 (combined from two studies US, n=253; Brazil, Mexico, Australia and Japan n=300) **IG, n =** 274 **CG, n =** 279 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older with documented ED (score of 21 or less on IIEF) **Exclusion:** BP of 90 mmHg or less or 170/110 mmHg or more; sign cardiac dx; use of nitrates, nitric oxide donors, or ritonavir; more than 6 dosed of sildenafil within 6 mo prior to study entry	**Age, mean (sd):** 56 (11) vs. 55 (12) y **Race:** White 55.5%; Black 15%; Asian 5.5%; Other 23.5% **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight, mean (sd):** 86 (16) vs. 85 (16) kg	**Concomitant medications, n (%):** **Duration of ED, mean (sd):** 4.4 (4.5) vs. 4.3 (4.4) y **Underlying disease, n (%):** Not specific **Psychogenic ED, n (%):** 44 (16) vs. 55 (20) **Physiologic ED, n (%):** 119 (43) vs. 113 (41) **Mixed ED, n (%)**: 116 (41) vs. 106 (39)	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: NR Duration: 12 wks Frequency: NR Compliance: NR **CG:** Dose: NA Duration: NR Frequency: NR Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 12 wks (f/u intervals at 2, 4, 6, 8 wks)	**Primary outcome results:** IIEF, LS mean change from baseline (SE) EF: 11.0 (0.5) vs. 4.8 (0.5), p<0.001 OF: 2.5 (0.2) vs. .0 (0.2), p<0.001 SD: 1.3 (0.1) vs. 0.6 (0.1), p<0.001 IcS: 5.2 (0.2) vs. 2.9 (0.2), p<0.001 OS: 3.8 (0.2) vs. 1.7 (0.2), p<0.001 Successful sexual attempts, mean change %(sd): 59 (2.6) vs. 39 (42) GEQ, frequency of achieved erections at end of tx: 3.9 (1.5) vs. 2.7 (1.6), p<0.001 **Other outcomes assessed:** SEAR sexual relationship domain (sign more improved in IG) **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** 3 (1) vs. 1 (0.4) **TAE, n (%):** 129 (46) vs. 88 (32); included headache, flushing, dyspepsia, and rhinitis **SAE, n (%):** 1 (<1) vs. 1 (<1); one case of coronary artery disease in sildenafil grp and one case of urinary tract infection in placebo **Ascertainment of outcomes assessed:** SEAR; self-esteem, confidence and sexual relationship satisfaction; IIEF, GEQ, self reported event log

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Bank (2006) [4] **Funding source:** Pfizer Inc. (educational grant)	**N screened =** NR **N randomized =** NR (n=35 completed the trial) **IG1, n =** 12 **IG2, n =** 10 **CG, n =** 13 **ITT analysis used for primary outcome: NR** **Inclusion:** men 25-75 y, in a stable relationship, and normal libido, IIEF-5 < 21, with current use of sildenafil (evaluated after the 2-4 wks run in period tx with 100 mg sildenafil); with vasculogenic ED **Exclusion:** use of lipid lowering agents, angiotensin converting enzyme inhibitors, anti-depressants or nitrates; hx of prostate cancer or pelvic/ low back surgery	**Age, mean (SEM):** 59.2 (1.9) vs. 58.7 (3.3) vs. 63.8 (2.1) y **Race:** NR **Co-morbidities, n (%):** DM type II, 2 (5) only in CG **Previous ED treatment:** NR **Smoking status:** 3 (9%); one in each grp **Body weight:** NR **Other:** BMI, mean (SEM) 27.5 (1.5) vs. 29.7 (2.3) vs. 26.1 (0.9) kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** vasculogenic **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%)**: NR **Other:** lipid profiles reported, SBP; CBP; total cholesterol; LDL-c; HDL-c; TG, and CRP	**IG1:** Sildenafil + Atorvastatin **IG2:** Sildenafil + quinapril **CG:** Sildenafil + placebo **IG1:** Dose: 100 mg sildenafil + 40 mg atrovastatin Duration: 3 mo Frequency: sildenafil as instruction; atrovastatin once/d Compliance: NR **IG2:** Dose: 100 mg sildenafil + 10 mg quinapril Duration: 3 mo Frequency: as IG1 Compliance: NR **CG:** Dose: sildenafil as IG Duration: 3 mo Frequency: as IG Compliance: NR **Run In period:** 2-4 wks on 100 mg sildenafil **Wash out period:** NA **F/u duration:** 3 mo	**Primary outcome results:** Mean (SEM) baseline vs. post tx IIEF-5 IG1: 11.1 (1.5) vs. 16.7 (2.0) IG2: 9.9 (1.1) vs. 18.7 (2.2) CG: 10.2 (1.6) vs. 11.3 (2.1) IIEF-EF domain: IG1: 14.5 (2.2) vs. 20.8 (2.3) IG2: 13.8 (1.3) vs. 23.6 (2.3) CG: 12.8 (2.0) vs. 14.2 (2.5) N of intercourse attempts/3 mo, mean (SEM): IG1, 37.7 (12) vs. IG2, 22.5 (7.7) vs. IG3, 23.8 (13.9) **Other outcomes assessed:** NS differences between IG1/2 and CG for penile blood flow and vascular function, PSV, EDV, RI, and FMD; no differences for SBP, DBP, HDL-c and CRP, no correlation between IIEF scores and improvement on other measures **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** IIEF-5**;** Penile Doppler studies

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Bawa (2004) [5] **Funding source:** NR	**N screened =** NR **N randomized =** 59 crossover design **IG/ CG, n =** 59 **ITT analysis used for primary outcome:** NR **Inclusion**: Indian men with ED for 6 mo or longer **Exclusion:** NR	**Age, mean (range):** 32.8 (18-60) y **Race:** Asian (India) **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight**: NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 23 (6-120) mo **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** sildenafil **CG:** placebo **IG:** Dose: 50 mg Duration: 3 wks Frequency: NR Compliance (%): NR **CG:** Dose: N/A Duration: 3 wks Frequency: NR Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 1 y	**Primary outcome (EF)**: IIEF score, mean (SEM) EF domain Baseline: 18.5 (0.7) post tx: 25.6 (0.7) vs. 22.1 (0.7), P<0.05 Intercourse satisfaction: Baseline 8.2 (0.4) post tx: 11.9 (0.4) vs. 10 (0.4), not sign OF: baseline: 7.3 (0.3) post tx: 8.8 (0.2) vs. 7.9 (0.3), p<0.05 SD: Baseline: 6.9 (0.1) post tx: 7.1 (0.1) vs. 6.9 (0.2), not sign OS: pre tx: 5.8 (0.2) post tx: 7.0 (0.2) vs. 6.4 (0.2), p<0.05 GAQ (% improved): 81.3% vs. 28.8% (P<0.001) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** 0 **TAE:** 4 (6.8%) vs. 3.4% including Headache 30.2%; Flushing: 43.5%; Dyspepsia: 18.8%; Dizziness: 7.5% **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF; partner questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Becher (2002) [6] **Funding source:** Pfizer	**N screened =** 156 **N randomized =** 143 **IG, n =** 72 **CG, n =** 71 **ITT analysis used for primary outcome:** NR **Inclusion:** Men with ED who were in a stable relationship with a female partner of at least 6 mo **Exclusion:** penile anatomical defects, primary diagnosis of another sexual disorder, SCI, any major psychiatric disorder not well controlled, poorly controlled DM, Hx of alcohol or substance abuse, major haematological, renal or hepatic abnormalities, hypotension or malignant hypertension, recent stroke or myocardial infraction or if they were receiving nitrated.	**Age, mean (sd);** 57.2 (11.5) vs. 56.7 (10.9) y **Race, n (%):** White Southern Latin 6 (8.3) vs. 7 (9.8) Hispanic: 66 (91.7) vs. 64 (90.2) **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**, **n (%):**Current: 32 (44.4) vs.27 (38.0) Former: 28 (38.9) vs. 26 (36.6) **Body weight, mean (sd):** 84.2 (11.8) vs. 83.4 (14.2)	**Concomitant medications, n (%):** Any medication 51 (70.8) vs. 51 (71.8), with no sign difference between grps for use of any medication **Duration of ED,** mean (range)**:** 3.5 (0.5-22.4) vs. 2.6 (0.5-20.5) y **Underlying disease (diagnosis), n (%):** Diabetes: 12 (16.6) vs. 13 (18.3) Hypertension: 23 (31.9) vs. 28 (43.6) **Psychogenic ED:** 44.3% **Physiologic ED:** 39.3% **Mixed ED**: 16.4%	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 25-50 and 100mg tablets Duration: 12 wks Frequency: 1h before planned sexual activity, up to once/d Compliance: 90% **CG:** Dose: NA (14 tablets/bottle as IG) Duration: 12 wks Frequency: as IG Compliance: 89% **Run In period:** 4 wks **Wash out period:** None **F/u duration:** 12 wks (2, 4, 8, and 12 wks)	**Primary outcome results:**IIEF mean (SE): % Change, Q3: 3.8 (0.17) (66.2) vs. 2.7 (0.18) (15.1) % Change Q4: 3.6 (0.18) (77.6) vs. 2.5 (0.18) (21.2) EF: 20.5 (0.6) vs. 15.9 (0.7) OF: 8.2 (0.35) vs. 7.0 (0.37) S-D: 7.68 (0.18) vs. 7.0 (0.19) GEQ, % with Improved erections: (77.3) vs. (33.8) **Other outcomes assessed:** all IIEF questions (1-15) **Withdrawals/drop-outs/loss to f/u, n (%):** 3 (2) vs. 2 (3) **WDAE, n (%):** 7 (9.7) vs. 6 (8.5) discontinued treatment **TAE, n (%):** pts with AE 45 (59.1) vs. 21 (29.6) Flushing: 16 (22.2) vs. 3 (4.2); Headache: 17 (23.6) vs. 6 (8.4); Hypertension: 1 (1) vs. 3 (4); nasal congestion 2 (2.3) vs. 1 (1); tachycardia 3 (4) vs. 0 **SAE:** 2 (2.8) vs. 1 (1.4) died in due to MI **Ascertainment of outcomes assessed:** RigiScan test (nocturnal penile tumescence NPT), IIEF (q3 and 4) (investigator), GEAQ, self and partner reported event logs

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Boolell (1996) [7] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 12 (phase I: double blind, placebo controlled four way crossover trial; phase II: double blind, randomized placebo controlled two way cross over) **IG1-3/CG (both phases), n =** 12 **ITT analysis used for primary outcome:** NR **Inclusion**: men 18-70 y, with penile ED of at least 6 mo, with no known organic cause by clinical examination and blood test **Exclusion:** pts with DM, hypertension or alcohol abuse	**Age, range:** 36-63 y **Race:** NR **Co-morbidities:** NR **Previous ED treatment, n (%):** IC papaverine 4 (30), three responders and one non responder **Smoking status** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED:** NR	**Phase I** **IG:** single doese sildenafil + 2 hr visual stimulation 30 min post tx (VS) **CG:** placebo + VS **Phase II** **IG:** sildenafil + VS **CG:** placebo **IG (phasel):** Dose: 10, 25 or 50 mg Duration: NR Frequency: once/dose Compliance: 100% **IG (phase II):** Dose: 25 mg Duration: 7 d Frequency: once/d Compliance: 100% **CG:** Dose: NA Duration: Phase II= 7 d Frequency: phase phase II= once/d Compliance: 100% **Run In period:** NR **Wash out period:** phase I, 3 d between consecutive tx periods; 3 d between phases, phase II, at least 7 d **F/u duration:** 7 d	**Primary outcome results:** Phase I Duration of penile rigidity > 80%, mean (approximate values from figure): Base: < 4 vs. 8 vs. <12 vs. <2 min Tip: < 5 vs. <7 vs. < 8 vs. <2 min Phase II Erections of grade 3 or 4, mean: 1.6 vs. 0.5 N of erections phase I + phase II, mean (95% CI): IG vs. CG, p=0.005 6 (3.2-11.4) vs. 1.3 (0.5-2.7) Pts with improved erection, n/N (%): 10/12 (83) vs. 2/12 (16); p = 0.018 **Other outcomes assessed:** frequency of erection and time of dosing; pulse rate, BP, laboratory safety data **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE, n (%):** phase I: 2 (16) vs. 2 (16); phase II: 6 (50) vs. 5 (41) with headache, dyspepsia, pelvic musculoskeletal pain **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan (phase I); self diary, grading erection from 1=no erection to 4=max rigidity (phase II)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Boulton (2001) [8] **Funding source:** NR	**N screened =** NR **N randomized =** 219 **IG, n =** 110 **CG, n =** 109 **ITT analysis used for primary outcome:** NR **Inclusion:** men 37 or older; with diagnosed ED, and stable type II DM (≥2 y; HbA_{1c} <11%); also in stable heterosexual relationship for longer than 6 mo **Exclusion:** genital anatomical deformity; major psychiatric disorder; hx of alcoholism or substance abuse; ED resulting from SCI; MI, stroke, heart failure or unstable angina within previous 6 mo; hx of hypotension; nitrate tx; type I DM; HbA_{1c} ≥11%; recurrent hypoglycemic episodes; severe disabling autonomic neuropathy; diabetes secondary to pancreatic damage; Cushing's syndrome; acromegaly	**Age, mean (range):** 58 (range 38-80) vs. 59 (45-72) y **Race (%)**: White 96; Black 2 vs. 0; Asian 2; other: 1 vs. 2 **Co-morbidities, %:** Hypertension 40 vs. 52; Ischemic heart dx 6 v. 3; hypercholesterolemia 8 vs. 7 **HbA_{1c}, median, (range):** 8.3 (5.1-12.1) **Previous ED treatment**: NR **Smoking status (%): smokers** 22 vs. 24 **Body weigh, mean (range)**: 88 (60-146) kg	**Concomitant medications:** Insulin 32 vs. 37 **Duration of ED, mean (range):** 4.6 (0.4-21) vs. 3.7 (0.7-11) **Underlying disease:** DM **Psychogenic ED**: NR **Physiologic ED, %:** 100 **Mixed ED**: NR **Other:** duration of DM, mean (range) = 10 (1-34) y	**IG:** sildenafil citrate **CG:** placebo **IG:** Dose: 50 mg initially; could adjust to 25 or 100 mg Duration: 12 wk Frequency: NR Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: NR Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** IIEF- Q3, mean (SEM): pre: 1.8; post 3.4 (0.2) vs. 1.9 (0.2) IIEF- Q3, mean (SEM): pre: 1.5; post: 3.4 (0.2) vs. 1.8 (0.2) IIEF- EF: pre: 10.4; post: 20.4 (1.2) vs. 11.5 (1.2) Successful intercourse, %: pre 13.8; post 58.8 vs. 14.4 GEQ, %: 65 vs. 11 **Other outcomes assessed:** life satisfaction checklist; partner questionnaire **Withdrawals/drop-outs/loss to f/u:** NR **WDAE, %:** 0 **TAE:** 65 vs. 11; pts with AE= 38% vs. 6.4%; including headache 18.2 vs. 4; flushing 15 vs. 0; dyspepsia 2 vs. 0.9; abnormal vision 5 vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, GEQ, life satisfaction checklist

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Cappelleri (2000) [9 10] **Companion Lewis (2001)** **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 247 **IG, n =** 124 **CG, n =** 123 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older; with documented diagnosis of ED for at least 6 mo; in stable relationship with female partner for longer than 6 mo **Exclusion:** hx of retinitis pigmentosa; uncontrolled psychiatric disorder, hyper/hypotension or DM; serious CVD (MI, stroke or arrhythmia within previous 6 mo); evidence of alcoholism or substance abuse within previous 12 mo; current use of nitrates; nitric oxide donor	**Age, mean (range):** IG1 58 (range 38-77) CG 60 (range 31-81) **Race (%)**: NR **Co-morbidities, n (%):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications, n (%):** Anti-inflammatory analgesic 98 (40) Antihypertensive 93 (38) Antidiabetic 49 (20) Vitamins 49 (20) Analgesic 30 (12) Diuretic 30 (12) **Duration of ED, mean (range):** 4 (0.4-17) y **Underlying disease:** Essential hypertension 83 (34) DM, Type II 49 (20) Hypercholesterolemia 37 (15) Hyperlipidemia 22 (9) Prostatic hyperplasia 30 (12) **Psychogenic ED, n (%):** 4 (3) vs. 6 (5) **Physiologic ED, n (%):** 102 (82) vs. 99 (81) **Mixed ED, n (%):** 36 (15)	**IG:** sildenafil citrate **CG:** placebo **IG:** Dose: 50 mg, with option to titrate to 100 or 25 mg Duration: 12 wk Frequency: up to once/d, 1 dose 1 hr before sexual activity Compliance: NR **CG:** Dose: placebo, titration as IG Duration: 12 wk Frequency: as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** Mean response scores for questions 3 and 4 of IIEF- total, mean: pre: 9.5 vs. 9.6; post: 20 vs. 11 IIEF-EF, mean: pre: 1.7 vs. 1.6; post: 3.4 vs. 1.8 (Approximate mean values from figure): IIEF, Q3: pre: 1.8; post 3.7 vs. 2.2 IIEF, Q4: pre: 1.5; post 3.6 vs. 1.9 IIEF, Q7 (ICs): pre: 2.7; post: 3.9 vs. 2.2 GEQ-Q1, 2, %: 70 vs. 17 GEQ-Q3, least square mean: 3.5 vs. 1.8 **Other outcomes assessed:** EDITS; partner satisfaction; positive correlation between self-assessment and IIEF-EF at baseline and post tx **Withdrawals/drop-outs/loss to f/u:** 7 (6) vs. 12 (10) **WDAE, n (%):** 2 (1.6) vs. 0 **TAE:** NR; pts with AE, n (%)=52 (42) vs. 20 (16); including flushing 17 (14) vs. 1 (1); headache 14 (11) vs. 1 (1); dyspepsia 5 (4) vs. 0; abnormal vision (blue tinge to vision, ▲ sensitivity to light, eye pain, & photophobia) 3 (2) vs. 0 **SAE, n (%):** 3 (2) vs. 3 (2); cause NR **Ascertainment of outcomes assessed:** IIEF, GEQ; ED self assessment scoring system

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Cavallini (2005) [11] **Funding source:** Sigma Tau (Industrie Farmaceutiche Riunite)	**N screened =** 139 **N randomized =** 110 **IG1, n** = 37 **IG2, n** = 40 **CG, n** = 33 **ITT analysis used for primary outcome:** No **Inclusion**: Pts complaining of ED after having bilateral nerve- sparing radical retro pubic prostatectomy 6 mo or more before the study entry with completely functional erections before the prostatectomy and had not received adjuvant or neoadjuvant tx for prostate cancer or other ED txt, having undetectable PSA levels, involvement in a heterosexual relationship for at least 6 mo before surgery **Exclusion:** pts with Peyronie's dx, hormonal abnormalities, Myocardial or cerebral ischemia, major surgery, tobacco/alcohol use, DM, uncompensated hyper/hyoptension	**Age, mean (sd):** 63 (4) vs. 61 (4) vs. 60 (5) y **Race (%)**: NR **Co-morbidities, %:** compensated hypertension 53 vs. 54 vs. 62; Hyper-cholesteremia 53 vs. 48 vs. 55 obesity 9 vs.7 vs. 10 **Previous ED treatment**: None **Smoking status, %:** past smokers (56 vs. 56 vs. 55) **Body weight:** NR	**Concomitant medications:** gemfibrozil, simvastatin, cilazapril, enalapril, nifedipine, quinapril, losartan, lacidipine **Duration of ED (yr):** NR (mean time past surgery= 1 y) **Underlying disease:** prostate cancer/ prostatectomy **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED:** NR	**IG1:** Sildenafil + Carnitines (acetyl- and propionyl) **IG2:** Sildenafil + placebo **CG:** placebo **IG1:** Dose: 100 mg sildenafil + 2 g/d each carnitine Duration: 4 mo Frequency: once/d Compliance: NR **IG2:** Dose: 100 mg sildenafil Duration: 4 mo Frequency: once/d Compliance: NR **CG:** Dose: NR Duration: 4 mo Frequency: once/d Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 4 mo	**Primary outcome results:** IIEF, mean (sd), IG1 vs. IG2 vs. CG: IIEF, EF: pre: 13 (5) vs. 11 (4); post: 27 (5) vs. 22 (7) vs. 12 (4), $p < 0.05$ IIEF, ICs: pre: 3 (1); post: 9 (5) vs. 5 (3) vs. 3 (0.6), $p < 0.05$ IIEF, OF: pre: 3 (1); post: 9 (3) vs. 6 (3) vs. 3 (0.6), $p < 0.05$ IIEF, SD: pre: 7 (0.7) vs. 6 (0.8); post: 6 (0.6) vs. 7(0.6) vs. 6 (0.7), p => 0.05 General sexual well-being: pre: 3 (0.7) vs. 3 (0.9); post: 8.6 (2.0) vs. 5.4 (2.7) vs. 2.8 (0.7), $p < 0.05$ **Other outcomes assessed:** Peak systolic and diastolic velocity **Withdrawals/drop-outs/loss to f/u:** 14 (13.5%) discontinued **WDAE:** None **TAE, n (%):** NR; AEs included headache 8 (25) vs. 9 (28) vs. 0; flushing 7 (22) vs. 8 (23) vs. 0; dizziness 3 (9) vs. 3 (9) vs. 0; nasal congestion 2 (6) vs. 2 (6) vs. 0; nausea 2 (6) vs. 2 (6) vs. 0; euphoria 2 (6) vs. 0 vs. 0; abdominal pain 0 vs. 0 vs. 1 (3) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF, Doppler effect

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Chen (2001) [12] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 236 **IG, n =** 119 **CG, n =** 117 **ITT analysis used for primary outcome:** Yes **Inclusion:** men 26-80 y; well-documented hx of ED for at least 6 mo; in stable heterosexual relationship for at least 6 mo **Exclusion:** genital anatomical abnormality or SCI; other coexisting sexual disorder; elevated serum PRL level or low T level; major psychiatric disorder or hx of alcohol or substance abuse; major hematologic, renal or hepatic dx; poorly controlled DM associated with untreated proliferative retinopathy; stroke or MI in last 6 mo; hypotension or any other sign CVD; hx of retinitis pigmentosa; taking drugs known to be causally associated with ED, androgen therapy, trazodone, nitrates or nitric oxide donor compounds; receiving any tx for ED	**Age, mean (range):** 61 (26-80) y **Race (%):** Asian 100% **Co-morbidities:** Benign prostatic hyperplasia 40 (34) vs. 44 (38) Visual disturbance 46 (39) vs. 37 (32) Essential hypertension 30 (25) vs. 40 (34) DM 26 (22) vs. 29 (25) Arthropathies and related disorders 16 (13) vs. 14 (12) **Previous ED treatment**: NR **Smoking status, n (%):** current smoker: 27 (23) vs. 28 (24) **Body weight, mean (range):** 69 (46-98) kg	**Concomitant medications, n (%):** Antihypertensive 30 (25) vs. 43 (37) Antacid 52 (22) Antirheumatic/antigout 21 (18) Antidiabetic 38 (17) Hypnosedative/ anxiolytic 26 (11) Upper respiratory tract medication 33 (14) Vitamins 30 (13) Beta-adrenoceptor blocker 23 (10) Antibacterial 23 (10) **Duration of ED, mean:** 4 y **Underlying disease:** NR **Psychogenic ED, n (%):** 20 (8) **Physiologic ED, n (%):** 193 (82)) **Mixed ED, n (%):** 23 (10)	**IG:** Sildenafil citrate **CG:** Placebo **IG:** Dose: 50 mg for first 2 wk; option to titrate to 100 mg or 25 mg Duration: 12 wk Frequency: once/d; 1 hr before sexual activity Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** IIEF, Q3, mean change from baseline: 1.9 vs. 0.7 IIEF, Q4 mean change from baseline: 2.vs. 0.9 IIEF-EF: pre: 14; post: 24 vs. 18 IIEF-ICs: pre: 5.3; post: 10 vs. 8 IIE-OF: pre: 5; post: 8 vs. 6 IIEF-SD: pre: 6; post: 7 vs. 6 IIEF-OS: pre: 4; post: 7 vs. 6 Successful intercourse, %: 62 vs. 30 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 10 (8) vs. 6 (5) **WDAE, n (%):** 1(<1) in IG; skin rash **TAE, n (%):** in at least 3 pts= 76 (64) vs. 58 (50); including: CV 34 (29) vs. 14 (12); flushing 30 (25) vs. 11 (9); palpitation 4 (3) vs. 2 (2); body as a whole 22 (19) vs. 11 (10); headache 8 (7) vs. 4 (3); abdominal pain 5 (4) vs. 0; chest pain 3 (2.5) vs. 0; respiratory system 15 (13) vs. 14 (12); nervous system 15 (13) vs. 9 (8); dizziness 9 (8) vs. 6 (5); musculoskeletal events 9 (3 (3); myalgia 3 (3) vs. 0; arthralgia 3 (3) vs. 2 (2); special senses 9 (8) vs. 2 (2); abnormal vision 3 (3) vs. 1 (0.9); skin an appendages 7 (6) vs.12 (10); fungal dermatitis 3 (3) vs. 2 (2) **SAE, n (%):** 4 (3) vs. 4 (3) **Ascertainment of outcomes assessed:** IIEF, pts filled diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Choi (2002) [13] **Funding source:** Pfizer	**N screened =** 133 **N randomized =** 133 **IG, n =** 66 **CG, n =** 67 **ITT analysis used for primary outcome:** Yes **Inclusion:** men with ED for at least 6 mo, in a stable heterosexual relationship for 6 mo or longer **Exclusion:** penile anatomical abnormalities; SCI, other co-existing sexual disorders, serum PRL levels > 3x upper limit to normal, low free T (> 0% below lower limit of normal), major psychiatric disorder, hx of alcohol or substance abuse; hx of haematological, renal, hepatic dx, MI; stroke, hypotension, retinitis pigmentosa, poorly condoled or causing proliferative retinopathy DM, use of drugs associated with androgen therapy, vacuum devices or other tx for ED.	**Age, mean (range):** 51 (28-78) vs. 51 (32-67) y **Race (%)**: NR **Co-morbidities, n (%):** Eye disorders 21 (32) vs. 14 (21) Hypertension: 13 (20) vs. 10 (15) Hyperplasia of prostate: 11 (17) vs. 12 (18); DM: 10 (15) vs. 8 (12) GI disorders: 6 (9) vs. 5 (8) **Previous ED treatment**: NR **Smoking status, n (%):** Smokers 25 (37.9) vs. 30 (44.8) **Body weight, mean (range)**: 70 (52-102) vs. 71 (50-98)	**Concomitant medications:** NR **Duration of ED (yr):** 5 vs. 5.6 y **Underlying disease:** NR **Psychogenic ED n (%):** 21 (32) vs. 24 (36) **Physiologic ED:** 31 (47) vs. 26 (39) **Mixed ED:** 14 (21) vs. 17 (25)	**IG:** sildenafil **CG:** placebo **IG:** Dose: 50 mg, option for titration at 2 wks to 100, or 25 mg Duration: 8 wks Frequency: once/d Compliance (%): 100 **CG:** Dose: NA Duration: 8 wks Frequency: once/d Compliance (%): 97 **Run In period:** 4 wks **Wash out period**: NR **F/u duration:** NR	**Primary outcome results:** IIEF, mean score, IG vs. CG Q3: baseline=2.5; post tx: 4 vs. 3 Q4: baseline = 2; post tx: 4 vs. 2 EF domain: baseline=13; post tx: 23 vs. 15 IS: baseline= 6; post tx: 11 vs. 8 OF: baseline 5; post tx: 8 vs. 5 SD: baseline=6; post tx: 7 vs. 6 OS: baseline= 4; post tx: 7 vs. 5 GAQ, % yes: 81 vs. 28 Intercourse success, %: 62 vs. 26 **Other outcomes assessed:** Event logs of sexual activity **Withdrawals/drop-outs/loss to f/u, n (%):** 2 (3) **WDAE:** 0 **TAE, n of events (%):** 46 (70) vs. 25 (27); AE in at least 3 pts: CV=flushing 21 (32) vs. 3 (5); body as whole: 21 (32) vs. 9 (13); headache 17 (26) vs. 6 (9); Upper respiratory tract infection=nasal congestion: 5 (8) vs. 3 (4); digestive system events: 8 (12) vs. 9 (14); dyspepsia 3 (5) vs. 5 (8); special senses events: 10 (15) vs. 3 (5); abnormalities in colour vision: 4 (5) vs. 0; abnormal vision 3 (5) vs. 1 (2) **SAE, n (%):** 2 (3), in CG **Ascertainment of outcomes assessed:** IIEF, GAQ, also event logs, 12 lead ECG, standard laboratory tests

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Choppin (2001) [14] **Funding source:** Roche Bioscience	**N screened =** NR **N randomized =** 24 **IG1/IG2/CG, n =** 24 (Latin-Square design) **ITT analysis used for primary outcome:** yes **Inclusion**: ED of continual duration ≥6 mo with no established organic cause **Exclusion:** NR	**Age, mean (range):** 44 (18-65) y **Race (%):** black 41.7%, white 58.3% **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** **Duration of ED:** at least 6 mo **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Ro70-0004 (active alfa$_{1A}$-adrenoceptor) + VSS **IG2:** sildenafil + VSS **CG:** placebo + VSS **IG1:** Dose: 5 mg (oral) Duration: NA Frequency: single dose Compliance (%): NR **IG2:** Dose: 50 mg (oral) Duration: NA Frequency: as IG1 Compliance (%): NR **CG:** Dose: placebo (oral) Duration: NA Frequency: as IG Compliance (%): NR **Run In period:** NR **Wash out period:** 7 d **F/u duration:** 2.5 hrs post dosing **Note:** last tx was repeated at 4th visit	**Primary outcome results:** Duration of erection in 26 vs. 27 vs. 25 periods; for total of 20 pts): Base, >60% rigidity: 8.28 (3.7) vs. 22.64 (3.57) vs. 9.69 (3.71) min Tip, >60% rigidity: 5.52 (2.84) vs. 9.21 (2.75) vs. 5.33 (2.85) min Base, >80% rigidity: 0.45 (1.69) vs. 5.26 (1.63) vs. 0.67 (1.69) min Tip, >80% rigidity: 1.20 (1.20) vs. 3.18 (1.16) vs. 1.23 (1.21) min **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 4 (20) **WDAE:** NR **TAE, n (%):** any AE 2 (10) vs. 2 (9.1) vs. 1 (4.8); dizziness, hypotensive episode, GI disorder in IG1; dizziness, sedation and haematoma nose in IG2; an thrombophlebetitis in CG **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan (30 min pre dose to 2.5 hrs post dose)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Christiansen (2000) [15] **Funding source:** Pfizer Ltd.	**N screened =** NR **N randomized =** 205 **IG, n =** 99 **CG, n =** 106 **ITT analysis used for primary outcome:** Yes **Inclusion:** men 18-70 y with ED of psychogenic or mixed organic/psychogenic etiology for at least 3 mo; at least 1 grade 3 or 4 erection during 4 wk before screening or positive response to IC injection test (papaverine ≤40 mg or PgE_1 ≤20 µg) **Exclusion:** known vascular, neurological, endocrine or penile anatomical cause for ED; hx of major hematologic, renal or hepatic abnormality; stroke, subarachnoid haemorrhage, bleeding disorder or peptic ulceration; elevated serum PRL level; low serum T level; moderate to severe hyper/ hypotension; regular tx with nitrates, anticoagulants, major tranquillizers, estrogens or antiandrogens	**Age, mean (sd):** 53 (19-70) vs. 54 (21-70) y **Race (%)**: NR **Co-morbidities, %:** Most frequent: Hypertension 14 Ischemic heart disease 12 Diabetes 7 Depression 5 **Previous ED treatment, n (%):** IC injections 86 (42) **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 4.8 (0.3-20) vs.5.3 (0.3-23) y **Underlying disease:** NR **Psychogenic ED, %:** 38 vs. 40% **Physiologic ED:** NR **Mixed ED:** 62 vs. 60	**IG:** sildenafil citrate **CG:** placebo **IG1:** Dose: 10 or 25 mg, as determined during 16-wk tx phase prior to double-blind study Duration: 8 wk Frequency: up to once/d approximately 1 hr before sexual activity Compliance: NR **CG:** Dose: placebo Duration: 8 wk Frequency: as IG Compliance: NR **Run In period:** 2 wk with placebo **Wash out period:** NA **F/u duration (both on and off treatment):** 8 wk **Other:** 16-wk open-label treatment phase after run-in period to adjust dosage	**Primary outcome results:** IIEF frequency of erections when sexually stimulated, mean change in score: ▲ 1.53 vs. ▼ 0.3 Question assessing frequency of erections lasting long enough: IG1 ▲ 1.72, CG ▼ 0.13 Mean number of grade 3 or 4 erections per wk: 1.5 vs. 0.6 GAQ, % yes: 82 vs. 26 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 3 (3), all in IG1 **WDAE, n (%):** 4 (3), no grp designation **TAE:** NR, most frequent AEs in IG vs. CG/ IG in 1 y open label, n (%): headache 6 (6) vs. 2 (2)/19 (10); dyspepsia. 5 (5) vs. 3 (3)/26 (14); flushing 7 (7) vs. 1 (1)/24 (13); abdominal pain 0 vs. 4 (4)/10 (5); diarrhoea 1 (1) vs. 0; nausea 1 (1) vs. 0/4 (2); back pain 2 (1) vs. 1 (1)/11 (6); asthenia 2 (2) vs. 0/3 (2); abnormal vision including colour hue or brightness perception 2 (2) vs. 0/4 (2); conjunctivitis 2 (2) vs. 0/4 (2) **SAE:** 24 no grp designation, including MI in open label phase **Ascertainment of outcomes assessed:** IIEF, GAQ, Patient diary of grading erection (1=enlarged but not hard-4=full erection)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
DeBusk, (2004) [16] **Funding source:** Pfizer Inc	**N screened =** 186 **N randomized =** 151 **IG, n =** 75 (ITT=70) **CG, n =** 76 (ITT=72) **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older with diagnosed ED (≤ 21 on Sexual Health Inventory), confirmed, and stable CAD for at least 4 wks **Exclusion:** currently using prescription for and/or taking nitrates, hypotension, uncontrolled hypertension, high cardiac risk, unstable angina, hypotrophic obstructive cardiomyopathy, moderate/severe aortic stenosis, concomitant TX with drugs that inhibit P450, commercial tx for ED, previously taken sildenafil	**Age, mean (range):** 61 (39-82) vs. 62 (41-80) y **Race (%):** more than 90% White **Co-morbidities:** CV conditions 100% (listed in full text); Hyperlipidemia 53 (72) vs. 49 (65); pure hypercholesterolemia 38 (51) vs. 38 (50); other also listed in full text **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications, n (%):** medication taken by more than 50% of pts= anti-inflammatory analgesics 133 (88); hyperlipidemia 131 (87); anti-hypertensives: 113 (75); Beta Blockers: 90 (60) **Duration of ED, mean:** 5 y **Underlying disease:** NR **Psychogenic ED, n (%):** 5 (7) vs. 3 (4) **Physiologic ED, n (%):** 36 (49) vs. 34 (45) **Mixed ED, n (%):** 33 (45) vs. 39 (51)	**IG:** sildenafil **CG:** placebo **IG:** Dose: 50 mg with option to titrate to 100 or 25 mg Duration: 12 wks Frequency: up to once/d (total dose=36) Compliance (%): 80 **CG:** Dose: NA (titration as IG) Duration: 12 wks Frequency: up to once/d (total = 40) Compliance (%): 85 **Run In period:** 2 wks **Wash out period:** NR **F/u duration:** 12 wks Other: final dose, n (%)= 25 mg: 3 (4) v. 0 50 mg: 16 (22) vs. 13 (17) 100 mg: 55 (74) vs. 63 (83)	**Primary outcome results:** IIEF- least square mean (SE) score: Q3, baseline=2; post tx: 3.5 vs. 2.7 Q4, baseline=1.6; post tx: 3.3 vs. 2.3 GEQ, % of pts with improvement on: Erection: 59 vs. 28 Intercourse: 56 vs. 27 Intercourse success: 51 vs. 25 **Other outcomes assessed:** IIEF, % of max possible score (all but SD improved in IG vs. CG, p<0.02;); EDITS scores; life satisfaction checklist scores **Withdrawals/drop-outs/loss to f/u:** 7 (10) vs. 9 (13); including lack of efficacy in 0 vs. 4 (6) **WDAE, n (%):** 1 (1.4) vs. 1 (1.3) **TAE, %:** 47 vs. 32; AE in more than 3% of pts, n (%)=headache 6 (8) vs. 1 (1); chest pain 4 (6) vs. 2 (3); hypertension 4 (6) vs. 1 (1); flushing 6 (8) vs. 0; dyspepsia 2 (3) vs. 4 (5); leg cramps 3 (4) vs. 0; respiratory tract infection 4 (5) vs. 2 (3); nasal congestion 2 (3) vs. 0; abnormal vision 1 (1) vs. 1 (1) **SAE, n (%):** 1 (1.4) vs. 2 (2.6),One chest pain in IG, and urinary tract infection, severe angina pectoris in CG **Ascertainment of outcomes assessed:** IIEF, EDITS; GEQ, and intercourse success rate by diary; life satisfaction check list

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Deveci (2004) [17] **Funding source:** NR	**N screened =** NR **N randomized =** 40 **IG, n=** 20 **CG, n=** 20 **Intention to treat (ITT) analysis:** NR **Inclusion:** NR **Exclusion: presence of** any contraindication for sildenafil use; hormonal disorders; performance concern; unsteady sexual partnership, past trial/use of oral sildenafil; chronic dx Data reported as IG vs. CG	**Age, mean (range):** 55 (25-65) y **Race (%):** NR **Co-morbidities, n (%):** DM 6 (15); hypertension 5 (12.5); benign prostatic hyperplasia 7(17.5); pts with 2 or more risk factors 4(10) **Previous ED treatment:** NR **Smoking status, n (%):** current & past smokers 9 (22.5)	**Concomitant medications:** NR **Duration of ED:** more than 3 mo **Underlying disease:** NR **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** sildenafil sublingual **CG:** placebo **IG:** Dose: 20 mg during sexual stimulation Duration: NR Frequency: NR Compliance (%): NR **CG:** Dose: NR Duration: as IG Frequency: as IG Compliance (%): NR **Run In period:** NR **Wash out period:** NA **F/u duration:** NR	**Primary outcome results:** Mean ▲ in IIEF-5: 1.75 (endpoint vs. baseline p=0.02) vs. 0.6 (endpoint vs. baseline p>0.05) Overall success rates, n (%): 13 (65) vs. 3 (15) Mean onset of erection: 15.5 vs. 30 min Mean duration of erection: 40 vs. 20 min **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE, n (%):**NR; headache 2 (10) vs. 1 (5); flushing 2 (10) vs. 2 (10); sweating 2 (10) vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** pts self reports; & IIEF-5 (5 item version of IIEF)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Diamond, LE (2005) [18] **Funding source:** Palatin Technologies, Inc.	**N screened =** NR **N randomized =** 19 (cross over) **IG1/ IG2/CG, n =** 19 **ITT analysis used for primary outcome:** NR **Inclusion**: men 40-65 y, with diagnosed ED of at least 6 mo currently using viagra or levitra and having an adequate response to either of them **Exclusion:** ED caused by untreated endocrine dx, penile deformity, prostate cancer or prostatectomy, major hepatic, renal, CV, psychiatric or CNS dx, stroke, SCI	**Age, mean (sd):** 53 (6.7) **Race (%)**: White 70, Black 10, Hispanic 20 **Co-morbidities, %:** Diabetes 10, hypertension 20, hyperlipidemia 50, obesity 10 **Previous ED treatment:** Viagra and levitra **Smoking status**: 50% (past/current) **Body weight:** 87 (13) kg **Other:** Total T level, mean: 436 (168) ng/dl	**Concomitant medications:** **Duration of ED (yr):** 5.0 (SD=5.4) **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other**: IIEF mean score = 21.2 (6-29)	**IG1:** Sildenafil + PT141 **IG2:** Sildenafil + placebo **CG:** Placebo **IG1:** Dose: 25 mg+7.5 mg Duration: NR Frequency: NR Compliance: NR **IG2:** Dose: 25 mg Duration: NR Frequency: NR Compliance: NR **CG:** Dose: NA Duration: NR Frequency: NR Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** NR **Other:** Outcome assessments done on 3 visits 3-10 d apart and continuously monitored until 6 hrs after each dose	**Primary outcome results:** IG1 vs. IG2, mean (SE): Base rigidity => 60%: 112.9 (19.2) vs. 69.9 (14.3) min, p < 0.01 Base rigidity => 80%: 61 (16) vs. 40 (10) min, p=>0.05 Tip rigidity => 60%: 99.5 (16.6) vs. 40.6 (7.5) min, p < 0.001 Tip rigidity => 80%: 48.6 (12.2) vs. 20.7 (4.8) min, p < 0.05 Pts-assessed mean quality score of erection after sexual-visual stimulation (1-10) = 8.2 (0.41) vs. 6.8 (0.52), p < 0.05 Rigidity parameters improved in IG1 vs. placebo (p < 0.05) **Other outcomes assessed:** tumescence activity levels **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** None **TAE:** more and new AE observed with combination tx; flushing one also had nausea 4 (21%) vs. 0 vs. 0; headaches 0 vs. 1 vs. 1 **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan and questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Dinsmore, W (1999) [19] **Funding source:** NR	**N screened =** 127 **N randomized =** 111 **IG, n =** 57 **CG1, n =** 54 **CG2, n=** 109 *(separate parallel study, no treatment, age matched, healthy subjects, single-visit data not included in this table)* **ITT analysis used for primary outcome:** Yes **Inclusion:** men older than 18 with clinical diagnosis of ED of at least 6 mo, participated in a stable, heterosexual relationship for at least 6 mo and to forego self-injection programs **Exclusion:** advanced vascular, neurological, endocrine, or anatomic causes for ED, major hematologic, renal, or hepatic abnormalities, regular use of nitrates, hx of stroke in the past 6 mo. or currently active peptic ulceration, tx with any experimented drugs in the 3 mo. preceding the study	**Age, mean (range):** 56 (30-78) vs. 55 (29-89) y **Race (%)**: NR **Co-morbidities, %:** hypertension IG 9 vs. 11; DM 7 vs. 7; ischemic heart disease 1 vs. 1 **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED (%)**: 40 vs. 39 (CG1) **Physiologic ED (%):** 21 vs. 20 **Mixed ED (%):** 39 vs. 37	**IG:** sildenafil (self-administered) **CG:** placebo **CG2**: no treatment **IG:** Dose: 25 mg (option to ▲ to 50 mg, max. 100 mg) Duration: 12 wks Frequency: 1-hr pre sexual activity but not > once daily Compliance: 87 % **CG:** Dose: NA (option to ▲ to 50 mg, max. 100 mg) Duration: 12 wks Frequency: 1-hr pre sexual activity but not > once daily Compliance (%): NR **Run In period:** 2-4 wks **Wash out period:** NR **F/u duration (both on and off treatment):** 12 wks + 2 wks = 14 wks	**Primary outcome results:** IIEF-Q1-15, range: pre (except Q11, and 12) </= 2.52; post tx range 2.77-3.92 vs. 1.37-3.10, sign ▲ ($p < 0.01$) GEQ, % improved: 81% vs. 18% ($p<0.0001$) Grade 3 or 4 erection/mo, mean (event log): 6.9 vs. 2.4 ($p<0.0001$) Successful sexual intercourse attempts: 73% vs. vs. 30% ($p<0.0001$) **Other outcomes assessed:** all IIEF items **Withdrawals/drop-outs/loss to f/u, n (%):** 14 (13) including 3 in IG, and 11 in CG discontinued tx due to lack of efficacy **WDAE:** 0 **TAE, n (%):** 18 (30) vs. 3 (5.5) headache 7(12%) vs.1 0; flushing 5 (9) vs. 2 (4); dyspepsia 4(7) vs.1 (2); abnormal vision 2 (4) vs. 0 **SAE, n:** nr **Ascertainment of outcomes assessed:** 15-item IIEF; GEQ; event log with of erection using a 5-point scale grading system (0 =no sexual activity; 1=almost never; 5=almost always) (added")

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Dunzendorfer (2002) [20] **Funding source:** NR	**N screened =** NR **N randomized =** 77 (cross over) **IG1, n =** 44 **IG2, n =** 33 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion:** pts with ED, and low to non-response to 5 PDE inhibitors; with complaint of prostate disease **Exclusion:** NR	**Age, mean (range):** 62 (34-77) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment:** 100% with PDE-5 inhibitors; 4 wks screening drug program for low responders to (n=58), 3 hrs before sildenafil 100 mg intake (dose/ sexual activity): Midodrine 25 mg; Testosterone 250 mg/wk; Ginseng 900 mg; Yohimbine 15 mg; Akatinol 10 mg; Apomorphine4 mg; Hydergin-S 8 mg; Prazosi 4 mg; DHE 5 mg **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** DM 4 (5); hypertension 17 (22); prostate dx 77 (100); mixed vasculogenic 77 (100) **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%):** NR	**IG1:** A: Sildenafil/ B: Sildenafil + Dihydro-ergotamine (DHE) **IG2:** A: Sildenafil + DHE/ B: Sildenafil **IG1:** Dose: slidenafil 50 mg, titrated to 100 mg; DHE 5 mg Duration: NR Frequency: twice / wk Compliance: NR **IG2:** Dose: 50 mg (titration as IG1)+ 5 mg DHE Duration: NR Frequency: as IG1 Compliance: NR **Run In period:** 4 wks (see previous ED tx) **Wash out period:** 4 wks **F/u duration:** NR **Other:** Pts received tx A (IG1) or B (IG2) followed by a wash out period and then crossed over to B (IG1) or A (IG2) respectively	**Primary outcome results:** Mean IIEF Q3, 4, 5 and 6, range of mean scores per question, (SD range): Baseline (run in) = 1.1-1.8 (0.2-0.4) 50 mg sildenafil alone = 1.1-2.1 (0.2-0.4) 100 mg sildenafil =1.5-2.1 (0.3-0.4) DHE alone = 1.3-2.2 (SD range 0.2-0.5) Combination 50 mg sildenafil + DHE =2.9-3.2 (0.5-0.7) 100 mg sildenafil + DHE = 3.5-3.8 (.6-0.8) **Other outcomes assessed:** NO-cAMP (N1 oxide cyclic adenosine monophosphate), and cGMP (cyclic guanosine monophosphate) levels in corpora cavernosa; urodynamic profile **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE:** NR **TAE:** NR (authors claim that combination tx reduced AE) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF, lab measures

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (1999) [21] **Funding source:** NR	**N screened =** NR **N randomized =** 16 (cross over) **IG/CG =** 16 **ITT analysis used for primary outcome:** No **Inclusion:** men 18 or older, with ED of no known organic cause **Exclusion:** Hx of DM, untreated hypogonadism; tx with nitrates, antidepressants or tranquilizers. Concomitant sign.arterial disease; other tx for ED less than 2 wks prior to start of study	**Age, mean (range):** 35-68 (57) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 1.9 (0.25 – 8) y **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** 0 **Mixed ED**: NR	**IG:** sildenafil **CG:** Placebo **IG:** Dose: 100 mg Duration: 2-5 hrs Frequency: twice Compliance (%): 100% **CG:** Dose: NA Duration: 2-5 hrs Frequency: twice Compliance (%): 100% **Run In period:** 2 wks **Wash out period:** 7 d **F/u duration:** f/u assessments at 2 and 4 hrs post dosing	**Primary outcome results:** Pts with grade 3 or 4 erection, n (%): IG only 13 (81.25) Duration of erection 2 hrs post dosing, mean: RigiScan, erections with > 60% rigidity at base: At 2 hrs post dosing: IG 2.5 min (responders = 4.1 min) At 4 hrs post dosing: IG responders = 2.2 min, for IG1 = 1.4 min Pts rated erection, grade 3 or 4: responders: At 2 hrs post dosing: 23.8 minutes At 4 hrs post dosing: IG responders 17.2 min **Other outcomes assessed:** None **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE: 0** **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan, self-rating scale

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2001) [22] **Funding source:** Pfizer Inc.	**N screened =** 47 **N randomized =** 44 (crossover design) **IG/CG, n =** 44 **ITT analysis used for primary outcome:** Yes (n=40) **Inclusion:** men18-70 y; clinical diagnosis of ED of no established organic cause for longer than 6 mo; in stable relationship with female partner; have residual ED (at least one grade 3 or 4 erection) or positive response to papaverine or PgE_1 injection within 4 wk of study entry **Exclusion:** having 2 successive penetrative sexual intercourse acts per wk; hx of alcohol misuse; regular tx with nitrates, anticoagulants or acetylsalicylic acid within 2 wk; tx with antidepressants or major tranquillizers for psychoses or related conditions; continued use of other ED tx	**Age, mean (range):** grp: 53 (33-69) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 3 (0.5-10) y **Underlying disease:** NR **Psychogenic ED**: 100% **Physiologic ED:** 0 **Mixed ED:** NR	**IG1:** sildenafil **CG:** placebo **IG1:** Dose: 25 mg with option to titrate to 50 mg and then 75 mg if necessary Duration: median 29 d (two 28 d tx periods) Frequency: 1 dose 30-60 min before sexual activity; max. 1/d Compliance: 91% took at least one dose **CG:** Dose: placebo (titration as IG) Duration: as IG Frequency: as IG Compliance: as IG **Run In period:** None **Wash out period:** None **F/u duration:** 10 wk (2 wks post last tx period) **Other:** 24 pts received sildenafil first, and 20 received placebo first; each period lasted for 28 d	**Primary outcome results:** Geometric mean number of grade 3 or 4 erections per wk: 4.2 vs. 1.4 Erection of grade 3 or 4/ doses: I94 vs. 68 Intercourse success/ dose, %: 62vs. 12 GEQ-Q1 (improved erection), % yes: 34 (94) vs. 9 (25) GEQ-Q2 (ease of use), %: 33 (94) vs. 13 (37) **Other outcomes assessed:** partners' assessment of quality of erections **Withdrawals/drop-outs/loss to f/u:** 5 (11) **WDAE, n (%):** 0 vs. 1 (<1) **TAE, n (%):** all reporting AE 23 (53) vs. 14 (33); tx related AE: headache 11 (26) vs. 0; flushing 4 (9) vs. 0; dyspepsia 3 (7) vs. 1 (2); arthralgia 3 (7) vs. 2 (5) **SAE, n (%):** 0 vs. 1 (<1) MI in second period **Ascertainment of outcomes assessed:** daily log of erection (grading system 1-4), and intercourse satisfaction

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2002)[23] **Study a** **Funding source:** NR	**N screened =** 17 **N randomized =** 17 (two-way crossover study) **IG, CG, n =** 17 **ITT analysis used for primary outcome:** No **Inclusion**: age 35-70 y, clinical diagnosis ED, no organic cause for at least 6 mo **Exclusion:** hx of serious medical conditions (DM, untreated hypogonadism, sign arterial dx, migraine headaches, alcohol or substance abuse. Current tx with nitrates, antidepressants, tranquilizers or anticoagulants. Other therapies for ED (e.g. E_1 IC) discontinued 2 wks prior to start of study	**Age, mean (range):** 52yrs (37-70) **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** 4 received prostaglandin, 2 yohimbine, 1 an investigational drug **Smoking status**: NR **Body Weight:** NR **Other:** other conditions, n (%); vasectomy 3 (17.6%), 1 unilateral orchidectomy, prostatitis 1 (5.8%), caricosities 1(5.8%)	**Concomitant medications:** NR **Duration of ED:** 3.1 y (0.5-19) **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG**: sildenafil + 60 min visual sexual stimulation (VSS) **CG:** placebo + 60 min visual sexual stimulation **IG:** Dose: 50 mg Duration: NR Frequency: once Compliance (%): 100% **CG:** Dose: NA Duration: NR Frequency: once Compliance (%): 100% **Run In period:** NR **Wash out period:** 7 d **F/u duration:** NR	**Primary outcome results:** Proportion of responders with rigidity > 60%, n (%): 14 (82) vs. 9 (53) Pts with grade 3 or 4 erection: 12 (71) vs. 6 (35) Time to onset of erections (median): 27 min (range 12-70) vs. 50 min The onset of erections occurred only after VSS; 8 (47%) responded to both active and placebo tx **Other outcomes assessed:** none **Withdrawals/drop-outs/loss to f/u, n (%):** 1 **WDAE:** 0 **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan; physical exam, patient report; standard laboratory tests

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2002)[23] **Study b** **Funding source:** NR	**N screened =** 16 **N randomized =** 16 (two-way crossover) **IG/ CG, n =** 16 **ITT analysis used for primary outcome:** No **Inclusion:** men 35-70 yrs, clinical diagnosis ED, no organic cause for at least 6 mo **Exclusion:** hx of serious medical conditions (DM, untreated hypogonadism, sign arterial dx, migraine headaches, alcohol or substance abuse. Current tx with nitrates, antidepressants, tranquilizers or anticoagulants; other therapies for ED (IC injections) discontinued 2 wks prior to start of study.	**Age, mean (range):** 57 (35-68) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: none **Smoking status**: NR **Body weight** NR **Other:** pts conditions, n (%) vasectomy 7 (43.8), undescended right testicle 1 (6.3), prostatitis, redundant prepuce 1 (6.3), scrotal cyst 1 (6.3), hyperplasia of the prostate 1 (6.3)	**Concomitant medications:** NR **Duration of ED (mean yrs, range):** 1.9 (3-8.0) y **Underlying disease (diagnosis) (N or % of diseased/ grp):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG**: sildenafil+ 60 min visual sexual stimulation (VSS) **CG:** placebo + 60 min VSS **IG1:** Dose: 100 mg Duration: NR Frequency: twice Compliance (%): 100% **CG:** Dose: NA Duration: NR Frequency: twice Compliance (%): 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** four assessment at 3 hrs and 5 hrs **Other:** pts received 4 tx (2 active and 2 placebo)	**Primary outcome results:** Proportion of responders with rigidity > 60%, n (%): 3 hrs post VSS: 12 (75) vs. 5 (31) 5 hrs post VSS: 13 (81) vs. 5 (31) Duration of erection, mean (SE): 3 hrs post VSS: 19.4 (4.1) vs. 3.9 (2.1) min 5 hrs post VSS: 17.2 (4.0) vs. 3.6 (2.0) **Other outcomes assessed:** none **Withdrawals/drop-outs/loss to f/u, n (%):** 1 (6.3) **WDAE:** 0 **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan; physical exam patient report, standard laboratory tests

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2005) [24] **Funding source:** Lilly ICOS LLC	**N screened =** 411 **N randomized =** 367 **IG1, n =** 183 (first period) **IG2, n =** 184 (first period) **CG, n =** NA **ITT analysis used for primary outcome:** Yes **Inclusion**: Pts aged => 18 yr with documented ED of any aetiology and severity, in a steady relationship with the same female partner naïve to treatment for ED with drugs inhibiting PDE5 **Exclusion:** Pts with endocrine dx, premature ejaculation, prostatectomy, pelvic surgery, penile deformity, sign renal or hepatic dx, CHF, Within 6 mo, MI, coronary artery bypass surgery, sudden cardiac arrest, SBP (< 90 - > 170 mmHg) or diastolic (< 50 - > 100 mmHg), malignant hypertension, retinitis pigmentosa, current tx with nitrates, cancer chemotherapy, HIV infection, substance/drug abuse in last 6 mo	**Age, mean (sd):** 54 (12) y **Race (%)**: Caucasian 92, Black 4, Asian 3, other 1.3 **Co-morbidities, (%):** Hyperlipidemia 11, coronary artery dx 6.5, hypertension 26.4, DM 9.5, depression 4 **Previous ED treatment**: NR **Smoking status, (%)**: current = 24 **Body weight:** NR **Other:** current alcohol use (65%)	**Concomitant medications:** no other ED treatments **Duration of ED:** NR **(**pts with 1 y or more ED =74%) **Underlying disease:** NR **Psychogenic ED**: 12% **Physiologic ED:** 28% **Mixed ED**: 60% **Other:** ED defined as consistent change in the quality of erection that adversely affects subject's satisfaction with sexual intercourse **Other:** Mean IIEF (EF): 14 (6); Severity of ED: severe (IIEF1-10): 31%, moderate (IIEF 11-16): 30%, mild (IIEF 17-30): 39%	**IG1:** Sildenafil **IG2:** Tadalafil **IG1:** Sildenafil Dose: 25-100 mg Duration: 12 wks Frequency: NR Compliance: NR **IG2:** Tadalafil Dose: 10-20 mg Duration: 12 wks Frequency: NR Compliance: NR **Run In period:** 4 wks **Wash out period:** 7-10 d **F/u duration:** before and after crossover 24 wks (2 periods of 12 wks) **Other:** Dose was titrated up and down between 25-100 for Sildenafil and 10-20 mg for Tadalafil	**Primary outcome results:** Mean least squares change from baseline for IIEF domains and 95% CI (IG2 vs. IG1): EF: 0.5 (-0.07, 1.1) OF: 0.3 (0.02, 0.5) SD: 0.2 (0.02, 0.6) Intercourse satisfaction: 0.17 (-0.1, 0.42) Mean change in IIEF questions: erection firmness, intercourse satisfaction and enjoyment, desire level, OS, erection confidence: tadalafil > sildenafil OS: 0.3 (0.02, 0.5) SEP, mean change from baseline: SEP-Q2: 36 vs. 39 SEP-Q3: 53 vs. 58 **Other outcomes assessed:** mean scores of IIEF, drug preference **Withdrawals/drop-outs/loss to f/u:** IG1 (1^{st}) and IG2 (2^{nd}): n=42 IG1 (2^{nd}) and IG2 (1^{st}): n=39 **WDAE:** IG1 (1^{st}) and IG2 (2^{nd}): n=4 IG1 (2^{nd}) and IG2 (1^{st}): n=7 **TAE, n (%):** pts with 1 or more AE=125 (34) vs. 128 (35) **SAE, n:** 4 (2) vs.5 (3) **Ascertainment of outcomes assessed:** Questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Fava (2006) [25] **Funding source:** Pfizer Inc. (conflict of interest for authors; paid by Pfizer, and other sources)	**N screened =** NR **N randomized =** 142 **IG1, n =** 71 **CG, n =** 71 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older with ED diagnosed by Sexual Health Inventory for Men (SHIM) score of 21 or less, and diagnosed major depressive disorder (MDD) according to DSM-IV criteria in remission in stable relationship **Exclusion:** symptomatic for depression or anxiety despite tx; pts requiring tx with antipsychotics, mood stabilizers, other nonserotonergic antidepressant agents or lithium; use of nitrates or any commercially available for ED	**Age, mean (range):** 51 (27-74) y **Race, %:** White 86 vs. 92%; Black 6 vs. 3%; Asian 3 vs. 0%; other 6% in both grps **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight, mean (range):** 92 (57-191) vs. 92 (60-138) kg	**Concomitant medications, n (%):** antidepressant therapy, selective SRI 133 (94); serotonin-norepinephrine reuptake inhibitor 10 (7); other antidepressant drugs 10 (7) **Duration of ED, mean (range):** 2.7 (0.1-14.2) vs. 2.2 (0.2-11.6) y **Underlying disease, n (%):** depression **Psychogenic ED, n (%):** 100% **Physiologic ED:** NA **Mixed ED:** NR	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg titrated to up to 100 or down to 25 mg based on efficacy and tolerance Duration: 6 wks Frequency: NR Compliance: **CG:** Dose: NA Duration: 6 wks Frequency: NR Compliance: **Run In period:** **Wash out period:** **F/u duration:** Other: mean dose taken/ mo= 13.6 vs. 11; 65% on 100 mg 34% on 50 mg and 1% on 25 mg sildenafil at end of study	**Primary outcome results:** IIEF mean score: Q3: baseline 2.4; post tx 3.9 vs. 3.1, p=0.003 Q4: baseline 2.1; post tx 3.7 vs. 2.8, P<0.001 GEQ- Q1, % improved: 70.6 vs. 28.8 GEQ-Q2, % improved: 72.1 vs. 27.7 GEQ-Q3, mean (SE) scale of 1-5: 2.5 (0.2) vs. 1.3 (0.2) Event log, mean (SE) N of events/ wk: N of sexual intercourse attempts: 2.6 (0.2) vs. 1.9 (0.2) N of successful attempts: 1.9 (0.2) vs. 0.6 (0.2) Successful attempts/ wk, % (95% CI): 71 (60 to 80) vs. 31 (22 to 43) **Other outcomes assessed:** All EDITS questions indicated tx success with sildenafil **Withdrawals/drop-outs/loss to f/u, n (%):** 9 (12.7) vs. 4 (5.6) **WDAE:** NR **TAE, n (%):** NR; all included headache 6 (9) in all; dyspepsia 6 (9) vs. 1 (1); anxiety 4 (6) vs. 3 (4); abnormal/ blurry vision 2 (3) vs. 0 **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** IIEF, EDITS, GEQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Fowler (2004) [26] **Funding source:** Pfizer Inc.	**N screened =** 256 **N randomized =** 218 **IG, n =** 104/ (102, 98% completed) **CG, n =** 113/ (n= 88, 78% completed) **Intention to treat (ITT) analysis:** yes **Inclusion**: men 18 yr or older, ED of at least 6 mo; diagnosis of multiple sclerosis (MS) of at least 1 yr (criteria not defined/ type of MS not defined), with residual disability level of 2-6 (ambulatory) based on Kurtzke Extended Disability Status Scale (EDSS) **Exclusion:** penile deformities; major haematological, renal or hepatic abnormalities, coexistence /sexual dx as primary cause; uncontrolled psychiatric condition; cardiovascular disorder; unknown hx of retinitis pigmentosa; use of nitrates, or corticosteroids (last 2 mo); nitric oxide donors	**Age, mean:** 46 y **Race (%)**: NR **Co-morbidities:** 100% MS (mean duration 10.4 y) **Previous ED treatment**: NR **Smoking status**: NR **Note:** data reported for IG vs. CG	**Concomitant medications:** (used by > 10% of pts) analgesics; antibacterial; antidepressants; antihypertensive (> in CG); corticosteroids (> in IG); drugs affecting immune response, muscle relaxants; rheumatic diseases medication; vitamins **Duration of ED:** mean (range) 5.2 (0.7-23.1) vs. 6.1 (0.9-29) yr **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Sildenafil **CG:** placebo **IG:** Dose: 50 mg (32%); titrated up to 100 (64%), or down to 25 mg (4%) based on patient response & tolerability Duration: 12 wks Frequency: max once / d, 1 hr before sexual activity Compliance (%): NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance (%): NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks **Note:** this trial was followed by an open label period of 24-48 wks (n=206) & included those with non tx related AE; (50 mg sildenafil)	**Primary outcome results:**IIEF-Q1 (improvement in erection), % of pts: 90% vs. 24%, p<0.0001 Q2 (satisfactory erection for intercourse), % of pts: 92% of responders to Q1 Q3/Q4: IG better than CG, p<0.0001 Q9/ Q10: IG better than CG, p< 0.0001 Q11/ Q12: IG better than CG, p=0.0002 GEQ3, mean score: 4 vs. 2 **Other outcomes:** quality of life, IG did better in 5/8 variables than CG, (sexual life 86% of pts vs. 22%) **Withdrawals/drop-outs/loss to f/u, n (%):** 2 (2) vs. 25 (22) **WDAE:** 0 vs. 1% **TAE (%):** AE in more than 3% of pts in IG vs. CG/IG open label=66.3 vs. 43.4/73; headache 27 vs. 7/23; flushing 13 vs. 2/16; weakness 6 vs. 1/4; MS relapse 7 vs. 2/10; rhinitis 6 vs. 1/7; chromatopsia 4 vs. 0/4; dyspepsia 6 vs. 0/6 **SAE, n (%):** 3 (3) vs. 3 (3), urinary tract infection, worsening, & exacerbations of MS in IG; weakness, bone disorder, MI in CG **Ascertainment of outcomes assessed:** IIEF; GEQ, quality of life questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gentile (2004) [27] **Funding source:** Sigma-Tau, Italy	**N screened =** NR **N randomized =** 40 **IG, n =** 20 **CG, n =** 20 **ITT analysis used for primary outcome:** N **Inclusion:** men 18 or older, with ED, in a stable relationship of more than 6 mo; type 1 DM of at least 5 y or type 2 DM of at least 2 y (defined by National Diabetes Data Group), medical management of DM for 6 mo., HbA1C levels < 11% **Exclusion:** genital anatomical deformities, a primary dx of a sexual disorder other than ED, a poorly controlled major psychiatric disorder, a recent hx of major haematological, renal or hepatic abnormalities, MI, stroke, heart failure, unstable angina or hypotension, or tx with nitrates, HbA1C levels ≥ 11% (Complete list in full text article)	**Age, mean (range):** 64 (45-81) y **Race (%):** Caucasian 100 % **Co-morbidities, %:** hypertension 31 vs. 34; peripheral vascular dx 4 vs. 3; other 3 vs. 2 **HbA1C level, % (range):** 8.6 (5.7-11.3) vs. 8.4 (5.6-10.9) **Previous ED treatment**: Viagra monotherapy in all **Smoking status**: smoker 32 vs. 29 **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 5.7 (0.7-22) vs. 5.3 (0.6-19.5) y **Underlying disease, %:** DM type 1= 18 vs. 16; DM type 2= 82 vs. 84 **Organic ED, (%):** 65 vs. 66 **Mixed ED, %:** 35 vs. 34	**IG:** propionyl-L carnitine (PLC) + sildenafil **CG:** placebo PLC + sildenafil **IG:** Dose: 2 g PLC+ 50 mg sildenafil Duration: 24 wks Frequency: once/d + twice/wk Compliance: NR **CG:** Dose: 2 g (placebo) + 50 mg sildenafil Duration: 24 wks Frequency: as IG Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 24 wks	**Primary outcome results:** IIEF-Q3, mean (sd): 4.3 (0.6) vs. 3 (0.7), p<0.01 IIEF-Q4, mean (sd): 3.9 (1) vs. 2.7(0.9), p<0.01 GEQ, (% yes): 68 vs. 23, p<0.01 Successful attempts of intercourse (Event logs), %: ▲ from 11% to 34% vs. ▲ 10% to 76%, p<0.01 **Other outcomes assessed:** vascular evaluations [e.g. cavernosal artery; PSV, resistance index (RI)] **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** gastric pain 2 vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF; GEQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gingell (2004) [28] **Funding source:** Pfizer	**N screened =** 17 **N randomized =** 16 (four way crossover trial) **IG/ CG, n =** 16 **ITT analysis used for primary outcome:** yes (n=16) **Inclusion**: sildenafil naïve men 18 to 70 y and had been diagnosed with ED of no known organic cause for longer than 6 mo **Exclusion:** Men who had not experienced at least one erection of sufficient rigidity for penetrative intercourse in the previous 4 wks, or failed to give positive response to IC prostaglandin or papaverine at screening; hx of DM, untreated hypogonadism; sign arterial, renal or hepatic dx or used antidepressants, tranquilizers, nitrates, IC injections or any other tx for ED in 2 wks.	**Age, mean (range):** 55 (36-68) y **Race, n (%):** White 16 (94) **Co-morbidities:** NR **Previous ED treatment**: None within last 2 wks. **Smoking status**: NR **Body weight, mean (sd):** 83 (10) kg	**Concomitant medications:** None **Duration of ED:** ≥ 6 mo **Underlying disease:** None **Psychogenic ED:** None **Physiologic ED:** None **Mixed ED**: None	**IG:** Sildrnafil (mix of both given at diff time periods) **CG:** Placebo **IG:** Dose: 100 mg Duration: three 14 hr inpatient stay in 4 wks Frequency: once/ session (at one of either 12, 8, or 1 hr prior to VSS) Compliance: 100% **CG:** Dose: 3 tablets Duration: one14 hr inpatient stay Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** 7 d **F/u duration**: 4 wks **Other:** pts were randomized into sequence grps (I-IV) and sildenafil or placebo administered test periods (A-D)	**Primary outcome results:** Duration of erections of ≥60% rigidity, mean for IG at 1, 8, 12 hr prior to VSS vs. CG: 26, 11, 8 vs. 3.4 min Duration of grade 3 or 4 erection, (hard enough, completely hard) at 1, 8, 12 hr: 33, 23, 16 vs. 7 min (75% reported grade 3 or 4 after 2 hrs) **Other outcomes assessed:** Proportion of sildenafil responders 1,8, 12 hrs, %: 69, 60, 31; 82% after 8 hrs, and 54% after 12 hrs **Withdrawals/drop-outs/loss to f/u:** 1 pts excluded (use of IC injection during trial) **WDAE:** None **TAE:** NR; most common, AEs at 1, 8, and 12 hrs pre VSS 27 vs. 1; AEs included headaches 12 vs. 0; flushing 9 vs. 0; diarrhea 1 vs. 0; dry mouth 1 vs. 0; GI disorder 1 vs. 1; respiratory tract infection 1 vs. 0; visual disturbances (chromatopsia) 2 vs. 0 Most common headache: 12 Facial Flushing: 9 CG n: Gastro 1 **SAE:** None **Ascertainment of outcomes assessed:** RigiScan; self-assessed duration of grade 3 or grade 4 erections**:**

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Glina (2001) [29] **Companion Glina (2002)** [30] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 245 (Parallel grp) **IG, n =** 124 **CG, n =** 121 **ITT analysis used for primary outcome:** Yes **Inclusion**: Brazilian and Mexican men 18 or older with ED of broad-spectrum etiology ≥6 mo in a stable, heterosexual relationship for a duration of ≥ 6 mo. **Exclusion:** genital anatomical deformities; ED secondary to SCI, primary diagnosis of other sexual disorders; uncontrolled DM; hx of stroke, MI or sign. CV disease within previous 6 mo, hypotension or hypertension; alcoholism or substance abuse; receiving nitrates or nitric oxide	**Age, mean (range):** 58 (28-85) vs. 55 (27- 84) **Race, n (%):** Hispanic: 60 (48.4) vs. 57 (47.1); White 60 (48.4) vs. 58 (47.9); Other: 4 (3.2) vs. 6 (5) **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** antihypertensives, insulin and antidiabetics, beta-adrenoreceptor blockers, hypnotics, sedatives, anxiolytics, anti-inflammatory analgesics, diuretics, hyperlipidemia tx **Duration of ED, mean (range):** 3.7 (0.5 – 25.6) vs. 3.4 (0.5 – 21.7) y **Underlying disease (diagnosis); n (%):** Hypertension 36 (29) vs. 29 (24); DM 30 (24) vs. 22 (18); Prostatic hyperplasia 6 (5) vs. 8 (7); Visual disturbance 5 (4) vs. 7 (5.8) **Psychogenic ED; n (%):** 25 (20.2) vs. 18 (14.9) **Physiologic ED:** Organic: 51 (41.2) vs. 50 (41.3) **Mixed ED; n (%):** 48 (38.7) vs. 53 (43.8)	**IG:** Sildenafil citrate **CG:** Placebo **IG:** Dose: 25, 50 or 100mg Duration: 12 wks Frequency: once daily 1 hr before sexual activity Compliance (%): 91 **CG:** Dose: NA Duration: 12 wks Frequency: once daily 1 hr before sexual activity Compliance (%): 89 **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** IIEF, mean (SE): Q3 (penetration): 3.93 (0.15) vs.2.56 (0.16) Q4 (maintained erections after penetration): 3.83 (0.15) vs. 2.33 (0.15) GEQ, % improved erection: 81% vs. 36% GEQ, % with successful intercourse: 71% vs. 32% % maximal domain score from graph[30]: baseline (pre); post intervention IG vs. CG EF: pre 40; post 75 vs. 50 OF: pre 59; post 84 vs. 68 SD: pre 70; post 79 vs. 70 IS: pre 44; post 69 vs. 55 OS: pre 40; post 76 vs. 50 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 15 (12.1) vs. 16 (13.2) **WDAE, n (%):** 1 (0.8) vs. 0 **TAE (%):** 35% vs. 20%, flushing 11(8.9), vs. 0; headache 15 (12) vs. 6 (5); dyspepsia 9 (7) vs. 0; rash 5(4) vs. 0; dizziness 4(3) vs. 1(0.8); abnormal vision 4 (3.2) vs. 1 (0.8); rhinitis 3(2.4) vs. 1(0.8) **SAE:** 1 (<1) vs. 5 (4), no reasons provided **Ascertainment of outcomes assessed:** Q3 and Q4 and GEQ[29] 15 item IIEF questionnaire, and event log

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Goldstein (1998) [31] **Companion** [32] **Study a** **Funding source:** Pfizer	**N screened =** NR **N randomized =** 532 (dose response) **IG, n =** 316 (completers: IG1, n = 96; IG2, n = 105; IG3, n= 101) **CG, n =** 216 (completers =199) **ITT analysis used for primary outcome:** yes **Inclusion:** men in stable relationship 6 mo or longer, with ED confirmed by clinical exam and IC injection of vasoactive drug (31% of men), normal NPT, penile duplex ultrasonography, and endocrine testing **Exclusion:** penile deformities, another sexual disorder; SCI, major psychiatric dx; poorly controlled DM; peptic ulcer dx, hx or alcohol or substance abuse; hematologic, renal or hepatic abnormalities, recent stroke or MI in last 6 mo; nitrate therapy	**Age, mean (range):** 58 (24-87) vs. 57 (20-79) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean:** 3.2 y **Underlying disease (% of pts):** hypertension 30 vs. 26; ischemic heart dx 8; hyperlipidemia 19 vs. 16; hx or radical prostatectomy 12 vs. 10; DM 13 vs. 15 **Psychogenic ED (%):** 9 vs. 10 **Physiologic ED (%):** 78 vs. 77 **Mixed ED (%):** 13 (both grps)	**IG1/3:** Sildenafil- oral **CG:** placebo- oral **IG1-3:** Dose: 25 mg (IG1), 50 mg (IG2), 100 mg (IG3) Duration: 24 wk Frequency: once/d (one hr prior to sexual activity) Compliance: 97% **CG:** Dose: NA Duration: 24 wk Frequency: as IG Compliance: 99% **Run In period:** NR **Wash out period:** NR **F/u duration**: 24 wks	**Primary outcome results:** IIEF, Q3/ Q4 (similar values for both), mean (sd) score: Baseline: IG=CG 2 (0.2); Post tx: 3-4 (0.2) vs. 2 (0.2) IIEF-EF: increase in score with dose escalation, IG vs. CG p<0.001 Grade 3 or 4 erection, (%): 72, 80, 85 vs. 50% (80% of grade 3 and 94% of grade 4 erections resulted in intercourse; positive dose response) Improved erection (% of pts): 56, 77, 84 vs. 25, p< 0.001 **Other outcomes assessed:** IIEF, Q6, 7, 8, 13 and 14 (> in IG); SD (no change) **Withdrawals/drop-outs/loss to f/u, n (%):**IG=31 (10) [15 (15), 8 (7), 8 (7)] vs. CG =36 (17) **WDAE:** 4 (1) vs. 1 (<1) **TAE, n (%):** in 5% of pts or more IG 15 (15)/ 8 (7)/ 8 (7) vs. CG 36 (17); AE included headache 14-32 (14-30) vs. 14 (6); flushing 13-29 (13-27) vs. 3 (1); dyspepsia 3-17 (3-16) vs. 3 (1); rhinitis 1-12 (1-11) vs. 4 (2); visual disturbance 2-10 (2-9) vs. 1 (<1) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; ED validated questionnaire; self report event log (grading system)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Goldstein (1998) [31] **Study b** **Funding source:** Pfizer	**N screened =** NR **N randomized =** 329; (dose escalation + open label extension) **IG, n =** 163 **CG, n =** 166 **ITT analysis used for primary outcome:** yes **Inclusion:** men in stable relationship 6 mo or longer, with ED confirmed by clinical exam and IC injection of vasoactive drug (31% of men), normal NPT, penile duplex ultrasonography, and endocrine testing **Exclusion:** penile deformities, another sexual disorder; SCI, major psychiatric dx; poorly controlled DM; peptic ulcer dx, hx or alcohol or substance abuse; hematologic, renal or hepatic abnormalities, recent stroke or MI in last 6 mo; nitrate therapy	**Age, mean (range):** 60 (26-79) vs. 59 (31-81) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean:** 5 y **Underlying disease (% of pts):** hypertension 24 vs. 28; ischemic heart dx 15 vs. 8; hyperlipidemia 15 vs. 14; hx or radical prostatectomy 9 vs. 11; DM 8 vs. 11 **Psychogenic ED, n (%):** 14 vs. 16 **Physiologic ED, n (%):** 55 vs. 63) **Mixed ED, n (%):** 31 vs. 22	**IG:** Sildenafil -oral **CG:** placebo- oral **IG:** Dose: 50 mg (titrated at each f/u visit to double or 50% less based on the therapeutic response and AE) Duration: 12 wk Frequency: once/ d (one hr before sexual activity) Compliance: 94 **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: 92 **Run In period:** **Wash out period:** **F/u duration:** 12 wk (also at end of open label study of 32 wks)	**Primary outcome results:** IIEF, Q3/ Q4 mean (sd) score: Baseline (IG=CG): 2 (0.1)/ < 2 (0.1) post tx: 4 (0.1) vs. 2 (0.1)/ 4 (0.1) vs. 1.8 (0.1) IIEF-EF, mean score: 22 vs. 12, p<0.001 Successful attempts of sexual intercourse (%): 69 vs. 22 Mean n of successful attempts in last 4 wks: 6 vs. 1.5 Improved erection, n (%): 101 (74) vs. 23 (19), p< 0.001 **Other outcomes assessed:** IIEF, Q6, 7, 8, 13 and 14 (> in IG); SD (no change) **Withdrawals/drop-outs/loss to f/u, n (%):** 9 (6) vs. 13 (8), open label (n=225)= 18 (8) **WDAE, n (%):** **TAE, n (%):** in 5% or more of all IG vs. CG/ IG open label: headache 30(18) vs. 14 (6)/ 28 (12); flushing 30 (18) vs. 1 (1)/ 22 (10); dyspepsia 9 (6) vs. 4 (2)/ 12 (5); rhinitis 8 (5) vs. 1(1)/ 4 (2); visual disturbance 4(2) vs. 1 (1)/ 9 (4) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; questionnaire for clinical assessment of ED, & tx outcomes; self report by event log; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Goldstein (1998) [33] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 861 **Study I dose-response** **IG1, n =** 316 **CG1, n =** 216 **Study II dose-escalation** **IG2, n =** 163 **CG2, n =** 166 **ITT analysis used for primary outcome:** yes **Inclusion**: men with ED of 6 mo or longer, in a stable relationship with a female partner for at least 6 mo **Exclusion:** penile anatomical defects, another sexual disorder; SCI; major psychiatric disorder, poorly controlled DM; peptic ulcer disease, hx of alcohol or substance abuse, major systemic abnormalities, recent stroke or MI; nitrate therapy	**Age, mean:** 58 (NR) **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications: (n/grp)** NR **Duration of ED:** NR, at least ≥ 6 mos. **Underlying disease (%):** 100 ED **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED:** NR	**Study I dose-response** **IG:** oral sildenafil **CG:** oral placebo **IG:** Dose: 25 or 50 or 100 mg Duration: 12 wks Frequency: NR Compliance: NR **CG:** placebo (same as IG1) **Study II dose-escalation:** **IG1:** oral sildenafil **CG:** oral placebo **IG1:** Dose: 50 mg (dose could be doubled or reduced by 50% at f/u) Duration: 24 wks Frequency: NR Compliance: NR **CG:** placebo (same as IG1) **Run In period:** NR **Wash out period:** NR **F/u duration:** dose-response 12 wks dose-escalation 24 wks	**Primary outcome results:** IIEF, % increase from baseline in IG vs. CG: Q3, successful penetration Study I: 60 (25 mg), 84 (50 mg), 100 (100 mg) vs. CG 5 ($p < 0.001$); Study II, 95 vs. 10 ($p< 0.001$) Q4, maintaining erection Study I: 121 (25 mg), 133 (50 mg), 130 (100 mg) vs. 24 ($p < 0.001$); Study II: 140 vs. 13 ($p< 0.001$) All domains Study I & II: IG sign. higher with each dose vs. CG ($p< 0.001$) GEQ, % increase from baseline Study I: 56 (25 mg), 77 (50 mg), 84 (100 mg) vs. CG 25 ($p<0.001$) Study II: 74 vs. 19 ($p< 0.001$) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR (AE in IG included headache, flushing, dyspepsia, transient visual disturbances) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; GEQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gómez (2002) [34] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 159 **IG, n =** 76 **CG, n =** 82 **ITT analysis used for primary outcome:** Y **Inclusion**: men 18 or older; with ED for 6 mo or longer; in stable relationship with female partner for at least 6 mo **Exclusion:** genital anatomic deformity; hyperprolactinemia; low free T level ;uncontrolled psychiatric disorders; alcoholism or substance abuse; hx of major hematological, renal or hepatic abnormality; uncontrolled DM; untreated proliferative diabetic retinopathy; hx of stroke, MI or CVD in last 6 mo; hypotension; known hx of retinitis pigmentosa; medication causally associated with ED; taking androgens, trazodone, nitrates (or nitric oxide donors); used vacuum devices, IC injection or any other ED tx	**Age, mean (sd):** 58 (11) vs. 55 (12) y **Race, n (%)**: White 20 (13) Black 4 (2.5) Hispanic (mistizo) 123 (77) Other 11 (7) **Co-morbidities:** Hypotension 25 (33) vs. 17 (21) DM 13 (17) vs. 9 (11) **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 3 (0.4-12) y **Underlying disease:** NR **Psychogenic ED, n (%):** 10 (13) vs. 16 (20) **Physiologic ED, n (%):** IG1 48 (63) vs. 44 (54) **Mixed ED, n (%):** 18 (24) vs. 22 (27)	**IG:** Sidenafil **CG:** placebo **IG:** Dose: 50 mg; titration to 25 or 100 mg Duration: 12 wk Frequency: NR Compliance (%): NR **CG:** Dose: placebo Duration: 12 wk Frequency: NR Compliance (%): NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** IIEF, change in mean score (approximate values from figure): Q3: 1.6 vs. 0.8 Q4: 1.8 vs. 0.8 EF: pre=13.6; post 22.1 vs. 18.4 OF: pre=6.9; post: 8.4 vs. 7.7 SD: pre=7; post 7.3 vs. 7.1 IC s: pre=7.4; post 10.8 vs. 9.4 OS: pre=4.6; post: 7.5 vs. 6.3 GAQ, % yes: 77 vs. 46 Successful intercourse attempts (last 4 wks), %: 65 vs. 35 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 12 (16) vs. 10 (12) **WDAE, n (%):** 1 syncope (1) vs. 0 **TAE:** pts with at least one AE=39 (51) vs. 27 (33); including headache 19 (25) vs. 10 (12); flushing 9 (12) vs. 6 (7); dyspepsia 5 (7) vs. 0; rhinitis 5 (7) vs. 1 (1); abnormal vision 5 (7) vs. 4 (5); conjuctivities 3 (4) vs. 0; diarrhea 3 (4) vs. 2 (2); chromatopsia 2 (3) vs. 0; palpitation 1 (1) vs. 2 (2); dizziness 0 vs. 3 (4); gastritis 0 vs. 2 (2); also laboratory abnormalities elevated blood urea nitrogen level in 4 (10) vs. 1 (1), elevated creatinine level in 3 (8) vs. 0; **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF (EF=1-5,15), event log on sexual function

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gopalakrishnan (2006) [35] **Funding source:** Christian Medical College grant; Sun Pharmaceuticals provided the medication	**N screened =** 150 (40 were identified with ED) **N randomized =** 32 (randomized two way cross over) **IG/CG, n =** 32 **ITT analysis used for primary outcome:** yes **Inclusion:** married men with schizophrenia or delusional disorder on current tx; with ED **Exclusion:** regular use of nitrates, anticoagulants, or aspirin 2 wks prior to study entry; comorbid depressive syndrome; tx with antidepressants; alcohol or other substance dependence; hx of use of sildenafil citrated and continued use of other measures to improve ED	**Age, mean (sd):** 35.1 (5.5), range 24-45 y **Race:** NR **Co-morbidities, n (%):** paranoid schizophrenia 20 (62.5); catatonic schizophrenia 1 (3), undifferentiated schizophrenia 5 (16), delusional disorder 3 (9.3), **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** all pts on chlorpromazine equivalents dose 556.3 (198.6) range 200-1000 mg; mean dose of trihezyphenidyl 1.2 mg/d; 3 pts also on diazepam **Duration of ED:** NR **Underlying disease, n (%):** as in comorbid conditions **Psychogenic ED, n (%):** 10% **Physiologic ED, n (%):** 0 **Mixed ED, n (%)**: NR	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 25 mg titrated to 50 mg based on efficacy outcomes at 1st wk Duration: 2 wks Frequency: up to 1/d Compliance: 100% **CG:** Dose: NA Duration: 2 wks Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** none **F/u duration:** end of each 2 wks period	**Primary outcome results:** N of grade 3 or 4 erections, mean (sd) combined for two wks of tx: 6.52 (3.92) vs. 3.32 (3.5); P< 0.001 duration of erection, mean (sd): 3.38 (2.25) vs. 2.20 (2.14) min, P<0.055 Combined N of satisfactory intercourse attempts, mean (sd): 5.29 (3.84) vs. 2.45 (3.33); P<0.001 **Other outcomes assessed:** tx interaction effects (NS) **Withdrawals/drop-outs/loss to f/u, n (%):** 1(3) **WDAE, n (%):** 0 **TAE:** 13 (41) vs. 3 (9.3) AEs, n (%): nasal congestion 4 (12.5) vs. 0; headache 3 (9.4) vs. 1 (3.1); loss of appetite 1 (3.1) vs. 0; retarded ejaculation 2 (6.3) vs. 1 (3.1); dyspeptic symptoms 1 (3.1) vs. 1 (3.1); giddiness 1 (3.1) vs. 0; rash 1 (3.1) vs. 0 **SAE, n (%):** NR **Ascertainment of outcomes assessed:** pts log

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Hartmann (1999) [36] **Funding source:** NR	**N screened =** NR **N randomized =** 315 **IG, n =** 159 **CG, n =** 156 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older with documented diagnosis of ED for 6 mo or longer **Exclusion:** other sexual disorders, high serum PRL levels, low levels of free testosterone. Hx of renal, hepatic, haematological or bleeding disorders. Stroke or myocardial infarction ≤ 6 mons, poorly controlled diabetes, retinitis pigmentosa, treatment with androgens, trazadone, nitrates, nitrogen oxide donors	**Age, mean:** **IG1:** 54 **CG:** 55 **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** IG1: 5 CG: 5 **Underlying disease:** NR **Psychogenic ED:** 50 **Physiologic ED, %:** 46 **Mixed ED, %**: 54 **Unknown:** 3 vs. 6%	**IG:** sildenafil **CG:** oral placebo **IG1:** Dose: 25 mg option to titration to 50 or 100 mg Duration: 26 wks Frequency: as needed Compliance (%): NR **CG:** Dose: NA Duration: 26 wks Frequency: as IG Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration (both on and off treatment):** NR **Other:** Final doses: 25 m: in 25% 50 mg in26% 100 mg in 49%	**Primary outcome results:** IIEF, Q7, mean: pre= 2.0; post tx: 3.6 vs. 2 IIEF, Q3, and 4: as Q7 GEQ, % improved: 79% vs. 23% **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 13 (8) vs. 0 **WDAE, n (%):** 8 (5) vs. 0 **TAE:** NR; most common AE reported headache, flushing, dyspepsia, rhinitis, respiratory tract infection (could not be extracted from table, bad scan); visual disturbances NR (1) vs. 0 **SAE:** NR **Ascertainment of outcomes assessed:** IIEF Q3, 4, 7, 13, and GEQ, Patient logbook

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Heiman (2007) [37] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 180 **IG, n =** 86 **CG, n =** 94 **ITT analysis used for primary outcome:** yes (n=85 vs. n=91) **Inclusion:** men 21 y or older with ED (score of 21 or less on Sexual Health Inventory for Men) and in stable relationship with female partner; with satisfactory sexual intercourse of 50% or less as reported by their female sexual partner **Exclusion:** couple with sign. dyspareunia or lifelong sexual dysfunction or men with more than six doses of any ED tx including PDE-5 inhibitor within 6 mo; use of nitrates, nitric oxide donors; medical or psychological conditions (i.e. CV, arthritis, hx of retinitis pigmentosa)	**Age, mean (range):** 58 (30-86) y **Race:** White 79%; Black 7%; Asian 2%; other 12.5% **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** current smokers 15% vs. 19% (43% never smoked) **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED, mean (range):** 4.7 (0.2-21.6) vs. 6.1 (0.1-34.7) y **Underlying disease, n (%):** NR **Psychogenic ED (%):** 16 vs. 12 **Physiologic ED (%):** 59 vs. 62 **Mixed ED (%)**: 24 vs. 27 **Other:** IIEF baseline score, mean= 46.3 vs. 48.8; EF domain=13.2 vs. 12.6; OF domain= 5.6 vs. 5.5; SD domain=6.3 in both grps; IcS=6.7 vs. 6.1; OS=5; Q7=2.3 vs. 2.1	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: flexible dose 25, 50, and 100 mg Duration: 12 wks Frequency: as needed, 30 min to 1 hr prior to sexual activity Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 2 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** IIEF, change from baseline mean (SE): EF domain: 8.9 (1) vs. 3.4 (1) OF domain: 1.5 (0.4) vs. 0.9 (0.4) SD domain: 0.4 (0.2) vs. 0.1 (0.2) ICS domain: 2.1 (0.3) vs. 0.8 (0.3) OS domain: 2.1 (0.3) vs. 0.8 (0.3) Q7: 1.5 (0.2) vs. 0.3 (0.2) GEQ, % improved (95% CI): GEQ-1: 69 (57-79) vs. 25 (16-36) GEQ-2: 71 (60-80) vs. 30 (20-41) **Other outcomes assessed:** responses in partner; EDIT scores, SEAR **Withdrawals/drop-outs/loss to f/u, n (%):** 21 (12) **WDAE, n (%):** 0 **TAE, n (%):** reported as tx related AE: 29 in 18 (21%) vs. 11 in 10 (11%) of pts; including one severe case of rhinitis in IG, and one severe headache in CG Most common AE: headache, vasodilatation, rhinitis, dyspepsia, and abnormal vision or chromatopsia (n=3 vs. 1) **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** EDITS; IIEF; Self-Esteem And Relationship (SEAR)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Herrmann (2006) [38] **Funding source:** Pfizer Inc.	**N screened =** 16 (recruitment stopped; difficult recruitment due to concurrent release of vardenafil and tadalafil) **N randomized =** 12 **IG, n =** 8 **CG, n =** 4 **ITT analysis used for primary outcome:** NR **Inclusion:** men with moderate to severe ED despite an adequate sildenafil trial, of max 100 mg (ED defined as IIEF score of 16 or less); with serum low density lipoprotein (LDL) cholesterol 100 mg/dL or higher **Exclusion:** hx of Psychogenic ED; severe endocrinopathy including diabetics with neuropathy, recent suregery including prostatatectomy; acute	**Age, mean (sd):** 58 (13) y **Race:** NR **Co-morbidities, n (%):** DM 12% vs. 25%; elevated cholesterol 10 (83); hypertension 4 (33) **Previous ED treatment:** **Smoking status:** 38% vs. 75% **Body weight:** NR **Other:** LDL cholesterol 139 (19) vs. 146 (10) mg/dL; N of pts with DM is not consistently reported (text: n=2, 17% in total)	**Concomitant medications, n (%):** **Duration of ED:** 4.2 (4.8) vs. 2.6 (2.9) y **Underlying disease, n (%):**as co-morbidities **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** all **Mixed ED, n (%):** NR **Other:** IIEF- EF domain at baseline, mean (sd) 10.2 (7.4) vs. 4 (3.6)	**IG:** Sildenafil + Atoravastatin **CG:** Sildenafil + placebo **IG:** Dose: Sildeanfil 100 mg up to once/d; Atorvastatin 80 mg/d Duration: 12 wks Frequency: once /d (each medication) Compliance: **CG:** Dose: sildenafil as IG + Atorvastatin placebo tablets Duration: 12 wks Frequency: as IG Compliance: **Run In period:** NR **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** IIEF, Q-15, mean (sd): Baseline 10.3 (7.4) vs. 4 (3.6) Post tx (12 wks): 18 (10.6) vs. 12.3 (12.4); influenced by single outlier increasing from 9 to 29; increase in post tx score excluding this pts = 4.3 (sildenafil grp ▲ by 7.8) IIEF-Q6: improved in 100% vs. 25% GAQ-1, % improved: 62.5% vs. 25% GAQ-2, % improved: 62.5% vs. 25% GAQ, % improved: 62.5% vs. 25% **Other outcomes assessed:** LDL cholesterol levels ▼ from 135 (19) to 78 (20) mg/dL, or 43% with Atorvastatin vs. from 146 (10) to 139 (24) in placebo **Withdrawals/drop-outs/loss to f/u, n (%):** 0 **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; Blood analysis for lipid profile

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Hussain (2001) [39] **Funding source:** Pfizer	**N screened =** 24 **N randomized =** 17 (crossover design) **IG/CG, n =** 24 **ITT analysis used for primary outcome:** N **Inclusion**: Parkinson's (PD) disease or multiple system atrophy (MSA); resting and standing SBP 90-180 mm hg, and DBP 50-110 mm Hg, on tx if necessary **Exclusion:** no stable sexual partner; penile deformity; other sexual or psychological disorder; known hx of alcohol or drug dependence; DM; retinitis pigmentosa; hx of stroke or MI; sign cardiac hx; nitrate therapy; lipid abnormality; thyroid, renal, hepatic or hematologic dx	**Age, median (range):** PD 61 (48-68) MSA 54 (46-61) y **Race (%):** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease, n (%):** PD 12 (97) MSA 6 (33) **Psychogenic ED**: 0 **Physiologic ED, %:** 100 **Mixed ED**: 0	**IG:** sildenafil citrate **CG:** placebo **IG:** Dose: 50 mg with option ot titrate to100 or 25 mg Duration: 10 wks Frequency: up to once/d, 1 hr before sexual activity Compliance: NR **CG:** Dose: placebo, titration option as IG Duration: 10 wks Frequency: as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** None **F/u duration:** 20 wk (cross over at 10 wks without washout)	**Primary outcome results:** (CG, n=16; IG n=14) IIEF-Q3, mean: 3 vs. 2 IIEF-Q4, mean: 4 vs. 1.4 Quality of life questionnaire: Whole life, mean: 4.9 vs. 4.7 Sex life, mean: 4.2 vs. 2.2 **Other outcomes assessed:** Partner questionnaire **Withdrawals/drop-outs/loss to f/u, n (%):** 8 (27) including one pts in PD due to lack of efficacy, pt chose to return to IC injections. **WDAE:** 3 (12.5) in (50% of MSA pts) **TAE:** NR; 3 events of orthostatic hypotension (fall in standing BP), feeling unwell and unable to stand in IG (MSA) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF, quality of life (0-5 for each questions)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Incrocci (2001) [40] **Funding source:** Pfizer B.V., The Netherlands	**N screened =** 82 **N randomized =** 60 **(cross-over)** **IG/ CG =** 30 **ITT analysis used for primary outcome:** No **Inclusion:** men with progressive ED after 3-dimensional conformal external beam radiotherapy (3D-CRT) for prostate who agreed to perform sexual activity at least once/ wk; in a stable relationship **Exclusion:** hx of MI or CVA, prior radical prostatectomy; post-radiotherapy rise in PSA; use of nitrates or hormone therapy	**Age, mean:** 68 y **Race (%):** NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: None **Smoking status:** NR **Body weight:** NR **Other:** PSA/micrograms, mean (range): 8.5 (1-227) litre	**Concomitant medications:** NR **Duration of ED, mean (range):** time from radiation to trial 39 (15-55) mo **Underlying disease (%):** Hypertension: 10%; DM 3%; Transurethral resection of the prostate: 18% **Psychogenic ED:** NA **Physiologic ED:** 100% **Mixed ED:** NA	**IG:** sildenafil **CG:** placebo **IG1:** Dose: 50 mg with option to increase to 100 at 2 wks, or decrease to 25 mg in case of AE Duration: 6 wks Frequency: at least 1/wk, up to 1/d Compliance (%): 100% **CG:** Dose: NA Duration: 6 wks Frequency: at least 1/wk, up to 1/d Compliance (%): 100% **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wks (assessments at end of each 6 wks period) **Other:** 90% patients ▲ dose to 100 milligrams, 0% ▼ to 25 mg	**Primary outcome results:** IIEF baseline mean; post tx mean (sd) IG vs. CG Q1: 1.7; post 2.9 (1.6) vs. 1.8 (1.1) Q2: 1.5; post 2.8 (1.8) vs. 1.5 (1.1) Q3: 1.5; post 2.8 (1.7) vs. 1.6 (1.1) Q4: 1.3; post 2.6 (1.7) vs. 1.5 (1.0) Q5: 1.6; post 2.8 (1.1) vs. 1.8 (1.4) Q6: 1.2; post 2.8 (1.1) vs. 2.4 (1.0) Q7: 1.9; post 2.7 (1.6) vs. 1.9 (1.3) Q8: 1.6; post 2.8 (1.4) vs. 1.9 (1.1) Q10: 2.1; post 3.0 (1.6) vs. 2.4 (1.6) Q11: 2.8; post 3.0 (1.1) vs. 2.8 (1.2) Q12: 2.7; post 3.0 (1.0) vs. 2.6 (1.0) Q13: 2.3; post 3.0 (1.4) vs. 2.3 (1.2) Q14: 2.7; post 3.2 (1.4) vs. 2.8 (1.4) Q15: 2.1; post 3.0(1.1) vs. 2.4 (1.3) GEQ, % with improved: 45 vs. 8 Successful intercourse %: 55 vs. 18 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** AEs (%)= headache: 42 vs. 15; flushing: 13 vs. 2; myalgia 15 vs. 13; nasal congestion 22 vs. 12; dyspepsia 32 vs. 8; dizziness 17 vs. 10 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF; GEQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Incrocci (2003) [41] **Funding source:** Pfizer B.V.	**N screened =** NR **N randomized =** 60 (6 wk cross over); also open label phase **IG, n =** 30 **CG, n =** 30 **ITT analysis used for primary outcome:** No **Inclusion:** progressive ED after 3 dimensional external beam radiotherapy for prostate cancer; normal EF before radiotherapy; in stable relationship **Exclusion:** use of nitrates	**Age, mean (range):** 68 (56-79) y **Race (%)**: NR **Co-morbidities:** diabetes and/or hypertension 13% **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** Mean interval between completion of radiotherapy and study initiation = 39 mo (range 15-55)	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/ grp):** NA **Psychogenic ED**: NR **Physiologic ED:** N **Mixed ED**: NR	**IG:** sildenafil citrate orally **CG:** placebo orally **IG:** Dose: 50 mg for first 2 wk; option to increase to 100 mg for next 4 wk Duration: 6 wk Frequency: up to once/ d, 1 hr before sexual activity at least once/ wk Compliance: NR **CG:** Dose: placebo Duration: 6 wk Frequency: as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** None **F/u duration:** 6 and 12 wks (last fu at 2 y)	**Primary outcome results:**Mean IIEF mean score (sd), IG vs. CG: Q1- pre: 2 (2); post: 3 (2) vs. 2 (1) Q2- pre: 2 (2); post: 3 (2) vs. 2 (1) Q3=Q4=Q5=Q7: pre: 2 (1); post: 3 (2) vs. 2 (1) Q6- pre: 1 (1); post: 3 (1) vs. 2 (1) Q9- pre: 2 (2); post 3 (2) vs. 2 (1) Q10- pre: 2 (2); post: 3 (2) vs. 2.5 (2) Q11- pre: 3 (1); post: 3 (2) vs. 3 (1) Q12- pre: 3 (1); post: 3 (1) vs.2.6 (1) Q13- pre: 2 (1); post: 3 (1) vs. 2 (1) Q14- pre: 3 (1); post: 3 (1) vs. 2.8 (1) Q15- pre: 2 (1); post: 3 (1) vs. 2.3 (1) GAQ1, %: 61 vs. NR GAQ2, %: 65 vs. NR **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** NR; % with AE (IG vs. CG/ IG open label): headache 42 vs. 15/17; flushing 13 vs. 2/11; myalgia 15 vs. 13/6; nasal congestion 22 vs. 12/11; dyspepsia 32 vs. 8/24; vision disturbances 17 vs. 8/13; dizziness 17 vs.10/6 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, GEQ, 1 and 2

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kaplan (2007) [42] **Funding source:** Pfizer (conflict of interest reported)	**N screened =** **N randomized =** 62 (single center; open label) **IG1, n =** 21 **IG2, n =** 20 **CG, n =** 21 **ITT analysis used for primary outcome:** yes **Inclusion:** men with self reported ED and untreated LUTS **Exclusion:** criteria complied with contraindication of both drugs	**Age, mean (sd):** 63.4 (7.6) y **Race:** NR **Co-morbidities, %:** DM 27.4; hypertension 25.8%; Ischemic heart disease 14.5 **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** 24.8 (4.3) mo **Underlying disease, n (%):** **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%)**: NR	**IG1:** Sildenafil **IG2:** Alfuzosin **CG:** Sildenafil + Alfuzosin **IG1:** Dose: 25 mg Duration: 12 wks Frequency: one/d Compliance: **IG2:** Dose: 10 mg Duration: 12 wks Frequency: one/d Compliance: NR **CG:** Dose: combination of IG1 and IG2 doses Duration: 12 wks Frequency: one of each/ d Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** IIEF mean (sd) Q3: baseline 2.2 (0.9); % improvement from baseline 41.7% vs. 27.3% vs. 65.2% Q4: baseline 2.3 (1.1); % improvement from baseline 59.1% vs. 33.3% vs. 68.2% EF domain: baseline 15.9 (3.2); post tx IG= 21.4 (5.7) vs. IG2=20.3 (5.2) vs. IG3=25.7 (4.9); % change from baseline: 49.7% vs. 16.7% vs. 58.6% **Other outcomes assessed:** IPSS; PVRU volume **Withdrawals/drop-outs/loss to f/u, n (%):** 7 (11) **WDAE, n (%):** total 7 (11); 2 (10) vs. 2 (10) vs. 3 (14) **TAE:** NR; AE flushing and dyspepsia in sildenafil grp vs. dizziness in Alfuzosin vs. dizziness in combination grp **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF-EF; International Prostate Symptom Score (IPSS); post-void residual urine (PVRU) volume

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Katz (2005) [43] **Funding source:** Pfizer	**N screened =** 202 **N randomized =** 137 (parallel design) **IG, n =** 63 **CG, n =** 74 **Intention to Treat (ITT):** Yes (IG, n=60; CG n=72) **Inclusion**: men 18 y or older, with ED, (Sexual Health Inventory for Men score of 21 or greater), & documented evidence of stable coronary heart failure (CHF); naïve to sildenafil (discontinue at least by screening visit) **Exclusion:** hypotension, high cardiac risk, CHF secondary to hypertrophic cardiomyopathy; hx or myocarditis or implantable defibrillator firing 6 mo prior to entry; use of organic nitrates, drugs that inhibit cytochrome P450 (i.g. ritonavir) Data reported as IG vs. CG (unless otherwise indicated)	**Age, mean (range):** all, 60 (38-83) y **Race (%)**: NR **Co-morbidities:** all pts had one or more conditions including diabetes, hypercholestrrole mia, hypertension, ischemic heart dx, past coronary bypass **Previous ED treatment**: NR **Smoking status**: 22% in both grps; 19% vs. 33% were ex-smokers	**Concomitant medications:** ACE inhibitors; angiotension II receptor antagonist (29% vs. 15%); β blockers; loop diuretics, cardiac glycosides, oral anticoagulants, analgesics fro mild to moderate pain (11% vs. 22%) **Duration of ED, mean (range):** 5 (0.1-22) y **Underlying disease:** CHF, duration of 6 (0.27-31.7) vs. 4.8 (0.03-22.2) y **Psychogenic ED, %:** 2 vs. 1 **Physiologic ED, %:** 57 vs. 56 **Mixed ED, %:** 41 vs. 43	**IG1:** Sildenafil **CG:** placebo **IG1:** Dose: 50 mg, adjusted to 25 or 100 mg based on pts tolerability & efficacy Duration: 12 wk Frequency: NR Compliance (%): NR **CG:** Dose: NR Duration: as IG Frequency: NR Compliance (%): NR **Run In period:** 2 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** Baseline (mean); post tx (least square mean) scores: Q3 (improved erections): pre=1.7; post: 3.7 vs. 2.8 (p=0.0003); [74% of pts vs. 18% improved, (<0.002)] Q4 (improved intercourse), mean score: pre=1.4 post: 3.3 vs. 2.4 (p = 0.0012); [68% vs. 16% improved (p<0.002)] IIEF, EF: pre=33; post 71 vs. 53 IIEF Q9, 10: pre=45; post 77 vs. 67 IIEF Q11, 12: pre=61; post 69 vs. 63 IIEF, Q6, 8: pre= 35; post 69 vs. 55 IIEF, Q13, 14: pre=39; post: 79 vs. 58 Intercourse success (%): 53 vs. 20, Improved erection, %: 74 vs. 18 Improved intercourse, %: 68 vs. 16 **Other outcomes assessed:** IIEF Q 5-12; GEQ; life satisfaction check list; EDITS **Withdrawals/drop-outs/loss to f/u:** 20 (16) vs. 10 (14) **WDAE:** 2 (3) vs. 2 (3) **TAE: (%** of pts) 60% vs. 48% (headache 13% vs. 3%, also respiratory tract infection, asthenia, peripheral edema, rhinitis, back pain, rash, pain in both grps; vasodilatation; ▲ cough, neoplasm, chromatopsia only in IG) **SAE:** 3% vs. 5% **Ascertainment of outcomes assessed:** self administered IIEF; GEQ, EDITS

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kongkanand (2003) [44] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 125 **IG, n =** 63 **CG, n =** 62 **ITT analysis used for primary outcome:** yes (n=125) **Inclusion:** men ED ≥ 6 mo, stable heterosexual relationship ≥ 6 mo. **Exclusion:** Genital deformities, SCI, co-existing sexual disorders, raised serum PRL levels or low free T level, major psychiatric disorder, hx of alcohol or substance abuse; major haematological, renal or hepatic dx, DM; poorly controlled or associated with untreated proliferative retinopathy; hx of stroke or MI≤ 6 mo; hypotension or other sign CV dx, hx of retinitis pigmentosa; taking drugs associated with ED; use of vacuum devices or other tx for ED.	**Age, mean (range):** 54 (31-76) vs. 56 (26-77) **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status, n (%):** Smokers: 11 (18) vs. 9 (15) **Body weight, mean:** 68 vs. 69, range 54-90 kg	**Concomitant medications:** NR **Duration of ED, n (%):** ≤ 2 y: 42 (67) vs. 35 (57); >2 to ≤ 5 y: 15 (24) vs. 20 (32) > 5 y: 6 (10) vs. 7 (11) **Underlying disease:** NR **Psychogenic ED:** 7 (11) vs. 6 (10) **Physiologic ED, n (%):** 41 (65) vs. 39 (63) **Mixed ED, n (%):** 15 (24) vs. 17 (27)	**IG:** sildenafil citrate **CG:** placebo **IG:** Dose: initially 50 mg for 2 wks, then option to titrate up to 100 mg or down to 25 mg Duration: 12 wks (median= 84 d) Frequency: as needed Compliance (%): 92 **CG:** Dose: NA Duration: 12 wks (median=83 d) Frequency: as needed Compliance (%): 84 **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** IIEF, Q3 frequency of penetrate, mean: baseline= 2; post tx: 4 vs. 3 IIEF, Q4, frequency of maintaining erection after penetration, mean: baseline=2; post tx: 4 vs. 3 IIEF, EF, mean: baseline=13; post tx: 22 vs. 17 IIEF, OF, mean: baseline=5, post tx: 8 vs. 5 IIEF, SD, mean: baseline=5, post tx: 7 vs. 6 IIEF, intercourse satisfaction, mean: baseline=6; post tx 11 vs. 9 Intercourse success, %: 66 vs. 32 GAQ, % yes: 82 vs. 36 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 1 (2) in CG **WDAE:** 0 **TAE, n (%):** 19 (30) vs. 7 (11); including: flushing = 14%; headache = 6%; dizziness = 6%; laboratory abnormalities: included raised levels of eosinophils, total bilirubin, and blood urea nitrogen 1 (2) in IG; 4 sign laboratory abnormalities in n=2 in CG **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, pts event log, GAQ, physical exam

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Koulikov (2007) [45] **Funding source:** Pfizer Inc.	**N screened =** 82 **N randomized =** 60 (crossover) **IG, n =** 30 **CG, n =** 30 **ITT analysis used for primary outcome:** NR **Inclusion:** men between 45 and 75 y and older with ED and various urological complaints (LUTS, ED and nephrolithiasis), and diagnosis of ADAM (direct Tb less than 0.7 gm/l were defined as hypogonadal) **Exclusion:** penile anatomical defects; uncontrolled medical illness or psychological disorders; pts with high cardiac risk (according to Princeton guideline); or regular or intermittently use of drugs that alter androgen metabolism or hx of PDE-5i	**Age, mean (SEM):** 63.3 (7.85), range 47-75 y **Race:** NR **Co-morbidities, n (%):** hypogonadal 27 (48), low total T in 13/27 **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** various urological reasons **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%)**: NR	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg, titrated to 100 mg after 2 wks (if no improvement in EF with at least 3 pills) Duration: 1 mo Frequency: one pill 30-60 min before planned sexual activity up to once/d Compliance: NR **CG:** Dose: NA Duration: 1mo Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** at end of each tx period (each study period was 3 mo; washout and run in is not reported).	**Primary outcome results:** Improvement in EF, mean (SEM): 39 (1.9) vs. 52.7 (2) Improvement in IIEF-EF from baseline, mean (SEM): Normal men: 18.4 (3.6) Hypogonadal men: 6.7 (2.7) (no difference in baseline scores of EF between normal and hypogonadal men) **Other outcomes assessed:** FSH, LH, Total T, and Tb (numerical data NR) **Withdrawals/drop-outs/loss to f/u, n (%):** 19 (63.3) vs. 12 (40) **WDAE, n (%):** 1 (3.3) vs. 1 (3.3) **TAE, n (%):** difficulty in controlling BP 0 vs. 1 (3.3); non-Q MI 1(3.3) before ingestion of first tablet vs. 0 **SAE, n (%):** NR **Ascertainment of outcomes assessed:** serum hormone analysis

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Levinson (2003) [46] **Funding source:** Pfizer	**N screened =** 279 **N randomized =** 279 **IG, n =** 128 **CG, n =** 126 **ITT analysis used for primary outcome:** Yes **Inclusion:** men 18 or older with ED of at least mo in duration; in a stable relationship **Exclusion: penile abnormalities;** SCI, concomitant tx with nitrates, endocrine anomalies; major haematological, renal, or hepatic dx, CV dx for less than 6 mo, poorly controlled DM, concomitant use of other ED therapies, hx of alcohol or substance abuse, major psychiatric disorder	**Age, mean (range):** 52 (26-75) vs. 52 (28-76) **Race (%):** Asian: 6 vs. 7; Black: 2 vs. 2 Mediterranean: 52, vs. 48 White: 40, vs. 42 (all from Egypt and South Africa) **Co-morbidities (%):** DM: 27; hypertension: 24; unspecified visual disorders: 14; hypercholesterolemia: 6 **Previous ED treatment**: NR **Smoking status (%)**: 20 vs. 29 **Body weight:** NR	**Concomitant medications, %:** Antihypertensives: 24% Anitdiabetic drugs: 24% Anti-inflamatory agents: 15% Antibiotics: 11% Diuretics: 10% Drugs for hyperlipidemia: 8% **Duration of ED, mean:** 3.7 vs. 4.4 y **Underlying disease:** NR **Psychogenic ED (%):** 26 vs. 29 **Physiologic ED (%):** 38 vs. 43 **Mixed ED (%):** 37 vs. 29	**IG:** sildenafil citrate **CG:** placebo **IG:** Dose: 50 mg, titrated to 100 or 25 mg Duration: 12 wks Frequency: up to once/d (total dose=41) Compliance (%): NR **CG:** Dose: NA Duration: 12 wks Frequency: up to once/d (total dose=33) Compliance (%): NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** NR **Other**: pts information regarding dose of sildenafil used at the end of tx period, n: 25 mg: 7 vs. 1 50 mg: 32 vs. 5 100 mg: 86 vs. 114	**Primary outcome results:** Values are approximate (extracted from figure), mean: IIEF, Q3: baseline =2; post tx: 4 vs. 2.5 IIEF, Q4: baseline =2; post tx: 4 vs. 2 IIEF- Q7: baseline= 2; post tx: 4 vs. 2.3 GAQ, % yes: 74 vs. 27 Intercourse success, %: 69 vs. 28 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 15 (12) vs. 13 (10); including 0 vs. 4 (3) due to insufficient tx response **WDAE, n (%):** 3 (2) vs. 0 **TAE, n (%):** in at least 5%of pts= 63 (49) vs. 45 (36); including headache 26 (20) vs. 10 (8); dyspepsia 12 (9) vs. 1 (0.8); abnormal vision (chromotopsia) 10 (8) vs. 4 (3); flushing 8 (6) vs. 2 (2); rhinitis 7 (6) vs. 3 (2); flu syndrome) 5 (4) vs. 9 (7); CV events (including one re-infarction, and three pts with palpitations in IG and one hypertension in CG) 4 (3) vs. 1 (0.8) **SAE:** 3 (2) vs. 0; MI, accidental vertebral fracture, diverticulitis **Ascertainment of outcomes assessed:** physical exam, laboratory tests, questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Lindsey (2002) [47] **Funding sources:** Colorectal research fund, Pfizer	**N screened =** 43 **N randomized =** 32 **IG, n =** 14 **CG, n =** 18 (n=10 crossed over to open label sildenafil after placebo) **ITT analysis used for primary outcome:** No **Inclusion**: male, postoperative with ED and colorectal cancer **Exclusion:** pre-operative ED, medical contraindication to sildenafil	**Age, median (interquartile range):** 59.5 (51.1–64.9) vs. 58.7 (49.4–67.5) y **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** 18 pts with total ED, 14 with partial	**Concomitant medications:** NR **Duration of ED:** NR [time since surgery, median (IQR)= 5.6 (3.3-7.7) y] **Underlying disease, n (%):** proctectomy for rectal cancer 12 (37.5); proctectomy for Inflammatory Bowel Diseases 20 (62.5); stoma 11 (34.3) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** sildenafil **CG:** placebo **IG:** Dose: < age 65 50 mg; ≥ 65 y old pts 25 mg, max dose of 100 mg . Duration: 4 wks Frequency: NR Compliance (%): 100% **CG:** Dose: NA Duration: 4 wks Frequency: NR Compliance (%): 100% **Run In period: NR** **Wash out period:** NR **F/u duration:** 4 wks (duration of open label trial NR) **Other:** n=13, and n=11 were dosed up to 50, and 100 mg sildenafil respectively	**Primary outcome results:** IIEF total score, mean: Baseline: 26.7 vs. 29.5 Post tx: 57.4 vs. 34.5 (post open label: 67 vs. 39.7) GEQ, % with improved erection: 78.6% vs. 16.7% **Other outcomes assessed:** Subanalysis by disease grp and severity of impotence was performed on n=24 who receive sildenafil either as primary or crossover tx **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE, n (%):** 7 (50) vs. 4 (22), most common AE facial flushing followed by headache (46%, and 64% of pts on 50 and 100 mg respectively experienced AE at end of open label) **SAE:** 0 **Ascertainment of outcomes assessed:** GEQ, IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Mahon (2005) [48] **Funding source:** Pfizer Inc. (study medication & placebo)	**N screened =** 41 **N randomized =** 16 **IG/CG, n =** 16 (cross over) **ITT analysis used for primary outcome:** NR (analysis for n=13) **Inclusion:** men 18 y or older with ED and renal failure (on peritoneal dialysis) **Exclusion:** cerebro-vascular event within the last 6 mo, severe hepatic impairment, presence of penile anatomic deformities, severe cardiac dx, or concomitant nitrate therapy	**Age, mean (range):** 53 (26-74) y **Race (%)**: White 46%; Black 46%; Indian 8% **Co-morbidities:** NR **Smoking**: 8% smoked **Previous ED treatment**: NR **Other:** n=1 heavy drinker; n=8 social drinker (<3 to 4 units/d)	**Concomitant medications:** NR **Duration of ED:** 6 mo to 7 y **Underlying disease:** diabetes n=6 (46%); hypertensive (hypertensive nephropatny, diabetic nephropathy, focal segmental glomerulosclerosis, polycystic kidney disease) n=10 (77%) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** sildenafil (1st then swithced to placebo) **CG:** placebo (1st then switched to sildenafil) **IG:** Dose: 50 mg, titrated to 100 mg at wk 2 if no response was attained with the initial dose Duration: 4 wks Frequency: once/ d Compliance (%): 100% **CG:** Dose: 50 mg Duration: as IG Frequency: as IG Compliance (%): 100% **Run In period:** 4 wks **Wash out period:** none **F/u duration:** 12 wks (including the no treatment run-in period)	**Primary outcome assessed:** (some values extracted from figure and are approximate) IIEF-EF, mean score: pre: 6.7; post 20 vs. 12 IIEF-OF: pre: 3; post 6.5 vs. 3.8 IIEF- SD: pre: 5; post: 6.3 vs. 5.3 IIEF, ICs: pre: 2.8; post 9.8 vs. 5.7 OS: IG= 7 Q3 (ability to penetrate): post: 3.4 vs. 1.7 Q4 (maintaining erection): post: 3.2 vs. 1.6 GEQ, % improved: 75% vs. 28% PSV (20 min post PgE1 injection), median (range): 29.5 (7-66) m/s EDV (15 min post injection), median (range): 5 (0-13) m/s **Other outcomes assessed:** T levels, sex hormone binding globulin, PRL, luteinizing hormone, follicle stimulating hormone, HbA1C **Withdrawals/drop-outs/loss to f/u:** n=3 (1 died, reported unrelated to intervention) **WDAE:** 0 **TAE:** 1 headache in IG (no titration in this pts) **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** self administered IIEF; GEQ; Doppler ultrasound

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
McVary (2007) [49] **Funding source:** Pfizer Inc. (two of the authors declare financial interest /relationship with Pfizer/ Lilly ICOS)	**N screened =** 683 **N randomized =** 370 (from 41 centres in US) **IG, n =** 189` **CG, n =** 181 **ITT analysis used for primary outcome:** yes **Inclusion:** men at least 45 y with ED, score of 25 or less on IIEF-EF domain, and lower urinary tract syndromes (LUTS) associated with prostatic hyperplasia, I-PSS score of 12 or greater **Exclusion:** confirmed or suspected prostate malignancy; urinary tract dx; hypotension, hypertension, orthostatic hypotension or sign CV dx, use of nitrates; pts with hepatic or renal dysfunction, poorly controlled DM or hx of retinitis pigmentosa, use of antimuscarinics was prohibited	**Age, mean (sd):** 60 (8.7) vs. 60 (8.5) y **Race:** White 82%; Black 11.5%; Asian 2%; other 4% **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** 5.7 (<1-25) vs. 5.6 (<1-35) y **Underlying disease %:** LUTS, 100% **Psychogenic ED, n (%):** 5 (3) vs. 8 (4) **Physiologic ED, n (%):** 113 (60) vs. 97 (54) **Mixed ED, n (%)**: 71 (38) vs. 75 (42) **Other:** baseline IIEF-EF score, mean (sd): 13.4 (6.8) vs. 13.2 (6.6)	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg, titrated to 100 mg at 2 wks based on tolerability and efficacy (down to 50 mg if 100 mg was not toleated, and discountinued if 50 mg was not tolarable) Duration: 12 wks Frequency: once/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** **Wash out period:** **F/u duration:** 12 wks	**Primary outcome results:** IIEF-EF, mean IG vs. CG: Baseline= 13.4 vs. 13.2 12 wks: 23.5 vs. 15.9 IIEF-EF, LS mean change (95% CI): 9.17 (7.25, 11.09) vs. 1.86 (-0.03, 3.74) **Other outcomes assessed:** EDITS and SEAR questionnaire **Withdrawals/drop-outs/loss to f/u, n (%):** 21 (11) vs. 25 (13.8) **WDAE, n (%):** 10 (5) vs. 6 (3) **TAE, n (%):** 100 (53) vs. 78 (43); included headache, flushing dyspepsia and rhinitis in both grps **SAE, n (%):** 2 (1) vs. 3 (2); SAE included one case of moderated worsening of right knee arthralgia while on 100 mg sildenafil; and one case of severe acute cerebro-vascular stroke also on 100 mg sildenafil; no pts discontinued as result of SAE **Ascertainment of outcomes assessed:** IIEF; I-PSS; Qmax; SEAR; EDIT; BPHII and QOL

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Melnik (2005) [50] **Funding source:** NR	**N screened =** 287 **N randomized =** 30 **IG1, n =** 10 **IG2, n =** 10 **CG, n =** 10 **ITT analysis used for primary outcome:** No **Inclusion**: men 25-50 y, with exclusive diagnosis of non-organic, psychogenic (according to IDC-10) mild to moderate ED for at least 6 mo in duration; in a heterosexual relationship for at least 1 y **Exclusion:** clinical or psychiatric disease, primary sexual disorder, penile anatomic defects; use of medication known to interfere with sexual function; physical limitations for use of sildenafil citrate; patients with drug or alcohol use; smoking Data reported as IG1 n=8 vs. IG2 n=6 vs. CG n=8	**Age, mean:** 40 vs. 66 vs. 43 y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** baseline IIEF	**IG1:** Sildenafil + grp psychotherapy **IG2:** Sildenafil **CG:** grp psychotherapy **IG1/IG2:** Dose: 50 mg Duration: 6 mo Frequency: on demand Compliance: NR **CG:** Dose: NA Duration: 6 mo Frequency: time limited Compliance: NR **Run In period:** **Wash out period:** NR **F/u duration:** immediately after tx at 6 mo, and 3 mo post intervention at 9 mo	**Primary outcome results:** IIEF (ED severity) at baseline, % of pts: Score 11-16: n: 5 vs. 4 vs. 5 Score 17-26: (mild ED) 3 vs. 2 vs. 3 IIEF (ED severity) at 3 mo post tx, %: Score 11-16: 0 vs. 1 vs. 0 Score 17-26: 2 vs. 2 vs. 2 Score 26-30: 6 vs. 2 vs. 6 Severity of ED based on IIEF at 6 mo tx, %: Score 11-16: 0 vs. 1 vs. 0 Score 17-26: 4 vs. 3 vs. 2 Score 26-30: 4 vs. 2 vs. 6 IIEF total score, mean: Pre: 41 vs. 46 vs. 43 Post (6 mo): 58 vs. 49 vs. 62 9 mo post: 62 vs. 53 vs. 63, sign.higher mean scores in IG2 vs. CG, $p<0.05$ Sign.differences between IG1 and CG in remission of symptoms (EF 26 or higher), p= 0.0002 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, %:** 20 vs. 40 vs. 20 **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; clinical interview

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Meuleman (2001) [51] **Companion study** [36] **Funding source:** NR	**N screened =** NR **N randomized =** 315 **IG, n =** 159 **CG, n =** 156 **ITT analysis used for primary outcome:** Yes **Inclusion:** men 18 or older, with clinical diagnosis of ED for at least mo; in stable relationship with female partner for more than 6 mo **Exclusion:** sign genital anatomical deformities (e.g. Peyronie's dx); primary diagnosis of other sexual disorders; hyperprolactinemia; hx of major haematological, renal or hepatic abnormalities; poorly controlled major psychiatric disorder; ED attributable to SCI; poorly controlled diabetes or untreated proliferative diabetic retinopathy; occurrence of CVD, stroke or MI within 6 mo before study; tx with anticoagulants, androgens, trazodone or nitrates	**Age, mean (range):** 55 (24-77) vs. 54 (23-82) y **Race (%)**: NR **Co-morbidities, n (%):** Diabetes: 25 (16) vs. 24 (15); hypertension: 33 (21) vs. 30 (19); Ischemic heart dx 21 (13) vs. 10 (6); pelvic surgery 33 (21) vs. 27 (17) **Previous ED treatment**: NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 4.8 (1-35) vs. 5 (1-27) y **Underlying disease:** NR **Psychogenic ED**: 50 (32) **Physiologic ED, n (%):** 46 (29) **Mixed ED, n (%):** 60 (38) vs. 54 (35) **Other types of ED, n (%):** 0 vs. 3 (2)	**IG:** Sildenafil citrate **CG:** Placebo **IG1:** Dose: 25 mg titrated to 50 mg 100 mg at any of 5 times during tx period Duration: 28 wk Frequency: once daily, one hr before sexual activity Compliance: NR **CG:** Dose: Placebo Duration: 28 wk Frequency: once daily, one hr before sexual activity Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wks and 26 wks post tx	**Primary outcome results:**IIEF- at 12 wks (values very close to 26 wks result), mean (SEM) IIEF, Q3=Q4: pre=2 (2); Post 2 (0.2) vs. 4 (0.2) IIEF, EF: pre=12 (0.7); Post tx: 13 (0.7) vs. 21 (0.7) IIEF, OF: pre=6 (0.3); Post 6 (0.3) vs. 8 (0.3) IIEF, IS: pre=7 (0.4); Post: 8 (0.3) vs. 11 (0.4) IIEF, OS: pre=5 (0.2); post: 5 (0.2) vs. 7 (0.2) IIEF, SD: pre=6 (0.2); Post: 6 (0.2) vs. 7 (0.1) **Other outcomes assessed:** event log reports; partner satisfaction **Withdrawals/drop-outs/loss to f/u:** 35 (22) vs.77 (49) stopped tx **WDAE, n (%):** 5 (3) vs. 1 (<1); headache (3) and colour tinge to vision, dizziness, diarrhoea, nausea, and intermittent stomach ache in IG, one headache in CG **TAE, n (%):** NR; most common: flushing, headache, dyspepsia, and rhinitis; abnormal vision in IG 2 (1), star vision, colour perception **SAE, n (%):** 8 (5) vs. 6 (4); two death in IG, one due to accident and one cardiac arrest 1 mo post last dose **Ascertainment of outcomes assessed:** IIEF; GAQ; diary log

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Montorsi (1999) [52] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 514 **IG1, n =** 128 **IG2, n =** 132 **IG3, n =** 127 **CG, n =** 127 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older, with at least 6 mo primary clinical diagnosis of ED **Exclusion:** SCI, hx of stroke or MI in the last 6 mo or longer, major hematologic, renal or hepatic abnormalities, receiving regular tx with nitrates; poorly controlled DM	**Age, mean (range):** 56 (19-77) y (slightly older in IG3, range 30-76) **Race (%):** NR **Co-morbidities, n (range %):** Genitourinary procedures: 57 (12-19%); Essential hypertension: 74 (11-17%); DM: 45 (7-10%); Genitourinary disease: IG1 = 3 (2%) IG2 = 6 (5%) IG3 = 13 (10%) CG = 5 (4%) Depression: 1-2%; Ischemic heart disease: 1-2% **Previous ED treatment:** NR **Smoking status:** NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr) mean (range):** 5 (0.5-30) y **Underlying disease (diagnosis) (N or % of diseased/ grp):** NR **Psychogenic ED, n (%):** 129 (25) **Physiologic ED: n (%):** 166 (32) **Mixed ED:** 219 (42.5)	**IG1/IG2/IG3:** sildenafil **CG:** placebo **IG1:** Dose: 25 mg (IG1); 50 mg (IG2); 100 mg (IG3) Duration: 12 wks Frequency: up to once/d Compliance (%): NR **CG:** Dose: NA Duration: 12 wks Frequency: up to 1x/day Compliance (%): NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration (both on and off treatment):** mean 85 d	**Primary outcome results:** IIEF- EF, mean (values approximate extracted from graph): pre 13; Post IG 19 vs. 21 vs. 23 vs. CG 13 IEF- Q3, mean score: IG1= 3.18; IG2= 3.65; IG3= 3.79 vs. CG= 2.17 (IG vs. CG p<0.0001) IIEF- Q4, mean score: IG1= 2.99; IG2= 3.40; IG3= 3.63 vs. CG= 1.96 (IG vs. CG p<0.0001) GEQ, % improved: IG1=67%; IG2=78%; IG3=86%; vs. CG=24% Successful intercourse attempt, mean/mo: range 4.4-5.8 vs. 1.6 **Other outcomes assessed:** OF, intercourse satisfaction, OS (values NR; IG vs. CG p<0.0001; partner satisfaction **Withdrawals/drop-outs/loss to f/u:** 6 (2) vs. 1 (<1%) **WDAE, n (%):** 6 (1.6) vs. 1(0.8) **TAE, n (%):** 63 **(**49), 80 (61), 92 (72) vs. 42 (33); most common AE (range % in IG vs. CG)= headache 17-20% vs. 4%; flushing 13-20% vs. 2%; dyspepsia 2-11% vs. 2%; altered vision 0-11% (n 15 pts) vs. 2%; back pain 0-8% vs. 2%; nausea 1-6% vs. 1% **SAE:** NR (one case of MI in IG2) **Ascertainment of outcomes assessed:** IIEF, GEQ, partner questions

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Montorsi (2000) [53] **Funding source:** NR	**N screened =** 129 **N randomized =** 30 **(**cross-over design) **IG/ CG, n =** 30 **ITT analysis used for primary outcome:** No **Inclusion:** men with ED **Exclusion:** Depression; hx of sleep disorder; use of drugs affecting quality of sleep; hypogonadism; hx of low serum T, or hyperprolactinemia; MS; SCI; Parkinson's disease; hx of radical pelvic surgery; use of nitrates, complex (≥3 drugs) antihypertensive regimens, or drugs interfering with metabolic pathway of sildenafil; renal or hepatic failure	**Age, mean (range):** 58 (range 40-68) y **Race (%)**: NR **Co-morbidities, n (%):** hypertension 12 (40) CAD 10 (33) DM 10 (33) Hyperlipidemia 10 (33) **Previous ED treatment**: NR **Smoking status, n (%):** Current smoker 15 (50) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED, n (%):** 8 (27) **Physiologic ED, n (%):** 22 (73) **Mixed ED:** NR	**IG:** sildenafil **CG:** placebo **IG1:** Dose: 100 mg Duration: one night Frequency: once Compliance (%): 100 **CG:** Dose: placebo Duration: one night Frequency: once Compliance (%): 100 **Run In period:** 1 night adaptation with RigiScan™ attached but turned off **Wash out period:** none **F/u duration:** 3 d	**Primary outcome results:** Number of erectile episodes/ night, mean (SE): 3.8 (0.8) vs. 3.0 (0.5) Duration of erectile episodes, mean (sd): 46.1 (4.4) vs. 33.2 (5.2) min Duration of tip rigidity >60%: 17.5 (1.5) vs. 10.8 (1.7) RAU Tip: 90.5 (8.1) vs. 44.1 (7.8) Base: 101.8 (5.3) vs. 50.2 (4.2) TAU Tip: 55.8 (2.2) vs. 27.2 (1.8) Base: IG1 54.2 (3.1), CG 36.9 (2.2) **Other outcomes assessed:** None **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE, n (%):** 2 (7) vs. 1(3) slight self resolving headache upon awakening **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Nurnberg (2003) [54] **Funding source:** Pfizer Inc.	**N screened =** 117 **N randomized =** 90 **IG, n =** 45 **CG, n =** 45 **ITT analysis used for primary outcome:** No **Inclusion:** men 18-55; wit major depressive disorder in remission and tx with antidepressant for more than 12 wk (on stable dose for ≥4 wk); **Exclusion:** other than antidepressant-associated sexual dysfunction; SCI; uncontrolled psychiatric disorder or DM; proliferative retinopathy; alcohol or substance abuse; sign hematologic, renal or hepatic abnormality; stroke or MI within previous 6 mo; cardiac failure; unstable cardiac condition or arrhythmia; use of nitrates; BP lower than 90/50 or higher than 170/100 mm Hg; hyperprolactinemia, retinitis pigmentosa; investigational drug use within 3 mo; sexual dysfunction tx	**Age, mean (sd):** 45 (8) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** Antidepressant 100% **Duration of ED:** NR; pts with, n (%) ED= 37 (82) vs. 41 (91) **Underlying disease:** NR **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED:** NR	**IG:** sildenafil citrate **CG:** placebo **IG1:** Dose: initially 50 mg; could increase to 100 mg Duration: 6 wk Frequency: once/d approximately 1 hr before sexual activity Compliance: NR **CG:** Dose: NA (titrated as IG) Duration: 6 wk Frequency: as IG Compliance: NR **Run In period:** None **Wash out period:** NA **F/u duration:** 6 wk	**Primary outcome results:** IIEF, mean score IG vs. CG (baseline IG-CG where different) IIEF, total: pre: 69-40; post 60 vs. 41 IIEF, Q3=Q4: pre: 3; post 4 vs. 3 IIEF, EF, pre: 18-17; post: 27 vs. 17 IIEF, OF: pre 6; post: 8 vs. 6 IIEF, SD: pre: 6; post: 7 vs. 6 IIEF, ICs pre: 6-7; post: 11 vs. 7 IIEF, OS: pre: 4-5; post: 7 vs. 5 ASEX, EF: pre 4; post 3 vs. 4 MGH-SFQ- EF: pre 4; post 3 vs. 5 **Other outcomes assessed:** see below **Withdrawals/drop-outs/loss to f/u:** 3 (7) vs. 10 (23) **WDAE, n (%):** 1 (2) vs. 1 (2), one acute panic and chest pain in IG, one suicidal gesture in CG **TAE, %:** NR; most common=40.5 vs. 10; AE in headache: 17 (41) vs. 4 (10); dyspepsia 2 (7) vs. 0; flushing 7 (17) vs. 1 (2); visual disturbances 5 (12) vs. 2 (5); nasal congestion 5 (12) vs. 1 (2); palpitations 2 (5) vs. 0; restlessness/anxiety 0 vs. 8 (20); insomnia 4 (10) vs. 2 (5) **SAE:** 0 **Ascertainment of outcomes assessed:** Clinical Global Impression Scale -Sexual Function adapted (CGI-SF); Arizona Sexual Experience Scale (ASEX), Massachusetts General Hospital-Sexual Functioning Questionnaire (MGH-SFQ)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
O'Leary (2006) [55] **Funding source:** Pfizer Inc. (financial interest and/ or other relationships with Pfizer existed for all authors)	**N screened =** 326 **N randomized =** 256 **IG, n =** 129 **CG, n =** 127 **ITT analysis used for primary outcome:** efficacy for all who took at least one dose and presented outcome data; safety for all who took at least one dose **Inclusion:** men 18 or older with documented ED (score of 21 or less on IIEF) with low self esteem determined by Self-Esteem subscale of the SEAR **Exclusion:** BP of 90 mmHg or less or 170/110 mmHg or more; sign cardiac dx; use of nitrates, nitric oxide donors, or ritonavir; more than 6 dosed of sildenafil within 6 mo prior to study entry	**Age, mean (sd):** 56 (12) vs. 55 (13) y **Race:** White 62%; Black 25%; Asian 2%; Other 11% (16 vs. 6) **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight, mean (sd):** 92 (16) vs. 93 (18) kg **Other:** overall relationship subscale score, mean (sd)=44.4 (33.1) vs. 53.8 (29.8)	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** not specific cause **Psychogenic ED, n (%):** 18 (14) vs. 15 (12) **Physiologic ED, n (%):** 61 (48) vs. 62 (50) **Mixed ED, n (%):** 49 (38) vs. 48 (38)	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: flexible 25-100 mg Duration: 12 wks Frequency: up to once/d, 1 hr prior to sexual activity Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 2 wks **Wash out period:** NA **F/u duration:** 12 wks post dosing	**Primary outcome results:** IIEF, LS mean change from baseline: EF: 9.3 vs. 3.6, p<0.001 OF: 2.4 vs. 0.8, p<0.001 SD: 1.2 vs. 0.6, p<0.001 IcS: 4.0 vs. 2.2, p<0.001 OS: 2.1 vs. 3.1, p<0.001 Successful sexual attempts, mean change %(95% CI): 52% (44-60%) vs. 19% (11-27%)p<0.0001 GEQ, % (95% CI) more frequent erections allowing satisfactory intercourse: 3.6 (3.3-3.9) vs. 2.4 (2.1-2.7) p<0.0001 **Other outcomes assessed:** sign correlation between SEAR component scores and IIER-EF domain scores, r range 0.34-0.69, p<0.0001; and other IIEF domain scores **Withdrawals/drop-outs/loss to f/u, n (%):** 23 (18) vs. 18 (14.4) **WDAE, n (%):** 0 **TAE, n (%):** NR; most common %: headache 10 vs. 2; rhinitis 6 vs. 0; vasodilatation 6 vs. 0; dyspepsia 6 vs. 1; chromatopsia, photophobia, dry mouth, and nausea 2 vs. 0; **SAE, n (%):** 0 vs. 1 death **Ascertainment of outcomes assessed:** IIEF domains; SEAR

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Olsson (2000) [56] **Funding source:** NR	**N screened =** NR **N randomized =** 351 **IG1, n =** 90 **IG2, n =** 85 **IG3, n =** 81 **CG, n** = 95 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18-70 y with diagnosis of ED of at least 3 mo duration, who had at least a grade 3-4 (hard enough for penetration-fully rigid) erection at any time during 4 wks before entering the trial or positive response to papaverine (at least 40 mg) or PGE1 (at least 20 mg) **Exclusion:** Men with ED of organic causes; tx with nitrates, resting hypotension, uncontrolled hypertension, stroke, bleeding disorder, active peptic ulceration, taking anticoagulants, and a hx of a major haematological, renal, hepatic disorders	**Age, mean (range):** 52 (24-70) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment, n (%):** IG: 102 (40) CG: 41 (43) **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 5 (0.2-40) y **Underlying disease:** NR **Psychogenic ED, n (%):** 153 (60) vs. 51 (54) **Physiologic ED:** 2 (1) vs. 0 **Mixed ED, n (%):** 101 (39) vs. 44 (46)	**IG1-3:** sildenafil **CG:** placebo **IG1-IG3:** Dose: 10 mg (IG1), 25 mg (IG2), 50 mg (IG3) Duration: 4 wks Frequency: once/d Compliance: NR **CG:** Dose: NR Duration: 4 wks Frequency: once/d Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 wks	**Primary outcome results:** IG (1-2-3) vs. CG Mean N of grade 3-4 erections at wk 4, mean n: baseline: 2.1; post tx: 2.8 -3.0 - 3.6 vs. 1.8, p < 0.001 (IG vs. CG) GAQ, %: 64 -79 - 88 vs. 38, p < 0.001 Mean Sexual Function Questionnaire (SFQ) scores =improved in IG vs. CG % Partners reporting improved erection: 64 -78 - 83 vs. 39, p < 0.001 **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u, n (%):** 7.8 - 8.2% vs. 13.6% vs. 9.5% **WDAE, %:** 2.2 -4.7- 8.6 vs. 4.2 **TAE, %:** 24.3 – 58.8 - 45 vs. 15% AE in at least 5% of pts, n (%): headache 12-20-16 (13-24-20) vs. 7 (7); dyspepsia 4-9-5 (4-11-6) vs. 3 (3); flushing 4-7-7 (4-8-9) vs. 0; myalgia 1-3-6 (1-4-7) vs. 1 (1); arthralgia 1-6-0 (1-7-0) vs. 1 (1); flue syndromes 0-5-2 (0-6-3) vs. 2 (2); other (NR) 1-0-2 (1-0-3) vs. 0 **SAE, n (%):** n=3 (MI, renal cell carcinoma, epileptic crisis) **Ascertainment of outcomes assessed:** Questionnaire; GAQ; SFQ (15 question, of 14 d diary)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Olsson (2001) [57] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 224 **IG, n =** 136 **CC, n =** 88 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older, with ED of at least 6 mo duration, in a stable relationship for more than 6 mo, clinical diagnosis of stable CVD treated for more than 6 mo with beta blockers and/or ACE inhibitors and/or calcium-channel blockers, written informed consent **Exclusion:** concomitant tx with nitrates in any form, genital anatomical deformities, any major psychiatric disorder, known hx of alcoholism or substance abuse, SCI, sign CV event (hx of stroke or MI, cardiac failure, unstable angina, life threatening arrhythmia) within 6 mo, major haematological, renal or hepatic abnormalities, poorly controlled DM; BP < 90/50 mmHg or >180/ 110 mmHg	**Age, mean (range):** 62 (42-77) vs. 62 (41-76) y **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** no sign differences between grps **Duration of ED, mean:** 4.6 y **Underlying disease, n (%):** hypertension: 109 (80) vs.78 (89); Previous MI 25 (18) vs. 18 (20); chronic ischemic heart disease 27 (20) vs. 13 (15); angina 24 (18) vs. 14 (16), Previous coronary bypass 21 (15) vs. 12 (14) Peripheral vascular disease 19 (14) vs. 8 (9) **Psychogenic ED**: **Physiologic ED, %:** 63 vs. 60 **Mixed ED:** 36 vs. 40	**IG:** sildenafil **CG:** placebo **IG:** Dose: 50 mg with option to titration to 100 or 25 mg based on efficacy and tolerability Duration 12 wks Frequency: up to 1/d Compliance (%): 93% **CG:** Dose: NA Duration 12 wks Frequency: up to 1/d Compliance (%): 91% **Run In period:** 4 wks **Wash out period:** NR **F/u duration (both on and off treatment):** 12 wks **Other: final doses, n (%):** 25 mg: 2 (1) vs. 0 50 mg: 51 (38) vs. 9 (10) 100 mg: 83 (61) vs. 79 (90)	**Primary outcome results:** GEQ, % with improved erection: 71 vs. 24 IIEF, mean (SE): Q3: pre=2; post 3.7 vs. 2.2 Q4: pre=1.5; post 3.3 vs. 1.9 IIEF Q3, and Q4: sign higher in IG than CG (p=0.0001) **Other outcomes assessed:** partner sexual satisfaction **Withdrawals/drop-outs/loss to f/u, (%):** 4 vs. 3, due to insufficient clinical response **WDAE, n (%):** 0 vs. 1 (1) **TAE:** flushing17 vs. 2; headache 15 vs. 1; dyspepsia 5 vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF; GEQ; partner satisfaction questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Orr (2006) [58] **Funding source:** Pfizer Inc. Israel	**N screened =** 28 **N randomized =** 21 (cross over) **IG/ CG, n =** 21 **ITT analysis used for primary outcome:** **Inclusion:** men age 18-60 y, with diagnosis of chronic post traumatic stress disorder (PTSD), and ED (score of less than 50 in IIEF, and les than 20 in IIEF-EF domain), in a stable relationship **Exclusion:** hx of alcoholism or substance dependence within the last 12 mo; genital or anatomical deformities; SCI; poorly controlled DM; hx of malignant hypertension, resting SBP > 180 mm Hg, hx of stroke or MI within the last 6 mo prior to study entry; predisposing to priapism; any other unstable medical conditions; use of nitrates, or nitric oxide in any form use of sildenafil more than once; tx with T; current use of any ED tx	**Age, mean (sd):** 44.5 (9.69) y, range 22-55 y **Race:** NR **Co-morbidities, n (%):** psychiatric conditions: current major depressive episode 47% (past episodes 29%); dysthyia 7%; current maniac or hyomanid episode 4%; anxiety disorder: social phobia 39%; general anxiety disorder 61%, agoraphobia 61%; obsessive compulsive disorder 4%, psychotic symptoms reported in 38% **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** SSRIs 71%, tri-cyclic antidepressants 21%, other antidepressants 14%, anti-psychotics 25%, mood stabilizer 25%, and benzodiazepine 89% **Duration of ED, mean (sd):** 19.71 (10.21) **Underlying disease, n (%):** as in co-morbidities **Psychogenic ED, n (%):** 100% **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG:** Sildenafil **CG:** Placebo **IG1:** Dose: 50-100 mg Duration: 4 wks Frequency: one pill 1 hr before sexual activity; total of 6 pills Compliance: NR **CG:** Dose: NA Duration: 4 wks Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** no washout included **F/u duration:** **Other:** (pts were randomized to 2 grps, 1st grp started with 4 wks placebo, and 2nd grp started with 4 wks sildenafil)	**Primary outcome results:** IIEF, mean (sd) Total score: baseline 20 (12.32); post 45.19 (15.05) vs. 33.04 (12.99) EF: baseline 7.42 (5.3); post tx 18.57 (7.7) vs. 13.8 (5.3) SD: baseline 4.58 (2.23); post tx 4.95 (2.03) vs. 4.58 (1.8) OF: baseline 4.45 (3.74); post tx 5.59 (2.44) vs. 4.04 (2.15) IcS: baseline 4.39 (3.75); post tx 7.22 (1.92) vs. 6.20 (2.37) OS: baseline 3.37 (1.96); post tx 5.18 (2.55) vs. 4.20 (2.48) **Other outcomes assessed:** depression, subjective well being and PTSD symptoms score **Withdrawals/drop-outs/loss to f/u, n (%):** 6/27 (22) in placebo phase; 1/23 (4.3%) in sildenafil phase **WDAE, n (%):** NR **TAE, n (%):** NR, AEs included heartburn, decrease in appetite, constipation, diarrhea, nausea, vision blur, tinnitus, dizziness, headache, tiredness, backache, stomach ache, chest pain, hot flushes, rash, palpitation, sweating; no sign.between grps **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF domains; depression, subjective well being by SAS and ABS); PTSD symptom scores

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padam-Nathan (1998) [59] **Funding source:** Pfizer	**N screened =** NR **N randomized =** **IG, n =** 163 **CG, n =** 166 **ITT analysis used for primary outcome:** yes (last observation carried forward) **Inclusion:** men 18 or older, with ED of more than 6 mo, ED (ED aetiology determined at screening by medical hx, penile tumescence test, IC injection test, endocrine testing, and penile duplex ultrasonography) **Exclusion:** penile anatomical defects; SCI; other sexual disorders; low T; poorly controlled DM or untreated proliferative diabetic retinopathy; psychiatric dx; active peptic ulcer dx; hx of major haematological, renal, or hepatic abnormalities; recent hx of CV dx, stroke, or MI, or alcoholism; or substance abuse; tx with nitrates, androgens or trazodone	**Age, mean (range):** 60 (26-79) vs. 59 (31-81) y **Race:** NR **Co-morbidities, (%):** hypertension 24 vs. 28; Hyperlipidemia 15 vs. 15; ischemic heart dx 15 vs. 8; DM (any type) 8 vs. 11; depression 3 vs. 3; radical prostatectomy 9 vs. 11 **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED, mean (range):** 5 (0.5-26) y **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg (titrated to 100 mg, or 25 mg at 2 wks based on effecacy and tolerability); total 32 doses Duration: 12 wks (median=87 d) Frequency: up to one/d (approximately 1 hr before sexual activity) Compliance: NR **CG:** Dose: NA/ total of 29 doses Duration: 12 wks (median = 86 d) Frequency: as IG Compliance: NR **Run In period:** 4 wks no tx **Wash out period:** NR **F/u duration:** 12 wks **Other:** 23% of pts were on 50 mg; 74% on 100 mg at the end	**Primary outcome results:** GEQ, (% yes): 101/136 (74%) vs. 23/118 (16%), p<0.0001 Erection sufficient for intercourse, n (%): 94/137 (69) vs. 32/138 (23) Maintaining erection after penetration, n (%): 85/137 (62) vs. 22/138 (16) Maintaining erection on most occasions, n (%): 81/137 (59) vs. 21/138 (15) Successful intercourse, (%): 65% vs. 20%, p < 0.001 Frequency of successful intercourse attempts (n/mo): 5.9 vs. 1.5, p <0.0001 **Other outcomes assessed:** partner assessment of sexual performance **Withdrawals/drop-outs/loss to f/u, n (%):** 9 (8) vs. 13 (6) **WDAE, n (%):** 1 (<1) vs. 2 (1) **TAE, n (%):** AE in at least 5% of pts= headache 30 (18) vs. 6 (4); flushing 30 (18) vs. 1 (1); dyspepsia 9 (6) vs. 4 (2); abnormal vision (▲ sensitivity or light or blurred vision) NR (3) vs. NR (1) **SAE, n (%):** NR **Ascertainment of outcomes assessed:** GEQ; pts log (sexual stimulation, and successful intercourse); optional two item partner questionnaire; IIEF (15 item version); AE by examiner

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan (2003) [60] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 228 **IG, n =** 115 **CG, n =** 113 **ITT analysis used for primary outcome:** No **Inclusion**: pts 18 or older with clinically documented ED at least 6 mo duration who had previously responded successfully to sildenafil treated minimum. of 2 mo, in a stable 100-mg sildenafil dose, established single-partner relationship; had to discontinue all medications for ED **Exclusion:** tx with nitrates or nitric oxide donors and those with hypotension (BP less than 90/50 mmHg), hypertension (PB more than 170/110 mmHg), MI, unstable angina, stroke, or symptomatic or clinically sign cardiac abnormalities in the past 3 mo	**Age, mean (sd):** 61(10) vs. 59(11) **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Initial body weight**: NR	**Concomitant medications:** NR **Duration of ED (yr, SD):** 6.8(4.6) vs.7.2 (5.4) **Underlying disease:** NR **Psychogenic ED n (%):** 3 (3) vs. 4 (4) **Organic ED, n (%):** IG 61 (53) vs. 66 (58) **Mixed ED, n (%):** 36 (31) vs. 29 (26)	**IG:** sildenafil **CG:** placebo **IG:** Dose: 100 mg Duration: 4 wks Frequency: up to once/d; as need Compliance: NR **CG:** Dose: NA Duration: 4 wks Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** 2 wks **F/u duration:** 4 wks	**Primary outcome results:** IIEF: IG sign higher scores vs. CG for all domains p<0.001 (results provided in Figure 2) Sexual activity event log, mean time to onset of erection (min): 36.3 vs. 140.7 min. (sign, p<0.0001) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 4 (3.5) vs. 5 (4.4) **WDAE:** 2 (2) vs. 0 **TAE:** 41 vs. 18 in 29 (25%) vs. 15 (13%) of pts, most common AE, %: headache 6 vs.0; flushing 3.5 vs.0.9; respiratory tract infection 4.3 vs. 4.4; sinusitis 0 vs. 5 **SAE:** NR **Ascertainment of outcomes assessed:** Sexual activity event log: recorded at home time duration of sexual activity using a stopwatch. Other question: whether erection lasted long enough for successful intercourse. IIEF: questionnaire.

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan, (1999) [32] **Funding source:** NR	**N screened =** NR **N randomized =** 532 **IG, n =** 316 **CG, n =** 216 **ITT analysis used for primary outcome:** No **Inclusion**: ED **Exclusion:** penile anatomical deformities, hyperprolactinaemia or testosterone deficiency, stroke, MI, or sign. CVD in the previous 6 mo, poorly controlled DM or major psychiatric disorder, untreated proliferative diabetic retinopathy, major haematological, renal or hepatic abnormalities, active peptic ulcer dx, retinitis pigmentosa, concomitant tx with nitrates, nitric oxide donors, androgens or trazodone, hx of alcoholism or substance abuse	**Age, mean (range):** 58 (20-87) **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean:** 3.2 y **Underlying disease (%):** NR **Psychogenic ED (%):** 9 **Organic ED (%):** 77 **Mixed ED (%)**: 13	**IG:** sildenafil **CG:** placebo **IG1:** Dose: 25, 50 or 100 mg Duration: 6 mo Frequency: as need before sexual activity Compliance: NR **CG:** Dose: placebo Duration: 6 mo Frequency: as need before sexual Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 6 mo	**Primary outcome results:** Erections hard enough for sexual intercourse, mean %: 72 (25mg), 80 (50 mg), 85 (100mg) vs. CG 50 ($p < 0.001$) Number of erections, mean/mo: Grade 3= 2.1(25 mg), 2.4 (50 mg), 3.1 (100 mg) vs. CG 2.4 ($p < 0.001$); Grade 4=2.2 (25 mg), 4.2 (50 mg), 3.4 (100 mg) vs. CG 0.7 ($p < 0.001$) Successful intercourse (%, grade 3,4): grade 3 = 80 vs. NR grade 4 = 94 vs. NR **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE, n (%):** 25 mg =1(1), 50 mg= 1 (1), 100 mg =2 (2) vs. CG= 1 (4) **TAE, n (%):** headache 25 mg =14(14), 50 mg= 23 (21), 100 mg= 32(30) vs. CG= 14 (6); flushing 25 mg= 13 (13), 50 mg= 29 (27), 100 mg 21 (20) vs. CG= 3 (1); Dyspepsia 25 mg= 3 (3), 50 mg= 12 (11), 100 mg= 17(16) vs. CG= 3 (1) Abnormal vision, 25 mg= 2(2), 50 mg =6 (6), 100 mg =10(9), CG= 1 (1) Rhinitis, 25 mg= 1(10), 50 mg =3 (3), 100 mg= 12(11), CG= 4 (2) **SAE:** NR **Ascertainment of outcomes assessed:** event log (4-point erection hardness scale and successful sexual intercourse attempts)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Palmer (1999) [61] **Funding source:** Pfizer Inc.	**N screened =** NR **N randomized =** 8 (crossover study) **ITT analysis used for primary outcome:** No **IG/CG, n =** 8 **Inclusion:** men with ED and spina bifida **Exclusion:** NR	**Age, range:** 19-35 y **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** sildenafil **CG:** placebo **IGa/ IGb:** Dose: a=25 mg; b=50 mg (one set for each dose; 5 tablets/ set) Duration: NR Frequency: 1/d Compliance (%): 100% **CGa/ CGb:** Dose: NA (two sets of tablets) Duration: NR Frequency: 1/d Compliance (%): 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** Duration of erection, mean Baseline: 8.9 min Low dose: 17.9 vs. 10.4 min High dose: 25.6 vs. 13.5 min (improvement of 101% and 188% for IG a and b respectively) IIEF, high dose; low dose IG vs. CG mean score: Q1 baseline 2.1; post: 3.3; 4.4 vs. 2.5 (improvement of 57% and 110% for IG grps) Q15 baseline 2.3; post 3.0; 3.8 vs. 2.6 (improvement of 30% and 65% for IGa and b respectively) Erectile score: baseline 3.4; post 5.8, 6.9 vs. 3.7 (improvement of 71% and 103% for IG a and b respectively) **Other outcomes assessed:** None **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Palmer (2000) [62] **Funding source:** Pfizer, Inc	**N screened =** 17 **N randomized =** 17 (cross over) **IG/CG, n =** 17 **ITT analysis used for primary outcome:** No **Inclusion**: men 18-35 with diagnosed spina bifida, and ED, medical clearance from primary care physician **Exclusion:** abnormal haematological evaluation, medical contraindications	**Age, range:** 19-35 y **Race (%):** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** Spina Bifida 100% **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1/2:** sildenafil- oral **CG:** placebo- oral **IG1/ IG2:** Dose: 25 mg (IG1), 50 mg (IG2) Duration: NR Frequency: up to once/d, one hr before sexual activity; pts were given 4 sets of tablets (sildenafil 25 mg, 50 mg and two identical looking placebo tablet), 5 tablets/ set in a random order) Compliance: 88% **CG1:** Dose: NA Duration: NR Frequency: as IG Compliance: 88% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** IIEF, mean score (values approximate from figure): Q3- baseline= <2.5 vs. <3; 12 wks: <3 vs. >3.5, p=0.001 (improvement in 35.7% vs. 19.9% of pts) Q4- baseline: <2; 12 wks: <2.5 vs. >3, p=0.001 (improvement in 68.4% vs. 26.5% of pts) Number of successful intercourse attempts (event log), %- baseline: 20; 12 wks 40 vs. >65, p=0.001 (improvement in 63% vs. 33% of pts) EF domain- baseline: <14; 12 wks: 15 vs. 20, p=0.001 GEQ, % improved: 66.6 vs. 28.6 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 4 (24) **WDAE:** 0 **TAE, n (%):** 5 (33) only with 25 mg including dyspepsia 1 (7); nausea 1 (7); headache, flushing and nasal congestion 1(7); urinary tract infection 1 (7), and haematological changes 1 (7) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, Q1 and 15, patient ratings of erection

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Perimenis (2004) [63] **Funding source:** NR	**N screened =** NR **N randomized =** 30 **IG1, n =** 15 **IG2, n =** 15 **CG, n =** NA **ITT analysis used for primary outcome:** Yes **Inclusion**: Men with clinically diagnosed ED and obstructive sleep apnea syndrome (OSAS) **Exclusion:** deformity in external genitals, taking nitrates, being treated for ED, hormonal deficiency, had not had a stable relationship for at least 6 mo	**Age, mean (sd):** 55.7 (3.6) vs. 56.4 (3.3) **Race (%)**: NR **Co-morbidities:** DM (NR), atherosclerosis (NR), CAD (NR), hypertension (NR) % Pts with => 1 disease: n=11 (73%), in each arm **Previous ED treatment**: NR **Smoking status, n (%):** smokers 23 (77) **Body weight:** most pts were overweight	**Concomitant medications:** NR **Duration of ED:** 16.7 (7.6) vs. 15.7 (6.1) mo **Underlying disease:** OSAS (100%) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Continuous Positive Air Pressure (CPAP) **IG2:** Sildenafil **IG1:** Dose: NA Duration: 12 wks Frequency: nightly Compliance (%): NR **IG2:** Dose: 100 mg Duration: 12 wks Frequency: NR Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** Mean (sd) scores IG1 vs. IG2: IIEF total: pre=21.7 vs. 23.3; post = 27.3 (8.6) vs. 37.7 (10.5), p = 0.0025 IIEF-EF: pre=7 vs. 8; post 9 (3) vs. 13 (4) IIEF-OF: pre=3; post: 3 (1.6) vs. 5.5 (1.9) IIEF-SD: pre=7; post: 7 (1.4) vs. 7.7 (0.8) IIEF ICs: pre=3.3 vs. 3.7; post: 4.6 (1.7) vs. 6.4 (2) IIEF-OS: pre=2; post 2.9 (1.6) vs. 4.5 (2.3) pts satisfied with the treatment, n/N (%) = 3/15 (20) vs. 8/15 (53.3), p = 0.13 Successful attempts for intercourse, n/N (%) = 33/138 (23.9) vs. 97/180 (53.9), p = 0.001 Mean N of attempts per patient = 9.2 vs. 12, p = 0.005 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** None **WDAE:** 0 **TAE:** NR **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan, IIEF; pts diary questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Perimenis (2007) [64] **Funding source:** NR	**N screened =** **N randomized =** 40 **IG1, n =** 20 **IG2, n =** 20 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion:** men with ED and sleep apnea (complete cessation of airflow for at least 10 s and hypopnea as the reduction in airflow by at least 50% for 10 s or more) **Exclusion:** genital deformity, use of nitrates; on tx with ED; hormonal deficiency, not in a stable relationship for at least 6 mo	**Age, mean (range):** 55.3 (42-64) vs. 55.5 (48-62) y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** None **Smoking status:** NR **Body weight:** NR **Other:** respiratory disturbance index (RDI) 9.9 (6-24) vs. 8.9 (6-25)	**Concomitant medications, n (%):** NR **Duration of ED:** 17.5 (6-36) vs. 18.7 (8-36) mo **Underlying disease, n (%):**NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%)**: NR	**IG1:** Sildenafil **IG2:** Continous Positive Airway Pressure (CPAP) **CG:** **IG1:** Dose: 100 mg on demand, 1 hr prior to sexual activity Duration: 12 wks Frequency: once/d Compliance: NR **IG2:** Dose: NA Duration: 12 wks Frequency: during night time sleep Compliance: NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks (every 4 wks)	**Primary outcome results:** Rate of successful intercourse attempts, per pts: 128/249 (51.4%) vs. 51/193 (26.9%) IIEF-EF, mean (sd): Baseline: 7.8 (1.2) vs. 7 (1.9) Post tx: 14.3 (5.0) vs. 10.8 (4.4), p = 0.025 **Other outcomes assessed:** satisfaction with tx (better with sildenafil, 50% vs. 25%, p=0.007) **Withdrawals/drop-outs/loss to f/u, n (%):** 0 **WDAE, n (%):** 0 **TAE, n (%):** NR **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** pts diary; IIEF, EDITS

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Pickering (2004) [65] **Funding source:** Pfizer	**N screened =** 670 **N randomized =** 568 **IG, n =** 281 **CG, n** = 287 **ITT analysis used for primary outcome:** yes **Inclusion**: men 18 or older with ED and hx of arterial hypertension treated with 2 or more different antihypertensive drugs, with stable dose for at least 4 wks; in stable relationship **Exclusion:** hypotension or uncontrolled hypertension, sign CV dx in previous 6 mo; current use of nitrates; past tx with sildenafil	**Age, mean (sd):** 59 (8) vs. 59 (9) **Race:** NR **Co-morbidities:** None **Previous ED treatment**: None **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** None **Duration of ED, mean (sd):** 4.6 (4.1) vs. 4.5 (4.6) y **Underlying disease:** Arterial hypertension **Psychogenic ED, n (%):** 23 (8.2) vs. 24 (8.5) **Physiologic ED, (%):** 145 (52) vs. 142 (50.2) **Mixed ED**, **n (%):** 111 (39.8) vs. 117 (41.3)	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50mg (after2 wks adjusted to 25 or 100 mg) Duration: 6 wks Frequency: before sexual intercourse Compliance (%): (94) **CG:** Dose: 1 tablet Duration: 6 wks Frequency: before sexual intercourse Compliance (%): (95) **Run In period:** 2 wks screening period **Wash out period:** None **F/u duration** (on and off treatment)**:** Trial followed up by 6 wks open label phase where all participants received Sildenafil.	**Primary outcome results:** IIEF mean (sd) IG1 vs. CG Q3: pre= 3.6 (0.1) vs. 2.7 (0.1) Q4 (penetration): 3.6 (0.1) vs. 2.5 (0.1) GEA-Q1, % improved: 71 vs. 18 1: Improved erections: (71) vs. (18) GEA-Q2, %: 69 vs. 20 Intercourse success rate, %: 62 vs. 26 **Other outcomes assessed:** EDITS: Patients who took sildenafil score higher mean scores on EDITS **Withdrawals/drop-outs/loss to f/u, n (%):** 7 (2.5) vs. 5 (2) **WDAE, n (%):** 4 (1.4) vs. 4 (1.4) **TAE, n (%):** 111 (39.9) vs. 73 (26) including headache 28 (10.1) vs. 10 (3.6); flushing 17 (6.1) vs. 1 (0.4); dyspepsia 15 (5.4) vs. 3 (1.1); dizziness 11 (4) vs. 1 (0.4); nasal congestion 7 (20.5) vs. 1 (0.4); abnormal vision 7 (2.5) vs. 0 **SAE:** 2 (0.7) vs. 2 (0.7); including one due to MVA in CG **Ascertainment of outcomes assessed:** IIEF-Q3, and 4; GEA-Q1 and 2; pts event log

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Price (1998) [66] **Funding source:** Pfizer	**N screened =** NR **N randomized =** 21 (3 way cross over; two periods) **IG1/IG2/CG, n =** 21 **ITT analysis used for primary outcome:** NR **Inclusion**: men 18-70 y with hx of DM type 1 or 2, for 5 y or more, ED of at least 6 mo (ED definition and diagnosis is described) **Exclusion:** sign ischemic heart dx or peripheral vascular dx, tx with antidepressants/tranquillizer, nitrates, anticoagulants, or salicylates in last 2 wks prior to study, hx of bleeding dx, severe untreated proliferative diabetic retinopathy, no ED tx in past 2 wks	**Age, mean (range):** 51 (42-65) y **Race:** NR **Co-morbidities:** **Blood glucose (or HbA1C):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, median (range):** 3 (1-14) y **Underlying disease:** 100% DM, with mean duration of 11 (range 3-32) y; evidence of peripheral or autonomic neuropathy n=6 (28%) **Psychogenic ED:** NR **Physiologic ED:** 100% **Mixed ED:** NR	**Phase I** **IG:** single dose sildenafil + 90 min visual sexual stimualtion (VS) **CG:** placebo **Phase II** **IG:** sildenafil **CG:** placebo **IG phase I:** Dose: 25 mg (IG1), 50 mg (IG2) Duration: NA Frequency: single dose Compliance: NR **IG phase II:** Dose: 25 mg (IG1), 50 mg (IG2) Duration: 10 d Frequency: once/d Compliance: NR **CG phase I & phase II:** Dose: NA Duration: as IG in respective phase Frequency: as IG Compliance: NR **Run In period:** 2 wks **Wash out period:** NR **F/u duration:** immediately post tx	**Primary outcome results:** Phase I, duration of erection with > 60% rigidity, mean (95% CI): Base: 5 (1.9-12.4) vs. 10.1 (4.2-23.1) vs. 2.8 (0.7-8.4) min Tip: 1.2 (0.2-3.8) vs. 2.2 (0.7-6) vs. 0.4 (-0.2-2.1) min Phase II (home study) N of erection sufficient for intercourse (grade 3 or 4), mean (95% CI): 1.3 (0.9-1.8) vs. 1.6 (1.1 –2.1) vs. 0.6 (0.4-0.9) % of pts with improved erection, n (%): 10 (50) in 25 mg vs. 2 (10) in placebo 11 (52%) in 50 mg vs. 2 (10) in placebo **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR; tx related AEs=8 vs. 8 vs. 3 including headache 4 vs. 0, myalgia 3 vs. 2, nausea 2 vs. 1, and dyspepsia 5 vs. 0 **SAE:** 1 (4.7) vs. 0; pneumococcal pneumonia with 25 mg dose **Ascertainment of outcomes assessed:** RigiScan (phase I); self report on grading system (phase II)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Randell (1999) [67] **Funding source:** study medications by Pfizer (author has served as paid consultant for Pfizer)	**N screened =** NR **N randomized =** 268 **IG, n =** 136 **CG, n =** 132 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older, medically documented ED for at least 6 mo, managed and stable DM (type 1at least 5 y, type 2 at least 2 y); in a stable relationship for at least 6 mo **Exclusion:** penile anatomical deformities, primary diagnosis of sexual disorder other than ED; sign psychiatric dx; SCI, hx of major haematological, renal, or hepatic abnormalities; stroke or MI, in past 6 mo; active peptic ulcer; hypo/hypertension, diabetic retinopathy or severe autonomic neuropathy; hx of ketoacidosis in last 3 y; tx with nitrates or androgens	**Age, mean (range):** 57 (27-79) y **Race:** NR **Co-morbidities, n (%):** hypertension 139 (51); ischemic heart dx 70 (26) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** antihypertensive agents 141 (53); diuretics 33 (12); beta blockers 19 (7); antidepressant agents 13 (5) **Duration of ED:** NR **Underlying disease, n (%):** DM type I= 50 (18); type II = 136 (50); **Psychogenic ED:** NR **Physiologic ED, (%):** 256 (96) **Mixed ED, n (%):** 12 (4)	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg (titrated up to 100, or down to 25 mg according to pts tolerability and efficacy) Duration: 12 wks Frequency: up to once/d (1 hr prior to sexual activity) Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wk (no tx) **Wash out period:** NA **F/u duration:** 12 wks **Other:** pts receiving sildenafil 100 mg (high for placebo)= 126 (93%) vs. 127 (96%); 50 mg (medium) = 10 (7%) vs. 5 (4%); 25 mg (low) = 0 vs. 0	**Primary outcome results:** IIEF, Q1, 2, 3, 4 (baseline = 2), at 12 wk, mean (SE) for individual questions: 3 (0.2) vs. 2 (0.2); increase of 78% vs. 25%, P<0.001 IIEF, EF (Q5, 15): pre=1, post: individual questions, mean (SE): 3 (0.2) vs. 2 (0.2) Pts with at least 1 successful attempt at sexual intercourse: 61 (71/117) vs. 22 (25/114), p<0.001 **Other outcomes assessed:** sexual satisfaction and OF; IIEF 11 & 12 (no change); efficacy variables for subgrp of DM pts **Withdrawals/drop-outs/loss to f/u, n (%):** 16 (6); IG 11 (8), vs. CG 5 (4) **WDAE:** 1 (<1) vs. 1 (<1); no detail **TAE:** AE in at least 3% of pts= 22 (16) vs. 5 (5); including: headache 15 (11) vs. 2 (2); dyspepsia 12 (9) vs. 0; respiratory tract disorder 8 (6) vs. 2 (2); CV 4 (3) vs. 6 (5); flushing 5 (4) vs. 0; abnormal vision 5 (4) vs. 1 (1) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF Q1, 2, 5-15 self report ability to achieve and maintain erection for sexual intercourse

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Safarinejad (2004) [68] **Funding source:** NR	**N screened =** 373 **N randomized =** 282 **IG, n =** 144 **CG, n =** 138 **ITT analysis used for primary outcome:** Yes **Inclusion:** pts 18 or older, with ED (NIH consensus), and DM longer than 6 mo; in a heterosexual stable relationship for at least 6 mo, and no tx for ED 4 wks prior to trial **Exclusion:** anatomaical defects, another sexual disorder, major haematological, renal, hepatic, uncontrolled psychiatric disorder, tx with nitrates, androgens, CAD, hx of MI or stroke, peptic ulcer dx, poorly controlled DM, hx of drug/alcohol abuse, SCI, hypotension (resting < 90/50 mmHg) or hypertension (resting > 100 mmHg), proliferative retinopathy or autonomic neuropathy and hx of ketoacidosis	**Age, mean (range):** 46 (36-68) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** NR (none in 4 wks prior to trial) **Smoking status**: NR **Body weight:** NR **Other:** HbA1C, % = < 0.12	**Concomitant medications, %:** ACE inhibitors without diuretics 22; ACE inhibitors with diuretics 22.5, diuretics 12; β-blockers 4 **Duration of ED (yr):** 3.6 (2.5-12) **Underlying disease, %:** DM type I =17; type II= 83 **Psychogenic ED**: None **Physiologic ED:** 96% **Mixed ED**: 4%	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 100 mg Duration: 16 wks Frequency: once/d Compliance: NR **CG:** Dose: NR Duration: 16 wks Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 16 wks	**Primary outcome results:** IIEF-Q3, mean (SE): pre: 1.8 (0.2); post: 2.8 (0.2) vs. 2.2 (0.2), p < 0.002 (vs. baseline) IIEF-Q4, mean (SE): pre 1.7 (0.2); post: 2.9 (0.2) vs. 2.0 (0.2), p < 0.002 (vs. baseline) GEQ, n (%) with positive response: 68 (51) vs. 14 (11), p < 0.003 **Other outcomes assessed:** Mean scores of IIEF 1,2,5-10,13-15 (improved with sildenafil, p <0.05) **Withdrawals/drop-outs/loss to f/u, n (%):** 10 (7) vs. 10 (7) **WDAE, n (%):** 8 (6) vs. 0 **TAE**: NR; most common AEs=22 vs. 1.4 (p < 0.001); AE included headache 29 (20) vs. 3 (2), flushing 27 (19) vs. 0; dyspnea 13 (9) vs. 3 (2); rhinitis 9 (6) vs. 0; CV events 10 (7) vs. 0; prolonged erection 1 (1.4) **SAE:** NR [CV events in sildenafil grp = four chest pain (two MI), two heart failures and four hypertensions] **Ascertainment of outcomes assessed:** Questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Safarinejad (2006) [69] **Funding source:** not sponsored	**N screened =** 430 (486 entered a preliminary phase to emphasize the timing and instruction of sildenafil; responders were excluded) **N randomized =** 402 **IG1, n =** 205 **IG2, n =** 197 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 y or older with ED; in a stable relationship, non-responders to sildenafil, and no tx of ED within the last 4 wks prior to entering the study **Exclusion:** penile anatomical defects, primary dx of another sexual disorder, use of psychotropic and antidepressant medications, poorly controlled DM, uncontrolled congestive or ischemic heart dx or renal or liver impairment, hx of alcohol or drug abuse, SCI, hx of prostate cancer, neurological dx causing ED	**Age, mean (range):** 41.5 (21-59) y **Race:** NR **Co-morbidities, n (%):** DM 44 (12); hyper-cholesterolemia 91 (24.6); hypertension 87 (23.5); Ischemic heart dx 52 (14) **Previous ED treatment:** NR **Smoking status:** smokers 192 (52) **Body weight:** NR	**Concomitant medications, n (%):** **Duration of ED, mean (range):** 2.8 (1.9-7) y **Underlying disease, n (%):** NS between grps: arteriogenic 132 (32.8); mixed vasculogenic 105 (26); veno-occulsive dysfunction 97 (24); corporeal fibrosis 8 (2) **Psychogenic ED, n (%):** 15 (7.3) vs. 13 (6.6) **Physiologic ED, n (%):** 374 (93) **Mixed ED:** NR	**IG1:** Sildenafil + Cabergoline **IG2:** Sildenafil + placebo **IG1:** Dose: sildenafil= 50 ▲ rapidly to 100 if not results were observed with the attempt; cabergoline= 0.5 mg ▲ by 0.25 biwkly up to 1 mg/wk Duration: 6 mo Frequency: sildenafil: pkg instruciton up to 1/d; cabergoline: wkly Compliance: NR **IG2:** Dose: sildenafil as IG1+ placebo Duration: 6 mo Frequency: as cabergoline Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 mo	**Primary outcome results:** IIEF, LS mean (SE) scores: Q3: baseline 1.8 (0.2); post tx 3.3 (0.2) vs. 2 (0.2) Q4: baseline 1.7 (0.2); post tx 3.7 (0.2) vs. 2 (0.2) All other IIEF individual questions sign improved with cabergoline, p=0.04 IIEF- IcS domain mean score: baseline 10 vs. 11; post tx 15 vs. 10 Successful intercourse attempts (% with at least one success): 36% vs. 6% **Other outcomes assessed:** IVELT sign difference between tx grps (p=0.001) **Withdrawals/drop-outs/loss to f/u, n (%):** 19 (9.3) vs. 13 (6.6) **WDAE, n (%):** 12 (5.9) vs. 2 (1) **TAE, n (%):** pts with AE 25 (12.2) vs. 4 (2) including nausea, headache, dizziness, somnolence **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF, Intra-vaginal ejaculatory latency time (IVELT) evaluation, serum T, and PRL levels

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Seibel (2002) [70] **Funding source:** NR	**N screened =** 226 **N randomized =** 48 **IG, n =** 24 **CG, n =** 24 **ITT analysis used for primary outcome:** NR **Inclusion**: men aged <70 yr; on hemodialysis for ≥6 mo; in stable relationship with female partner **Exclusion:** penile anatomic abnormality; cirrhosis; diabetes; angina; severe anemia; nitrate treatment; hx of recent (within previous 6 mo) stroke or myocardial infarction; illiteracy; current ED treatment	**Age, mean (sd):** 49 (10) vs. 46 (9) **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Initial body weight:** NR **Other:** Duration of hemodialysis, mean (sd): 42 (31) vs. 36 (26) mo	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** Nr **Mixed ED**: NR **Other:** ED severity, n: Severe 2 vs. 3 Moderate 11 vs. 10 Mild-moderate 5 vs. 6 Mild 2 vs. 2	**IG:** sildenafil orally **CG:** placebo orally **IG:** Dose: 50 mg Duration: 1 mo Frequency: 1 dose 1 hr before sexual intercourse; max. 1/d; no drug when on hemodialysis Compliance (%): NR **CG:** Dose: placebo Duration: 1 mo Frequency: as IG Compliance (%): NR **Run In period:** NR **Wash out period:** NA **F/u duration:** 1 mo	**Primary outcome results:** IIEF -change from baseline (mean): Q3: 1.2 vs. 0.05 Q4: 1.4 vs. no change EF: 7.0 vs. 0.2 OF: 1.7 vs. 0.4 SD: 0.5 vs. 0.4 ICs: 2.6 vs. 0.7 OS: 2.3 vs. 0.6 **Other outcomes assessed:** change in severity of ED; **Withdrawals/drop-outs/loss to f/u:** 4 (17) vs. 3 (13) **WDAE:** 0 **TAW:** 5 vs. 3; pts with AE =3 (13) vs. 3 (13); including headaches, facial flushing, dyspepsia vs. headaches and facial flushing **SAE:** 2 deaths in CG (neither associated with placebo ingestion or sexual intercourse) **Ascertainment of outcomes assessed:** IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Seidman (2001) [71 72] **Funding source:** Pfizer Inc.	**N screened =** 300 **N randomized =** 152 **IG, n =** 74 **CG, n =** 78 **ITT analysis used for primary outcome:** yes **Inclusion**: men 18 or older, with ED of at least 6 mo in duration, and in stable heterosexual relationship for > 6 mo, ED, DSM-IV (not defined) criteria for depressive disorder, 24-item Hamilton depression scale score $\geq$ 12 at both screening interviews. **Exclusion:** other psychiatric disorder, substance abuse or dependence, current use of nitrates or antidepressant medication, abnormal serum hormone levels, hx of major hematologic renal or hepatic abnormalities, poorly controlled diabetes, retinitis pigmentosa, spinal cord injury, serious CV dx	**Age, mean (sd):** 57 (10) vs. 55 (12); range 25-81 y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: NR **Body weight:** NR **Other:** baseline depression scores: Beck Depression inventory, mean, (sd): 15 (8) vs. 16 (7)	**Concomitant medications:** NR **Duration of ED (yr (sd):** 6 (6) vs. 5 (5) range 0.3-33 y **Underlying disease:** 1 radical prostatectomy **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** oral sildenafil **CG:** oral placebo **IG:** Dose: 50 mg with option to titrate up to 100 mg or down to 25 mg Duration: 12 wks Frequency: once/d Compliance (%): 87.8 **CG:** Dose: NA Duration: 12 wks Frequency: once/d Compliance (%): 76.9 **Run In period:** NR **Wash out period:** NR **F/u duration:** 12 wks **Other:** pts in dose grps at 12 wks, n (%): 100 mg: 57 (79) 50 mg: 14 (19) 25 mg: 1 () in IG, 73 (97) in CG.	**Primary outcome results:** Overall IIEF mean (SE) score: 23 (1.5) vs. 12 (1), p < 0.001 Ability to achieve erection; mean (SE): 4 (0.3) vs. 2 (0.2) Maintaining erection: 4 (0.3) vs.2 (0.2) CGI, improved erections, n (%): 60/66 (91) vs. 8/70 (11) Successful sexual intercourse, n (%): 59/66 (89) vs. 9/70 (13) % Pts responders = 73% vs. 14% **Other outcomes assessed:** Depressive symptoms, quality of life **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:**0 **TAE, n (%):** 43 (58) vs. 7 (9); AE in at least 5% of pts: headache 15 (20) vs. 5 (6); dyspepsia 11 (15) vs. 0; flushing 11 (15) vs. 1 (1); abnormal vision 6 (8) vs. 1 (1) **SAE:** NR **Ascertainment of outcomes assessed:** Clinical Global Impression Improvement (CGI); Self report questionnaires, Hamilton depression scale, Clinical Global Improvement scale, Beck Depression Inventory, IIEF, Life Satisfaction Checklist, physical exam

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Shabsigh (1999)[73] **Funding source:** NR	**N screened =** NR **N randomized =** 329 **IG, n =** 163 **CG, n =** 166 **ITT analysis used for primary outcome:** NR **Inclusion**: men with ED of 6 mo or longer **Exclusion:** NR	**Age, mean:** NR **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: NR, all had tx for at least 6 mo prior to trial **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease (%):** ED 100 **Psychogenic ED (%):** 15 **Organic ED (%):** 59 **Mixed ED (%)**: 26	**IG:** sildenafil **CG:** placebo **IG:** Dose: 5 mg Duration: 12 wks Frequency: 1 hr before sexual activity Compliance: NR **CG:** Dose: placebo 5 mg Duration: 12 wks Frequency: 1 hr before sexual activity Compliance: NR **Run In period:** 2 wks (efficacy and toleration) **Wash out period:** NR **F/u duration:** 12 wk	**Primary outcome results:** IIEF, mean score: Q3: 3.9 vs. 2.3 ($p < 0.001$) Q4: 3.6 vs. 1.8 ($p < 0.001$) **Other outcomes assessed:** NA; aetiology of ED had no sign effect on outcome **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** IIEF question 3 and 4 (/5)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sharma (2006) [74] **Funding source:** Zydus Cadila	**N screened =** NR **N randomized =** 32 (randomized cross over) **IG/ CG, n =** 32 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older and medically documented ED, who were renal transplant recipients with stable graft function in the last 6 mo; also in a stable relationship **Exclusion:** penile anatomic deformities, hx of recent stroke, MI, in last 6 mo, proliferative diabetic retinopathy, sever autonomic neuropathy, regular tx with nitrates/ androgens; SCI	**Age, mean (sd):** 40 (8) **Race:** NR **Co-morbidities, n (%):** chronic glomerulonephritis 14 (43); chronic interstitial nephritis 8 (25); diabetic nephropathy 7 (22); other basic diseases 3 (9.4) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** blood levels of hemoglobin, nitrogen, creatinine was reported	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** renal allograft **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%):** NR	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg titreated up to 100 mg or down to 25 mg based on investigator's judgment of efficacy/ tolerability Duration: 8 wks Frequency: up to once/d Compliance: NR **CG:** Dose: NA Duration: 8 wks Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** 2 wks **F/u duration:** end of each 8 wks study period **Other:** mean number of tablets= sildenafil 24.3 (3.3); placebo 23.8 (2.6)	**Primary outcome results:** IIEF, mean (sd): Q3: baseline 2.28 (0.72); post tx 3.9 (0.85) vs. 2.28 (0.73), P<0.001 Q4: baseline 2.09 (0.92); post 3.80 (0.66) vs. 2.15 (0.98), P<0.001 EF: baseline: 13 (3.3); post tx 22.3 (3.3) vs. 13.3 (3.43), P<0.001 OF: baseline 5.4 (1.8); post 10.4 (2.0) vs. 5.4 (1.77), P<0.001 SD: baseline 6.3 (1.4); post 6.65 (1.0) vs. 5.9 (1.99), P<0.32 IcS:baseline 5.1 (5.4); post 7.7 (1.4) vs. 5.4 (1.99), P<0.001 OS: baseline 4.8 (0.97); post 7.31 (0.9) vs. 5.1 (1.31), P<0.001 GEQ-1, % improved: 81.3% vs. 18.7% **Other outcomes assessed:** individual IIEF questions (Q13 placebo effect) **Withdrawals/drop-outs/loss to f/u, n (%):** 1 (<1) **WDAE, n (%):** 1 (<1) **TAE, n (%):** NR (AE included headache, flushing, generalized body ache, and typical bluish visual hallucination in IG) **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; diary card; laboratory blood analysis

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sharma (2006) [75] **Funding source:** NR	**N screened =** NR **N randomized =** 32 (cross over) **IG/ CG, n =** 32 **ITT analysis used for primary outcome:** NR **Inclusion:** renal transplant men with confirmed ED, and stable allograft function for the preceding 6 mo; in a stable relationship **Exclusion:** proliferative diabetic retinopathy or penile anatomic deformity; recent stroke	**Age, mean:** 40 y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED, mean:** 17 mo **Underlying disease, n (%):** renal surgery **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG:** Sildenafil **CG:** Placebo **IG:** Dose: 50 mg Duration: 8 wks Frequency: 1 hr before sexual activity Compliance: NR **CG:** Dose: NA Duration: 8 wks Frequency: as IG Compliance: NR **Run In period:** NA **Wash out period:** 2 wks **F/u duration:** 18 wks; evaluation at end of each 8 wks tx period	**Primary outcome results:** IIEF, scores: NR IG: improved in all questions (except SD domain), p<0.001 CG: ▲ only for Q13 (relationship satisfaction), p=0.03 GAQ, % improved: 81.3% vs. 18.7%, p</=0.01 **Other outcomes assessed:** concentration of ciclosporin assessed in n=5; serum creatinine level; blood urea nitrogen **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** 8 (25) vs. 2 (6.3) Headache 5 (15.6) vs. 2 (6.3); rhinorrhea and flushing 2 (6.3) vs. 0; blush visual hallucination 1(3.1) vs. 0 **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sommer (2007) [76] **Funding source:** No outside support	**N screened =** NR **N randomized =** 112 (open label; also reported on n=18 non randomized who refused treatment) **IG, n =** 56 **CG, n =** 56 **ITT analysis used for primary outcome:** yes **Inclusion:** men 20-70 y with ED defined by IIEF –EF score of <26 for at least 6 mo in duration with mild to moderate, arteriogenic aetiology and responsive to ED treatments (PDE-5 or IC injection) **Exclusion:** penile anatomical abnormalities, primary hypoactive SD, ED of endocrine origin, radical pelvic surgery without erection, poorly controlled DM, or clinically sign. liver kidney, CV, or CNS disorders. Non responders to ED treatment (8 trials of sildenafil 100 mg, or 40 µg IC injection of PgE1), also pts with concurrent tx with nitrates, androgens or anticoagulants	**Age, mean (range):** 44.7 vs. 46.1 y **Race:** NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** BMI, mean (kg/m^2)= 26.9 vs. 27.7 ED severity at baseline, IIEF-EF: Severe=0 Moderate (11-16), 16 (29) vs. 20 (36) Mild to moderate (17-21) 28 (50) vs. 28 (50) Mild (22-25) 12 (21) vs. 8 (14) Peak flow velocity, men (sd): 25.8 (7.5) vs. 23.1 (6.9) cm/s	**Concomitant medications:** NR **Duration of ED, mean:** 4.3 vs. 5.5 y **Underlying disease (% of pts):** NR **Psychogenic ED (%):** NR **Physiologic ED (%):** NR **Mixed ED (%):** NR	**IG1:** sildenafil **IG2:** sildenafil **IG1-3:** Dose: 50 mg Duration: 12 mo Frequency: every evening at bedtime Compliance: NR **IG:** Dose: 50 or 100 mg on demand for anticipated sexual activity Duration: 12 mo Frequency: Compliance: NR **Run In period:** 4 wk **Wash out period:** NR **F/u duration:** 18 mo	**Primary outcome results:** % of pts with normal (at least 26) IIEF-EF at 12 mo: 32/48 (66.7%) [95% CI 51.6-79.6] vs. 33/49 (67.3%) [95% CI 52.5-80%] 28/48 (58.3%) [95% CI 43.2-72.4%] vs. 4/49 (8.2%) [95% CI 2.3-19.6%] had normal EF domain scores 6 mo after completing the course of study **Other outcomes assessed:** PSV of cavernous arteries improved by 11.2 cm/s (95% CI 4.7-21.4; p=0.012) from 25.8 (7.5) to 37 (10.4) after 4 wks washout period (IG1); improved by 3.4 cm/s (95% CI –5.1-14.7; p=0.435) **Withdrawals/drop-outs/loss to f/u, n (%):** 8 (14.3) vs. 7 (12.5) **WDAE, n (%):** 4 (7) vs. 4 (7) **TAE, n (%):** NR (AE included rhinitis in one man (IG1) vs. headache in 5, flushing in four, dyspepsia in four, and rhinitis in two (IG2) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Stuckey (2003) [77] **Funding source:** Pfizer Inc, New York	**N screened =** 244 **N randomized =** 191 **IG, n =** 97 **CG, n =** 94 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older with clinical dx of ED for at least 6 mo and controlled type 1 diabetes for longer than 1 y (HbA1c levels < 11%); in a stable heterosexual relationship **Exclusion:** penile anatomical deformities, major psychiatric disorder, hx of alcoholism, substance abuse, SCI, MI, stroke, heart failure, unstable angina, nitrate use; severe autonomic neuropathy, diabetes secondary to pancreatic damage; cushings syndrome or acromegaly	**Age, mean (range):** 47(25-69) y **Race (%):** White: 96 vs. 91; Black: 0 vs. 2; Asian: 4 vs. 7 **Co-morbidities:** unspecified GI 6 (9) vs. 5 (8); unspecified disorders of eye: 21 (32) vs. 14 (21) **HbA1C, % (range):** 9 (6-13) **Previous ED treatment, %:** 28.4 vs. 20.4 including IC, and IU injections; pump; and sildenafil (reported dose only in IG, =28% used 50 mg, and 72% used 100 mg) **Smoking status**: Current 40 vs. 29 **Body weight, mean (range):** 80 (56-118) vs. 77 (53-139) kg	**Concomitant medications, %:** Insulin: 100 (all pts) Oral antidiabetic: 3.2 vs. 2.1 **Duration of ED, mean (range):** 5 (0.6-19) vs. 6 (0.7-27) **Underlying disease, %:** CVD= 34 vs. 39; hypertension= 30 vs. 33; Peripheral vascular dx: 1 vs. 5; DM 10 (15) vs. 8 (12) **Psychogenic ED, %**: 0 vs. 1 **Physiologic ED, %:** 79 vs. 66 **Mixed ED, %:** 21 vs. 33	**IG:** sildenafil citrate **CG:** placebo solution **IG:** Dose: 50 mg, option to titrate to 100 mg or 25 mg Duration: 12 wks Frequency: once/d Compliance (%): 88 **CG:** Dose: NA (titration as IG) Duration: 12 wks Frequency: once/d Compliance (%): 82 **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** IIEF Q3, improvement in mean scores from baseline, %: 36 vs. 20; post tx, mean (sd): 4 (0.5) vs. 3 (0.5) IIEF, Q4, improvement in mean score from baseline, %: 68 vs. 27; post tx, mean (sd): post tx: 3 (0.5) vs. 2 (0.5) GAQ, % yes: 66 vs. 29 Successful intercourse, %: 63 vs. 33 **Other outcomes assessed:** subgroup analysis based on severity of ED for IIEF- OF; SD, intercourse satisfaction and OS (all values in figures); all sign better in IG vs. CG **Withdrawals/drop-outs/loss to f/u:** 8 (8) vs. 7 (7); including lack of efficacy: 2 (2) vs. 3 (3) **WDAE, n (%):** 1 (1) vs. 2 (2) **TAE:** 48.4vs. 14 (n of AEs); including headache 20% vs. 7.5%; flushing 18% vs. 3%; dyspepsia 8% vs. 1%; visual disturbances 2% vs. 2% (headache, flushing and dyspepsia in >5% of pts) **SAE, n (%):** 0 vs. 1 (1) **Ascertainment of outcomes assessed:** IIEF, GAQ; Questionnaires, personal diary logs

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Tan (2000) [78] **Tan (2002)** [79] **Funding source:** Pfizer pharmaceuticals group (South East Asia Region)	**N screened =** NR **N randomized =** 254 **IG, n =** 127 (final n=119) **CG, n =** 127 (final n=119) **ITT analysis used for primary outcome:** yes (n=16, 8 in each grp were excluded from analysis) **Inclusion:** men 26-78 with ED of at least 6 mo, in a stable heterosexual relationship for at least 6 mo **Exclusion:** genital anatomic abnormalities, SCI, co-existing sexual disorders, PRL levels 3 times higher than ULT, free T 20% below lower limit of normal in morning; hx of major psychiatric disorders, alcoholism, substance abuse, major hematologic, renal or hepatic abnormalities, stroke, MI, sign CVD for under 6 mo; hypotension, poorly controlled DM, retinopathy, retinitis pigmentosa, androgens, trazodone, nitrates or nitric oxide donor agents	**Age, mean (range):** 52 (31-78) vs. 51 (26-70) **Race (%)**: 100 Asian **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status, n (%):** 36 (28) vs. 34 (27) **Initial body weight, mean:** 72 vs. 71 kg	**Concomitant medications:** Antidiabetic drugs 87 (34); antihypertensives 67 (26); lipid-lowering drugs 23 (9) **Duration of ED, mean:** 3.6 y **Underlying disease, n (%):** DM 91 (36); hypertension 61 (24); visual disturbance: 47 (19) **Psychogenic ED, n (%):** 15 (12) vs. 18 (14) **Physiologic ED, n (%):** 82 (65) vs. 78 (61) **Mixed ED, n (%):** 30 (24) vs. 31 (24)	**IG:** oral sildenafil **CG:** oral placebo **IG1:** Dose: 50 mg with option to titrate to 100 or 25 mg Duration: 12 wks Frequency: up to once/d Compliance (%): NR **CG:** Dose: NA Duration: 12 wks Frequency: up to once/d Compliance (%): NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** IIEF mean scores IG vs. CG: IIEF-Q3: 4.2 vs. 2.6 IIEF-Q4: 4.2 vs. 2.4 IIEF-EF: pre=13.3; post: 25 vs. 15.5 IIEF-OF: pre=5.6; post: 8.6 vs. 3.4 IIEF-SD: pre=7; post: 8 vs. 7 IIEF-IS: pre=6.7; post: 10.7 vs. 8.4 IIEF-OS: pre =4.5; post: 8.4 vs. 5.1 GAQ, % yes: 87 vs. 33 Intercourse success, %: 78 vs. 29.6 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 11 (4) **WDAE, n (%):** 1 (<1) vs. 1 (<1) **TAE, n (%):** 42 (33) vs. 29 (23), AE reported in at least 2 pts=body as a whole 18 (14) vs. 21 (17); CV events 13 (10) vs. 6 (5); respiratory system = nervous system events 7 (6) vs. 5 (4); digestive system events 5 (4) vs. 1 (0.8); special senses 5 (4) vs. 0; musculoskeletal events 4 (3) vs. 3 (2); laboratory abnormalities 2 vs. 3 **SAE, n (%):** 1 (<1) vs. 1 (<1); one severe angina pectoris 4 hr post medication with 100 mg sildenafil; one accidental hand injury in CG **Ascertainment of outcomes assessed:** IIEF, sexual activity & medication logs, GEQ, physical exam

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Tignol (2004) [80] **Funding source:** Pfizer Inc. (authors also supported by Pfizer)	**N screened =** 170 **N randomized =** 168 **IG, n =** 83 **CG, n =** 85 **ITT analysis used for primary outcome:** Yes **Inclusion:** men 18 or older, with ED, and in a stable relationship with a female partner for at least 6 mo **Exclusion:** major psychiatric disorder other than depression, ongoing major depressive disorder, reactive depression, hypotension, hypertension, stroke, MI, CVD, taking nitrates within 2 wks of entry	**Age, mean (sd):** 53 (10) y **Race (%)**: White (100%) **Co-morbidities, %:** hypertension 10.8 vs. 16.5; DM 8.4 vs. 7.1 **Previous ED treatment**: median duration: 89 (4-133) d vs. 86 (13-154) d **Smoking status, %:** present smoker 31.3 vs. 34.1 **Body weight:** NR **Other:** mean (range) depression duration 4.8 (0-28.5) vs. 3.1 (0.2-20.5) y	**Concomitant medications, %:** antihypertensives = 13 vs. 14; diabetes drugs= 10 vs. 6 **Duration of ED:** 4.3 (0.4-20.8) vs. 4.2 (0.3-32.9) y **Underlying disease:** NR **Psychogenic ED, n (%):** 51 (61) vs. 64 (75) **Physiologic ED, n (%):** 5 (6) vs. 2 (2.) **Mixed ED, n (%):** 27 (33) vs. 19 (22)	**IG:** sildenafil **CG:** placebo **IG:** sildenafil Dose: 50 mg (flexible dosing) Duration: 12 wks Frequency: once/d Compliance (%): NR **CG:** placebo Dose: NR Duration: 12 wks Frequency: once/d Compliance (%): NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** IIEF Q3: IG: NR vs. CG: NR, p < 0.0001 (improved in IG) IIEF Q3: IG: NR vs. CG: NR, p < 0.0001 (improved in IG) Successful intercourse attempts, % = 74 vs. 29, p = 0.0001 GAQ, % yes: 83 vs. 34 O**ther outcomes assessed:** mean IIEF scores for 5 other functional domains demonstrated in figures, mean Life Satisfaction Checklist (LSC) score **Withdrawals/drop-outs/loss to f/u:** 9 (11) vs. 10 (12) **WDAE, n (%):** 1 (1) vs. 0; also 3 (4) vs. 2 (2) temporarily discontinued or reduced dose **TAE, n (%):** 34 (41) vs. 14 (17); most common AEs were headache and flushing; abnormal vision in 2 (2) vs. 1 (1) including a change in colour vision (bluish tinge) in placebo **SAE:** NR **Ascertainment of outcomes assessed:** Questionnaires (IIEF, LSC, GEA)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Ugarte (2002) [81] **Funding source:** Pfizer Inc.	**N screened =** 249 **N randomized =** 242 **IG1, n =** 123 **IG2, n =** 119 **CG, n =** NA **ITT analysis used for primary outcome:** Y **Inclusion**: men 18 or older, with mild to moderate ED for at least 6 mo; in stable sexual relationship with female partner **Exclusion:** psychological or social risk factor for entering the trial; genital /anatomic deformity impairing erection; ED due to another primary sexual disorder, SCI or radical prostatectomy, marked liver function abnormality, hx of gastro-duodenal ulceration, retinitis pigmentosa); use of investigational drugs in last 6 wk; or medications associated with ED unless prescribed 2 wk before study entry and no dosage adjustments anticipated; use of nitrates, nitric oxide donors or alpha blockers	**Age, mean (range):** 53.6 (25-75) vs. 55.2 (28-80) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (range):** 79.9 (43-115) vs. 77.1 (51-155) kg	**Concomitant medications:** NR **Duration of ED (range):** 6 mo – 34 y **Underlying disease:** NR **Psychogenic ED, n (%):** 19 (15.4) vs. 17 (14) **Physiologic ED, n (%):** 42 (34) vs. 41 (34.5) **Mixed ED, n (%):** 62 (50) vs. 61 (51)	**IG1:** sildenafil citrate **IG2:** phentolamine **IG1:** Dose: 50 mg, titration option to 25 or 100 mg Duration: 8 wk Frequency: up to 1 dose/ d; 1 hr before sexual activity; max. 1/day Compliance (%): NR **IG2:** Dose: 40 mg Duration: 8 wk Frequency: up to 1 dose/ d; 30 minutes before sexual activity Compliance (%): NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 13 wk	**Primary outcome results:**IIEF domain scores, Least square mean score (sd): EF: pre= 16.3 vs. 15.4; post: (1-5,15): 27.2 (0.6) vs. 19.4 (0.7) OF (9,10): pre= 6.6 vs. 6; post: 9.3 (0.2) vs. 7.5 (0.2) SD (11,12): pre=6.8; post: 7.9 (0.1) vs. 7 (0.1) IC s (6-8): pre=8.2 vs. 7.9; post: 13.7 (0.3) vs. 1.3(0.3) OS (13,14): pre= 4.8 vs. 4.6; post: 8.5 (0.2) vs. 5.7 (0.2) GEQ, improved erection % yes: 95 vs. 51 GEQ, improved sexual ability % yes: 94.4 vs.46.4 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 29 (12) **WDAE, n (%):** 1 (<1) vs. 4 (3.4) **TAE, n (%):** 41 (33) vs. 49 (41), pts with at least 3% incidence of AE including headache 14 (11.4) vs. 6 (5); rhinitis 6 (5) vs. 15 (12.6); flushing 5 (4) vs. 3 (<1); tachycardia 1 (0.8) vs. 7 (5.9); nausea 1 (0.8) vs. 6 (5) **SAE:** 1 (0.8) vs.3 (2.5) **Ascertainment of outcomes assessed:** IIEF; EF and other domains; GEQ (two questions); event log of sexual function

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Webster (2004) [82] **Funding source:** Grant from University of Alberta Hospital Foundation	**N screened =** 41 **N randomized =** 35 (cross over) **IG/ CG, n =** 35 **ITT analysis used for primary outcome:** Yes **Inclusion:** pts with moderate to severe heart failure who had documented ED **Exclusion:** Pts with hypotension or SBP less than 80 mmHg; hx of myocardial ischemia, receiving psychotropic tx, hx of drug/alcohol abuse, abnormal ECG	**Age, mean (SEM):** 60 (2) y **Race (%):** NR **Co-morbidities, %:** ischemia 60; idiopathic 26; hypertension 69; DM 26 **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, %:** ACE inhibitors=β-blockers 94; diuretics 89; aspirin 66, coumadin= digoxin 63; Ca channel blocker 11 **Duration of ED:** NR **Underlying disease:** CHF **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** Mean (SEM) IIEF score = 9(1)	**IG:** Sildenafil **CG:** Placebo **IG1:** Sildenafil Dose: 50 mg Duration: 6 wks Frequency: once/d Compliance: 100% **CG:** Placebo Dose: NR Duration: 6 wks Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** before and after crossover 12 wks	**Primary outcome results:** Mean (SE) IIEF score (IG1 vs. CG) before crossover at 6 wks = improved in IG1 ($p < 0.001$) Mean (SE) IIEF score (IG1 vs. CG) after crossover = improved in IG1 ($p < 0.001$) Overall response on IIEF scores before and after crossover (IG1-CG vs. CG-IG1) = NS (p=0.98) **Other outcomes assessed:** Mean scores of IIEF (shown in figure); no sign reduction of BP, or HR in IG **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** NR **TAE:** NR; arterial fibrillation in 2 (5.7); heart failure/dyspnea 1 (2.8), all during placebo phase **SAE:** 2 deaths (study personnel) **Ascertainment of outcomes assessed:** IIEF Questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Young (2002) [83] **Funding source:** Pfizer Inc.	**N screened =** blacks (B) 310, Hispanics (H) 257 **N randomized =** 443 (B, n =246, H, n = 197); open label, n = 191 (B=211; H=144) **IG, n =**223 (B= 124, H = 99) **CG, n =**220 (B= 122, H =98) **ITT analysis used for primary outcome:** Yes **Inclusion**: black American or Hispanic American, 18 or older; documented clinical diagnosis of ED for longer than 6 mo; in stable relationship **Exclusion:** previous txt with sildenafil for ED; other sexual disorders as primary dx; ▲ PRL levels or low free-T levels; uncontrolled DM; hx of stroke or MI within previous 6 mo; ED as consequence of SCI; concomitant use of nitrates, androgens or trazodone	**Age, mean (sd):** B= 53 (25-73) vs. 54 (23-81) H=55 (31-84) vs. 53 (22-75) y **Race, n (%):** black 246 (56), Hispanic 195 (44) **Co-morbidities:** % with ≥1 current medical condition B= 90; H= 90 vs. 86 **Previous ED treatment:** NR **Smoking status (%):** current B= 38 vs. 31; H= 18 vs. 26 **Body weight, mean (range):** B=95 (50-182) kg H= 85 (56-133) kg	**Concomitant medications:** % with any B= 86 vs. 87 H =80 vs. 75 **Duration of ED, mean (range):** B= 4 (0.3-33) vs. 5.2 (0.3-30) H= 4 (0.2-43) vs.3 (0.2-20) y **Underlying disease:** NR **Psychogenic ED (%):** B=13; H 10 vs. 11 **Physiologic ED (%):** B =56 vs. 54; H= 66 vs. 60 **Mixed ED (%):** B 32 vs. 33; H 24 vs. 29 **Other:** **Severity of ED (%)** Mild to moderate: B= 61 vs. 60, H= 46 vs. 62; Severe, B =31 vs. 30, H =39 vs. 26	**IG:** sildenafil **CG:** placebo **IG:** Dose: 50 mg, option to titrate to 100 or 25 mg Duration: 12 wk Frequency: up to. 1/d, one hr before sexual intercourse Compliance (%): NR **CG:** Dose: placebo Duration: 12 wk Frequency: as IG Compliance (%): NR **Run In period:** None **Wash out period:** None **F/u duration:** 12 wk parallel (option to switch to opposite arm during the 12 wk parallel period)+ 12 wk of open-label tx extension (safety results shown) **Other:** results reported for 6 wks post intervention; n of pts who switched also reported	**Primary outcome results:** IG vs. CG, (B-H where not equal), mean score at 6 wks: IIEF, Q3: pre: 2.6-2.4; post: 4 vs. 3 IIEF, Q4: pre: 2; post 4 vs. 3 IIEF, EF: pre 14; post 23 vs. 18-16 IIEF, OF: pre 6; post: 8 vs. 6-7 IIEF, SD: pre 7; post 7 vs. 7-6 IIEF, ICs: pre: 6-7; post 11 vs. 9-8 IIEF, OS: pre 4-5; post 8 vs. 6 GEQ-Q1, %: B: 79 vs. 38; H: 82 vs. 30 GEQ-Q2, %: B: 81 vs. 36; H: 80 vs. 29 GEQ-Q3: B: 4 vs. 3; H: 3.5 vs. 2.5 **Other outcomes assessed:** barriers to tx; subgrp ED severity; EDITS, EPQ **Withdrawals/drop-outs/loss to f/u:** B: 6 (5) vs. 10 (10); H: 13 (11) vs. 9 (9) Open label phase, B: 20 (9), H: 19 (13) **WDAE, n (%):** B=0; H: 2 (2) vs. 0 **TAE, n (%): 12 wks,** B: 18 (15) vs. 3 (3); H: 27 (22) vs. 11 (11); most common, % in IG/ pts switched to IG vs. CG: headache B: 11 vs. 2; H: 16/12 vs. 7; vasodilation B: 2 vs. 0; H: 7/9 vs. 2; rhinitis B: 2 vs. 0; H: 2/4 vs. 0; nausea B: 1 vs. 0, H: 2/1 vs. 0; dizziness B: 0; H: 3/1 vs. 0; abnormal vision B: 2 vs. 0, H: 2/1 vs. 0 **SAE, n (%):** 1 (<1) in IG (H) **Ascertainment of outcomes assessed:** IIEF, GAQ; EDITS; erection problem question (EPQ)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Zinner (2007) [84] **Funding source:** Pfizer Inc. (conflict of interest: author has spoken for Pfizer)	**N screened =** **N randomized =** 48 (double cross over design- impact of food) **IG/CG 1&2, n =** 24 **IG/CG 3&4, n =** 24 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older in a stable relationship or 6 mo or longer taking 50 or100 mg sildenafil; with IIEF of 25 or less and minimum 4 sexual attempts/ mo **Exclusion:** no response to sildenafil 100 mg; CVD in last 3 mo; current use or likely prescription of nitric oxide donors; use of an alpha-blocker; use of other ED tx; hx of retinitis pigmentosa; tx with ritonavir, or an investigational drug within 6 wks of screening; any known medical or psychological conditions; blood donation within 4 wks; drug or alcohol abuse; potential non-compliance	**Age, mean (range):** 57 (29-79) y **Race:** NR **Co-morbidities, n (%):** heart disease IG1&2= 4 (16.7) IG3&4 =1 (4.2) **Previous ED treatment:** 100% had been treated with sildenafil 50 or 100 mg **Smoking status:** NR **Body weight:** NR **Other:** recreational drug use, n (%) IG1-2= 14 (58.3) IG3-4= 19 (79.2)	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG1-4:** Sildenafil **CG1-4:** placebo **IG1-4 (sildenafil):** Dose: 100 mg Duration: 16 wks (4 wk s/ tx period) Frequency: 1 hr berore meal (IG1); 30-60 min before sexual activity (IG2&4); during meal (IG3) Compliance: **CG1-4 (placebo):** Dose: NA Duration: 16 wks as IG Frequency: 30-60 min berore coitus (IG1&3); 1 hr before meal (IG2); during meal (IG4) Compliance: **Run In period:** 1-2 wks (stopped sildenafil dosing) **Wash out period: NR** **F/u duration:** end of each tx period	**Primary outcome results:** IG1 vs. IG2 & IG3 vs. IG4 IIEF-EF change from baseline, mean: 11.4 vs. 11.4 & 11.2 vs. 11.2 SEP-Q2 intercourse attempts: 93.9% vs. 91.8% & 91.4% vs. 92.6% SEP-Q3: 84.7% vs. 85.9% & 83.4% vs. 87.5% Time between dosing and intercourse attempt ▼ responses to SEP-3 (from max 92.8% at 1.5-2 hr to 81.6% when taken >10 hrs prior to coitus) **Other outcomes assessed:** mean interval between dosing and coitus in IG2 & IG4 =1.3 (0.6) & 1.1 (0.5) hr Intervals between dosing and coitus in IG1 & IG4= 4.8 (1.8) & 3.6 (1.9) hr No sign differences for EDITS responses or preference and satisfaction for any of the regiments **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE:** NR **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF; SEP- Q2 & 3; EDITS

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C2-Oral Vardenafil

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Carson (2004) [85] [86] **Companion Hatzichristou (2005)** [86] **Funding source:** Bayer Corporation and GlaxoSmithKline	**N screened =** NR **N randomized =** 463 **IG, n =** 233 **CG, n =** 230 **ITT analysis used for primary outcome:** yes (N =454, n = 229 vs. n = 225) **Inclusion:** men 18 or older with ED, no response to 100 mg sildenafil indicated by at least 4/ 6 unsuccessful intercourse attempts; in heterosexual relationship for past 6 mo **Exclusion**: penile anatomical abnormalities; hypoactive SD; ED due to SCI or radical prostatectomy; retinitis pigmentosa; hepatitis B, C surface antigen or; unstable angina pectoris; MI, stroke, ischemia; DM; hypotension; use of anticoagulants, androgens, trazodone, antiandrogens, alpha1 antagonist, potent HIV protease inhibitor, nitrates, itraconazole, ketokonazole, erythromycin (more in full text)	**Age, mean (range):** 60 (29-83) vs. 59 (23-88) y **Race, n (%):** White: 404 (87); Asian: 18 (10); Hispanic: 14 (3); Black: 13 (3); Other: 5 (1) **Co-morbidities:** NR **Previous ED treatment:** Sildenafil up to 100 mg **BMI, mean (sd):** 29 (4) vs. 28 (4) kg/m^2 **Body weigh:** NR **Other:** Severity of ED, Severe: 242 (52); moderate 164 (36); mild to moderate 9 (2); mild 8 (2) IIEF-EF domain= 9.3 vs. 9.7	**Concomitant medications:** NR **Duration of ED, mean (sd):** 5 (4) y **Underlying disease, n (%):** Hypertension 90 (39) vs. 92 (41) DM 78 (34) vs. 7 (25); Benign prostatic hyperplasia: 39 (17) vs. 40 (18); CAD 8 (3) vs. 11 (5) **Psychogenic ED, n (%):** 8 (3) vs. 20 (9) **Physiologic ED, n (%):** 148 (65) vs. 128 (57) **Mixed ED, n (%):** 3 (32% vs. 77 (34)	**IG:** vardenafil **CG:** Placebo **IG:** Dose: 10 mg (option to titrated to 5 or 20 mg at 4 and 8 wks) Duration: 12 wks Frequency: max 1/d Compliance: 99% [n=2 (<1%) did not complete] **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: 98%; [n=4 (2%) did not complete] **Run In period:** NR **Wash out period:** 24 hrs **F/u duration:** 12 wks + 24 hrs post final visit. **Note:** topical formulas were allowed in this study; investigational drugs within 30 days of screening therapy for ED within 7 d or vardenafil at any time prior to study.	**Primary outcome results:** IIEF-EF: baseline=<10 (severe ED); post tx pts with normal scores, n (%)=67 (31) vs. 12 (6) SEP- Q2, % yes, n (%): 0.25 hr post dosing= 57 (62) vs. 55 (30) >6 hr post dosing= 30 (77) vs. 18 (50) SEP-Q3, % yes, n (%): 0.25 hr post dosing= 57 (53) vs. 55 (12) >6 hr post dosing=30 (70) vs. 17 (24) GAQ, % yes: 61.6% vs. 15% 61.8% vs. 14.7% at LOCF, p<0.001) **Other outcomes assessed:** intercourse attempts data **Withdrawals/drop-outs/loss to f/u, n (%):** 25 (11) vs. 41 (18); including insufficient tx effect in 5 (2) vs. 17 (7) **WDAE, n (%):** 5 (2) vs. 3 (2) **TAE, n (%):** 40.7% vs. 22.6%; drug related in 2% or more=flushing 16 (7) vs. 2 (1); headache: 15 (6) vs. 4 (2); nasal congestion: 11 (5) vs. 1 (<1); dyspepsia: 8 (3) vs. 0; total mild AE= 55 (24) vs. 20 (9); total moderate AE= 34 (15) vs. 25 (11) **SAE, n (%):** 7 (3.0) vs. 3 (0.9) **Outcome ascertainment:** IIEF-EF; SEP, Q2 and 3; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Demir (2006) [87] **Funding source:** NR	**N screened =** NR **N randomized =** 60 **IG, n =** 39 **CG, n =** 21 (n=15 with no ED also served as ctrls, data not shown) **ITT analysis used for primary outcome:** NR **Inclusion:** men with ED (diagnose with color Doppler Ultrasound and IC injection of 60 mg papaverine) and functioning renal graft (serum creatinine level <2 mg/dL); in a stable relationship with a partner **Exclusion:** stroke, DM, MI, CHD, overt heart failure; sing penile anatomical deformities active peptic ulcer, chronic liver disease; sign hypo/hypertension; blood coagulation disorders; nitrate tx	**Age, mean (sd):** 48 (7.4) vs. 50 (7.1) y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** immuno-suppressant tx: cycloporine (14+8) or JD506 (25+13); low dose prednisolone and ycophenolate mofetil **Duration of ED:** NR **Underlying disease, n (%):** Renal transplant **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%):** NR	**IG:** Vardenafil **CG:** Placebo **IG:** Dose: 10 mg titrated to 20 mg based on efficacy measures Duration: 4 wks Frequency: up to once/d; 1 hr prior to sexual activity Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 4 wks	**Primary outcome results:** IIEF-EF, mean (sd): Baseline 12.8 (3.5) vs. 12.5 (3.7) Post tx 26.46 (2.4) vs. 13.27 (2.8) Tx effect, P<0.001 ED Severity, baseline- post tx in IG: Severe: 3 -0 Moderate 17- 0 Mild to moderate: 9 – 2 Mild 10-4 None 0 – 32 **Other outcomes assessed:** IIEF individual scores of Q1-5 and 15; serum T, FSH, and LH levels, not sign. between grps (data not provided) **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE:** NR **TAE, n (%):** 7 (18), including headache in 3, palpitation in one, flushing in two and dyspepsia in one **SAE:** NR **Outcome ascertainment:** self administered IIEF on renal transplant pts

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Edwards (2006) [88] **Funding source:** NR	**N screened =** 288 **N randomized =** 260 **IG, n =** 194 **CG, n =** 66 **ITT analysis used for primary outcome:** yes (LOCF; n=254) **Inclusion:** men 18 or older with ED for at least 6 mo; no prior hx of PDE5i use **Exclusion:** unstable medical, psychiatric condition; substance abuse; hypoactive SD; SCI, surgical prostatectomy; hereditary degenerative retinal dx; hepatitis B surface angina, hepatitis C, HIV; liver disease; sign hematologic disease; active peptic ulceration; any cardiovascular condition; MI, stroke, serious arrhythmia within 6 mo of entry; uncontrolled hypo/hypertension; hx of malignancy within 5 y; use of nitrates or nitric oxide donors; androgens or any other investigational drug	**Age, mean:** 53.6 vs. 54.2 **Race:** NR **Co-morbidities, %:** DM 27; hypertension 35; Hyperlipidemia 10 vs. 6 **Previous ED treatment:** **Smoking status:** NR **Body weight:** NR **Other:** BMI, mean 27.4 kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED:** 2 y **Underlying disease, n (%):** NR **Psychogenic ED, %:** 16 vs. 23 **Physiologic ED, %:** 29 vs. 24 **Mixed ED, %:** 55 vs. 53 **Other:** Baseline IIEF score: 13.6 Severity of ED, %: Severe 29% vs. 39%	**IG:** Vardenafil **CG:** Placebo **IG:** Dose: flexible dose starting dose of 10 mg for 4 wks; adjusted to 5 or 20 mg for the next 8 wks Duration: 12 wks Frequency: NR Compliance: 99% **CG:** Dose: NA Duration: 12 wks Frequency: NR Compliance: 100% **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks (excluding the 4 wks run-in period)	**Primary outcome results:** IIEF-EF, mean: baseline moderate; post tx 23.5 vs. 15.8; increase on score of 8.8 in IG vs. CG (95% CI 6.4, 11.1; p<0.0001) SEP-2, %: baseline 48 vs. 46 12 wks: 85 vs. 65 SEP-3, %: Baseline: 21 vs. 22 12 wks: 78 vs. 49 GAQ, % improved: 83% vs. 38%, p<0.0001 **Other outcomes assessed:** TSS, sign better score in IG vs. CG, p<0.0001 **Withdrawals/drop-outs/loss to f/u, n (%):** 12 (6.7) vs. 4 (6.1) **WDAE, n (%):** 3 (1.5) vs. 1 (1.5); IG included MI, aortic bifurcation graft; CG muscle cramp **TAE, n (%):** NR; tx related occurring in 2% or more of pts, %: headache 5.2 vs. 0; flushing 7.3 vs. 0; Influenza 1 vs. 3 **SAE, n (%):** 2 (1.0) vs. 0; aortic bifurcation graft and MI (MI occurred5 d after last dose of 10 mg); no death occurred **Outcome ascertainment:** SEP- 2, 3; GAQ; IIEF-EF; Treatment Satisfaction Scale (TSS)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Goldstein (2003) [89] **Funding source:** Bayer Corporation	**N screened =** 452 **N randomized =** 452 **IG1, n =** 153 (ITT = 149) **IG2, n =** 149 (ITT= 141) **CG, n** = 150 (ITT= 140) **ITT analysis used for primary outcome:** Yes **Inclusion**: men older than 18 y, and clinical diagnosis of type 1 or type 2 DM, Ed of 6 mo or longer. HbA1c ≥12%. **Exclusion:** ED due to radical prostatectomy, hypoactive SD; SCI. MI, stroke, ischemia; sign arrhythmia; uncontrolled atrial tachyarrhythmia, unstable angina pectoris, liver dx, haematological dx or bleeding disorder, resting hypo/hypertension, retinitis pigmentosa, progressive retinopathy, autonomic neuropathy, migraine headaches; AE or dissatisfaction with Sildenafil; Nitrates, anti androgens, anti coagulant androgens, trazodone hypochloride not allowed	**Age, mean (sd):** 57 (NR) y **Race n (%)**: White 350 (80); Black 41 (9); Hispanic 15 (8) Other 13 (3) **Co-morbidities, n (%):** Hypertension 231(53); depressive dx 45 (10) **HbA1C levels, n (%):** ≤ 6 = 12 (3); > 6 to < 8= 192 (43) ≥ 8.0 = 231 (53) **Previous ED treatment n (%)**: Sildenafil 256 (58) **Body weight:** NR **Other:** Severity of ED n (%): Severe (<11)=240 (55); Moderate (11-16) 102 (23); Mild to Moderate (17-21): 68 (15); Mild (22-25): 26 (9); Normal (≥ 26): 3 (<1), only in IG2 & CG	**Concomitant Medications, n (%):** Beta Blockers 52 (12); Renin-angiotension system acting agents 210 (50); Calcium-channel blockers 45 (10); Serum lipid-reducing agents 146 (33); Diuretics 71 (16); Other antihypertensives 40 (9); Insulin 152 (35); Glucose-lowering drugs 318 (72) **Duration of ED:** 3.5 y **Underlying disease:** 88% type 2 diabetes and poor glycemic control **Psychogenic ED:** 2 (<1) only in IG1: 2 (1) **Physiologic (organic) ED, n (%)**: 358 (81) **Mixed ED**: 77 (18)	**IG1:** vardenafil **IG2:** vardenafil **CG:** Placebo **IG1:** Dose: 10 mg Duration: 12 wks Frequency: as needed, no more than 1/day Compliance: NR **IG2:** Dose: 20 mg Duration: 12 wks Frequency: as needed, no more than 1/d Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: as needed, no more than 1/d Compliance: NR **Run In period**: 4 wk unmedicated phase **Wash out period:** NR **F/u duration:** 12 wk	**Primary outcome results:** IG1 vs. IG2 vs. CG IIEF-EF, mean final score: 17 vs. 19 vs. 13 (change from baseline: 1.4 vs. 6 vs. 8) SEP-Q2, mean least square success rate (%): 61 vs. 64 vs. 36 (in severe ED= NR vs. 40 vs. 11; in mild ED= NR vs. 75 vs. 47) SEP-Q3, mean least square per pts (%): 49 vs. 54 vs. 23 (type I diabetes= 48 vs. 65 vs. 10; type II= 49 vs. 52 vs. 25) GAQ, proportion of men with improved erection: 54% vs. 72% vs. 13% **Other outcomes assessed:** Blood chemistries, ECG **Withdrawals/drop-outs/loss to f/u:** 73 (17) **WDAE, n (%):** 4 (3) vs. 5 (3) vs. 2 (1); headache, cutaneous flushing, rhinitis **TAE, n (%):** 7 (5) vs. 9 (6) vs. 6 (4) **SAE, n:** 3 (2) vs. 4 (3) vs. 4 (3); including chest pain, dyspnea, larynx edema, asthma (n=1); depression, hypesthesia, or moderate amnesia; no death occurred **Outcome ascertainment:** IIEF, SEP, Q2 and 3; GAQ, diary questions

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Goldstein (2005) [90 91] **Companion study, by Fisher (2005)** **Funding source:** Bayer HealthCare (conflict of interest for authors paid by Bayer Health Care)	**N screened =** NR **N randomized =** 229 **IG, n =** 116 **CG, n =** 113 **ITT analysis used for primary outcome:** Yes **Inclusion**: men with ED of 6 mo or longer, previously treated for ED who had a stable heterosexual relationship for => 6 mo with a female partner without sexual disorder, Female Sexual Function Index (FSFI) > 26.55 **Exclusion:** pts with unstable medical conditions, sign penile deformities, SCI, hx of prostatectomy, retinitis pigmentosa, unstable angina pectoris, MI, uncontrolled atrial fibrillation, taking nitrates or nitric oxide donors, anticoagulants, androgens, antiandrogens, indinavir, intraconazole, or erythromicyn or any ED drug; female partner's having primary hypoactive sexual disorder measured by Female Sexual Function Index	**Age, mean (sd):** 58 (28-79) y **Race (%)**: White: 85%, Black: 8%, Other: 7% **Co-morbidities:** NR **Previous ED treatment**: prior sildenafil in 81% vs. 91% **BMI, mean:** 29 kg/m^2 **Smoking status**: NR **Body weight:** NR **Other:** Mean sexual intercourse activity: 6 during run in	**Concomitant medications:** NR **Duration of ED, mean:** 4.7 y **Underlying disease:** NR **Psychogenic ED, %:** 44.5% **Physiologic ED, %:** 5% **Mixed ED, %**: 50%	**IG:** vardenafil **CG:** placebo **IG:** Dose: starting dose 10 mg with option to titrate to 5 or 20 mg at 4 wks Duration: 12 wks Frequency: NR Compliance: NR **CG:** Dose: NR Duration: 12 wks Frequency: NR Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** IIEF-EF, mean score: baseline: 13; post tx 23 vs.13.5, p < 0.0001 (IG vs. CG) % Success rate of improved least squares mean on Sexual Encounter Profile: SEP-Q2, % yes: 80 vs. 47, p <0.0001 SEP- Q3, % yes: 68 vs. 28, p < 0.0001 Mean Erection Quality Scale (EQS) score: 37 vs. 16, p < 0.0001 (IG vs. CG) **Other outcomes assessed:** Women's sexual function **Withdrawals/drop-outs/loss to f/u:** 1 (<1) vs. 0 **WDAE, n (%):** 1 (<1) in IG; elevated creatinine **TAE, n (%):** drug related AEs in at least 2% of pts= 22% vs. 4%; including flushing 13 (11) vs. 0; nasal congestion 9 (8) vs. 0; headache 5 (4) vs. 3 (3); dyspepsia 4 (4) vs. 1 (<1) **SAE, n (%):** 1 (<1) vs. 0; unstable angina **Outcome ascertainment:** IIEF EF domain (Q1, 5,and 15); SEP Q2 and 3; Erection Quality Scale (EQS)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Hatzichristou (2004) [92 93] **Funding source:** Bayer Corporation, Bayer AG, GlaxoSmithKline	**N screened =** NR **N randomized =** 323 **IG1, n =** 157 (ITT, n = 154) **CG, n =** 166 (ITT, n = 155) **ITT analysis used for primary outcome:** Yes **Inclusion**: men 18 or older with ED (NIH consensus), stable heterosexual relationship for 6 mo or longer, at least 50% of 4 or more attempts at sexual intercourse on 4 separate d during the 4 wk baseline period unsuccessful; answer 'no' to at least 1 diary question (IIEF) **Exclusion:** penile abnormalities, primary hypoactive SD, ED due to SCI; radical prostatectomy, unstable angina, poorly controlled DM, hypertension; liver or hematologic dx; use of organic nitrates, other nitric oxide donors, or potent CYP3A4; sildenafil use permitted except for unresponsiveness or WDAE in last 7 d prior to screening	**Age, mean:** 54 vs. 53 y **Race (%)**: NR **Co-morbidities, (%):** hypertension 34 vs. 24; DM 16 vs. 20; hyperlipidemia 2 vs. 5; Cardiac dx 9 vs. 6; respiratory, thoracic **Previous ED treatment, (%)**: Prior sildenafil use 54 vs. 50 **BMI, mean:** 27 kg/m^2 **Smoking status**: Non smoker 61 % past smokers **Body weight, mean:** 81 vs. 82 kg	**Concomitant medications:** NR **Duration of ED, mean:** 2 y **Underlying disease:** NR **Psychogenic ED, %:** 21 vs. 22 **Physiologic ED, %:** 37 vs. 42 **Mixed ED, %:** 43 vs. 36	**IG:** Vardendafil (flexible dose) **CG:** placebo **IG1:** Dose: 10 mg titrated up or down if desired) Duration: 12 wks Frequency: as needed, no more than 1 dose/d Compliance: NR **CG:** Dose: placebo (titration as IG) Duration: 12 wks Frequency: as needed, no more than 1 dose/d Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wk **Other:** Titration data, n (%) At wk 4- down to 5 mg: 6 (4) vs. 0 At wk 4-up to 20 mg: 95 (61) vs. 136 (88) At wk 8- down to 5 or 10 mg: 7 (5) vs. 1 (<1) At wk 8- up to 20 mg: 20 (13) vs. 4 (3)	**Primary outcome results:** IIEF- EF, mean: Baseline=12.8; post tx: 24 vs. 16 SEP-Q2 (% yes): 84 vs. 53 SEP-Q3 (% yes): 74 vs. 34 GAQ; (% yes): 86 vs. 33 Erection hardness mean (%): 63 vs. 23 OS (%): 65 vs. 28 Penis enlargement (%): 92 vs. 75 Successful ejaculation (%): 79 vs. 56 (all p<0.005) **Other outcomes assessed:** sub-grp by dose; depression; self confidence **Withdrawals/drop-outs/loss to f/u:** 22 (14) vs. 45 (29) **WDAE, n (%):** 5 (3) vs. 3 (2); tx emergent AEs only: abdominal pain, headache, dysphagia, pneumonia vs. accidental injury, vascular anomaly, ▲ CPK) **TAE, %:** pts with at least one AE = 45 vs. 27 (data provided for AE of 2 or more incidence= flushing, headache, rhinitis, flu syndrome, dyspepsia, back pain, CPK increase, dizziness, accidental injury, hypertension and QT interval prolonged); total n of AE= 94 vs. 50 **SAE:** 4 (2.5) vs. 5 (3); cause NR **Outcome ascertainment:** IIEF, GAQ; SEP question 2 and 3; pts diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Hellstrom (2002) [94 95 96 97] **Funding source:** Bayer Pharmaceutical & Bayer Inc.	**N screened =** 1311 **N randomized =** 805 (parallel grps) **IG1:** n= 193 **IG2:** n = 199 **IG3:** n = 188 **CG:** n = 182 **ITT analysis used for primary outcome:** Yes (n=749; safety population: n=762) **Inclusion**: heterosexual men 18 y or older with ED, > 6 mo in duration; also with 50% or more failure rate in maintaining erection on at least 4 intercourse attempts on 4 separate d before tx **Exclusion:** Ed due to SCI, radical prostatectomy, retinitis pigmentosa, angina pectoris or poorly controlled DM; primary hypoactive SD, no response to sildenafil, hx of hepatitis B or C, & concomitant use of nitrates **Note:** Data reported as IG1 vs. IG2 vs. IG3 vs. CG	**Age, range:** 57-78 y (mean range per grp 57-58 y) **Race, %:** Caucasian 77 vs. 80 vs. 82 vs. 77 **Co-morbidities:** hypertension, prostatic hyperplasia, diabetes type II, depression, prior MI, hyperlipidemia, obesity, all not sign. between grps **Previous ED treatment** sildenafil (%): 77 vs. 74 vs. 66 vs. 68 **BMI, mean:** 29 kg/m^2 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean:** 1st diagnosed: 3.6 vs. 3.6 vs. 4.2 vs. 2.9 y (1st noticed: 5.9 vs. 6 vs. 6.6 vs. 5.1 y) **Underlying disease:** NR **Psychogenic ED, %:** 7 vs. 7 vs. 7 vs. 9 **Physiologic ED, %:** 61 vs. 59 vs. 60 vs. 54 **Mixed ED, %:** 33 vs. 34 vs. 33 vs. 37 **Other:** baseline IIEF score: 12.6 vs. 13.4 vs. 12.8 vs. 13.7	**IG1-3:** Vardenafil **CG:** placebo **IG1-3:** Dose: IG1 = 5 mg; IG2 = 10 mg; IG3= 20 mg Duration: 26 wks Frequency: once/ d Compliance (%): NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance (%): NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 26 wks (1 wk post last tx)	**Primary outcomes:** IIEF- mean score (LOCF), IG vs. CG: EF, Baseline=14; post tx: 18-22 vs. 15 IS (Intercourse satisfaction): 10 vs. 8 OS: 7 vs. 5 SEP-Q2, % yes: Baseline: 43 vs. 45 vs. 41 vs. 46 Post tx: 66 vs. 76 vs. 81.1 vs. 52 SEP-Q3: Baseline=15; Post tx: 52-67 vs. 33 GAQ, % yes: 65 vs. 80 vs. 85 vs. 28 **Other outcomes assessed**: self reported erection hardness; satisfaction with intercourse, and OS **Drop outs:** n=297 (37%): 38% vs. 27% vs. 30% vs. 54% (non compliance, consent withdraw, insufficient tx effect, protocol violation, & lost to F/u) **WDAE, n (%):** 8 (4.1) vs. 7 (3.5) vs. 15 (7.9) vs. 4 (2.2) reasons reported only for IG=headache, abnormal liver function, nausea, and kidney calculus **TAE:** NR; AEs included headache, rhinitis, flushing, dyspepsia, accidental injury; all numerically more frequent in IG compare to CG **SAE (%):** 5 vs. 3 vs. 4 vs. 5 (one MI, no death) **Outcome ascertainment:** IIEF, GAQ, diaries, SEP, Q2 and 3

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Ishii (2006) [98] **Funding source:** Bayer Yakuhin Ltd.	**N screened =** 954 (enrolled) **N randomized =** 780 **IG1, n =**340 **IG2, n =** 339 **CG, n =** 111 **ITT analysis used for primary outcome:** yes (12 wks LOCF) **Inclusion:** men with ED (according to NIH Consensus statement) and DM > 3 y; currently under hypoglycemic drug tx or HbA_{1c} >6.5% at visit 1; **Exclusion:** penile deformities; substance abuse; major heart or liver disorders; SCI, MI, hx of hepatitis B, or C, HIV infection; cancer; hypo/hypertension; prostatectomy; retinitis pigmentosa; tx with; non respondent to PDE5i; ED tx within 7 d of trial entry (randomization); low T levels; elevated creatinine levels; tx with nitrates or nitric oxides (other criteria listed in detail in full report)	**Age, mean (sd):** 53 (7.7); range 26-64 **Race:** Asian 100% (Japanese) **Co-morbidities, n (%):** NR **Previous ED treatment:** sildenafil 296 (37) **Smoking status:** NR **Body weight, mean:** 71.8 kg	**Concomitant medications, n (%):** Medication for DM **Duration of ED:** 5.4 y **Underlying disease, n (%):** DM **Psychogenic ED, n (%):** 0 **Physiologic ED, n (%):** 720 (92.3) **Mixed ED, n (%):** 58 (7.7) **Other:** ED severity on EF domain score, n (%): < 11: 275 (35.4) 11-16: 231 (30) 17-21: 184 (23.8) 22-25: 79 (9.8)	**IG1-2:** Vardenafil **CG:** Placebo **IG:** Dose:20 mg (IG1), 10 mg (IG2) Duration: 12 wks Frequency: 1 hr prior to sexual activity up to 1/d Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wks no ED tx **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** IIEF-EF, mean baseline: 13.7 12 wks LOCF, mean: 21.8 vs. 22.9 vs. 16.3 (more evident changes in pts, with baseline EF score of <11) SEP mean % (from graph): SEP- 2: Baseline 37.5 Post tx: 77 vs. 73 vs. 51 SEP-3, Baseline: 12.5 Post tx: 63 vs. 60 vs. 29 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to F/u, n (%):** 28 (8.4) vs. 11 (3.3) vs. 14 (13.2) **WDAE, n (%):** 9 (2.7) vs. 2 (0.6) vs. 2 (1.9) **TAE, n (%):** NR; AE in 2% or more palpitations in 7 (2) vs. 12 (4) vs. 2 (2); nasopharyngitis 17 (5) vs. 31 (9) vs. 6 (6); blood creatinine phosphokinase ▲ 1(<1) vs. 8 (2) vs. 3 (3); headache 20 (6) vs. 13 (4) vs. 2 (2); nasal congestion 6 (2) vs. 9 (3) vs. 0.; upper respiratory tract inflammation 6 (2) vs. 7 (2) vs. 2(2); hot flush 45 (13) vs. 32 (9) vs. 3 (3) **SAE, %:** 1 vs. 1 vs. 0 (detail NR) **Outcome ascertainment:** SEP-2, 3; IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Klotz (2001) [99] **Funding source:** NR	**N screened =** NR **N randomized =** 25 (cross over) **IG1/IG2/CG, n =** 25 **ITT analysis used for primary outcome:** NR **Inclusion**: men, able to have an erection with visual stimulation; diagnosed with ED as per Cologne Evaluation Form for Erectile Dysfunction (KEED) and IIEF ≤ 6 mo prior to study **Exclusion:** weak or no response to visual stimulation; no prior response to Sildenafil; ED of neurological or endocrine cause; anatomical abnormality (severe penile fibrosis); SCI, radical prostatectomy, retinitis pigmentosa, DM, any relevant comorbidities (not specified); major psychiatric illness; abnormal BP or heart rate or laboratory tests indicating AV-block] use of nitrites or nitrite oxide donors or user of any medication likely to interact with vardenafil.	**Age, mean (sd):** 34 (9), range 22-52 y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Initial body weight, mean (sd):** 77 (7), range 64- 89 kg Broca index: 1 (0.1), range 0.9-1.1 kg	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1/ IG2:** Vardenafil oral drinking solution + 20 min VS. (20 min post tx x 3) **CG:** placebo + 20 min VS. (20 min post tx x 3) **IG1/IG2:** Dose: 10 mg (IG1); 20 mg (IG2) Duration: N/A Frequency: once Compliance: 100% **CG:** Placebo Dose: NR Duration: N/A Frequency: once Compliance: 100% **Run In period:** NR **Wash out period**: 5 d Fasting overnight and 4 hr post initial dose **F/u duration:** immediately post tx	**Primary outcome (EF):** Duration of erection with 60% rigidity: Base: 54 (27) vs. 67 (39) vs. 31 (24) min Tip: 39 (26) vs. 45 (36) vs. 17 (20) min Duration of erection with >80% rigidity Base: 25 (25) vs. 31 (33) vs. 16 (19) min Tip: 9 (13) vs. 22 (30) vs. 7 (14) min Average event rigidity (%): Base: 64 (24) vs. 66 (20) vs. 53 (29) Tip: 47 (27) vs. 45 (23) vs. 32 (26) Circumference, mean (sd): Base= 8 (1); Tip = 7 (1) cm (similar in all 3 grps) **Other outcomes assessed:** duration of erection; pharmacokinetics; plasma concentration of vardenafil **Withdrawals/drop-outs/loss to F/u:** 5 (20); 3 not included in safety analysis **WDAE:** 0 **TAE, n (%):** 4 (18.2) vs. 2 (9.1) vs. 1 (4.5); including haematoma at the site of sampling IV cannlua; headaches, moderate tiredness, nasal congestion, flush and nasal congestion **SAE:** 0 **Outcome ascertainment:** RigiScan (15 s); measuring event rigidity of >20%

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Martin-Morales (2006) [100] **Funding source:** Química Farmacéutica Bayer	**N screened =** 159 **N randomized =** 121 (12 centres in Spain) **IG, n =** 64 **CG, n =** 65 **ITT analysis used for primary outcome:** yes (n=61 vs. n=60) **Inclusion:** men 18-64 y with ED of at least 6 mo duration **Exclusion:** successful intercourse on more than 50% of attempts during the run in; T value lower than permitted (NR); IC injection of PgE1 in a few days before visit 1 with diagnostic intention; elevated liver enzymes and abnormal ECG	**Age, mean (sd):** 52.5 (8.6) y (age in severe ED pts 52.8 vs. 52.1 y) **Race:** White 100% **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status, n (%):** past or present smoker 89 (71.2); pack per y hx 44.9 (26.9) vs. 33.7 (21.0), p=0.019 **Body weight:** 82.6 (12.1) kg **BMI, man (sd):** kg/m^2 **Other:** heavy alcohol consumption in 3 (2.4%)	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR **ED severity, n (%):** by IIEF score, no ED 3 (2.5) Mild 52 (43) Moderate 36 (29.8) Sever 30 (24.8)	**IG:** Vardenafil **CG:** Placebo **IG:** Dose: starting dose 10 mg, adjusted to 5 or 20 mg based on efficacy and tolerability Duration: 12 wks Frequency: NR Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: NR Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wks (in addition to 4 wks run in)	**Primary outcome results:** Change in score from baseline to 12 wks, LS mean (sd): IIEF-EF: 10.9 (6.4) vs. 1.6 (7.7); difference –8.8 [95% CI –11.4; -6.1], p<0.001 IIEF-Q3, mean at 12 wks: 4.6 vs. 3.02 IIEF-Q4, mean at 12 wks: 4.34 vs. 2.69 SEP,% of pts with positive response: SEP-Q2: 64.8% vs. 10.0% SEP-Q3: 62.7% vs. 0.7% GAQ, % improved: 73.8 vs. 25 **Other outcomes assessed:** individual IIEF question scores **Withdrawals/drop-outs/loss to F/u, n (%):** 3 (4.7) vs. 5(7.7) **WDAE, n (%):** NR **TAE, n (%):** 18 (29.5) vs. 11 (17.2), p=0.138; including headache 8.2% vs. 0, flushing (IG only), nasopharyngitis 4.9% vs. 4.7%, flushing 8.2% vs. 0 **SAE, n (%):** 1 (1.6) vs. 1 (1.5); one case of intestinal obstruction in IG prior to randomization; non-cardiac chest pain in CG **Outcome ascertainment:** IIEF-EF; GAQ, SEP, 2-3; Rosenberg Self-Esteem scale, Johnson and McCoy scale Medical Outcome Short Form (SF-36) scale

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Mazo (2006) [101] **Funding source:** NR	**N screened =** NR **N randomized =** 135 (study also included n=30 healthy men, data not shown) **IG, n =** NR **CG, n =** NR **ITT analysis used for primary outcome:** NR **Inclusion:** men with ED of at least 6 mo confirmed by pts hx and IIEF-EF domain; tx naïve; in a stable relationship **Exclusion:** tx with nitrates **Note:** all pts were examined with Doppler ultrasound of the penile arteries after IC injection of PgE1	**Age, mean (sd):** 51 (14.2) **Race:** NR **Co-morbidities, n (%):** DM 10 (6); hypertension 48 (29); CAD 20 (12.2), 10% vs. 14.5%; hyperlipidemia 56 (34.2); radical prostatectomy 15 (9) **Previous ED treatment:** none **Smoking status:** 27 (32.5) vs. 24 (29.3) **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** no specific cause **Psychogenic ED, n (%):** 42 (25.5) **Physiologic ED, n (%):** non-arterial 20 (12.1); arteriogenic 73 (44.3) **Mixed ED, n (%):** NR	**IG:** Vardenafil **CG:** Placebo **IG:** Dose: 20 mg Duration: NA Frequency: single doese Compliance: 100% **CG:** Dose: NA Duration: NA Frequency: once Compliance: 100% **Run In period:** NR **Wash out period:** NA **F/u duration:** NA (outcomes measured 1 hr post dosing)	**Primary outcome results:** No data assessed and reported **Other outcomes assessed:** % Increase of cavernosal arteries diameter, mean (sd) baseline 51 (26.5) vs. 51.1 (26.7) post tx 71.8 (22.1) vs. 51.6)(27.2) Brachial artery flow mediated dilation: Baseline 9.7 (5.4) vs. 10.6 (5.6) Post tx 13 (4.4) vs. 10.7(5.6); Also reported analysis of outcomes for ED etiology subgroup with greater FMD values in pts with arteriogenic ED, non-sign **Withdrawals/drop-outs/loss to F/u, n (%):** 0 **WDAE, n (%):** NR **TAE, n (%):** NR **SAE, n (%):** NR **Outcome ascertainment:** no ED outcome measures used; FMD by Ultrasound

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Montorsi, F (2004) [102] **Funding source:** Bayer Corporation, Pharmaceutical Division	**N screened =** NR **N randomized =** 732 **IG1, n =** 237 **IG2, n =** 248 **CG, n =** 247 **ITT analysis used for primary outcome:** yes (ITT: n=708; safety: n=724) **Inclusion:** men 18 or older, with ED of 6 mo or longer; with 50% or more failure in 4 attempts of intercourse during the run in period **Exclusion:** penile abnormality; hypoactive SD; uncontrolled DM; radical prostatectomy or malignancy; SCI; chronic haematological, liver dx; retinitis pigmentosa; unstable angina pectoris; atrial tachyarrhythmia; MI, or stroke ≤ 6 mo; use of nitrates, anticoagulants, androgens, anti-androgens, trazodone, selected CYP3A4 inhibitors, alpha blockers/ other ED; hx of unresponsiveness/AE to other PDE5 inhibitors	**Age, mean (range):** 56 (22-81) y **Race, n (%)**: Caucasian: 603 (83); Black: 22 (3); Hispanic: 13 (2); Asian: 9 (1) **Co-morbidities:** NR **Previous ED treatment, n (%):** Sildenafil 521 (72) **BMI, mean:** 27 kg/m^2 **Smoking status, n (%)**: 385 (53) **Body weight:** NR **Other:** Severity of ED, n (%): Normal (≥26)= 9 (2%); Mild (22-25)= 63 (9%); Mild-moderate (17-21)= 149 (21); Moderate (11-16)= 205 (28); Severe (≤ 10) =280 (39)	**Concomitant medications:** Drugs acting on renin-angiotensin system: 22% Lipid reducing agents: 17% Calcium channel blockers: 9% Beta-blockers: 9% **Duration of ED, mean:** 4 y **Underlying disease, %:** hypertension 30; lipid disorders 17; DM 17; prostatic neoplasms/hypertrophy 13 **Psychogenic ED**: 310 (43%) **Physiologic ED:** 118 (16%) **Mixed ED**: 295 (41%)	**IG1:** Vardenafil oral **IG2:** Vardenafil oral **CG:** Placebo oral **IG1:** Dose: 10 mg Duration: 4 wks Frequency: 1/d Compliance: NR **IG2:** Dose: 20 mg Duration: 4 wks Frequency: 1/d Compliance: NR **CG:** Placebo Dose: NA Duration: 4 wks Frequency: 1/d Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 4 wks	**Primary outcome results:** Onset of adequate erections At ≥ 25 min, (% yes): 50 vs. 53 vs. 26 At 10 min post intake in subgrps, %: Mild/moderate ED: 40 vs. 34 vs. 23 Moderate ED: 21 vs. 20 vs. 10 Severe ED: 6 vs. 12 vs. 8 IIEF, mean (sd) score, IG vs. CG: IIEF- EF: baseline= 13.4 (NR); post tx: 21 (8) vs. 14 (0.6) IIEF-IS: 10 (3) vs. 7 (0.4) IIEF-OS: 7 (3) vs. 5 (0.4) SEP-Q2, % yes: 71 vs. 73 vs. 46 SEP-Q3, % yes: IG 75-77 vs. CG 45-47 **Other outcomes assessed:** SEP-3 in various time intervals post tx; elapsed time to adequate erection **Withdrawals/drop-outs/loss to F/u, n (%):** 9 (4) vs. 6 (2) vs. 14 (6) **WDAE, n (%):** 0 vs. 0 vs. 1 (<1) **TAE (%):** NR; most common AE in ≥ 2% of pts = headache 7 vs. 12 vs. 1; flushing 6 vs. 9 vs. < 1; nasal congestion 2 vs. 4 vs. < 1; nausea <1 vs. 2 vs. 0; dyspepsia 2 vs. 1 vs. 0; abdominal pain <1 vs. 2 vs. 0 **SAE, n:** 0 vs. 5 (2) vs. 1 (<1); one patient in IG2 experienced two SAEs; IG included 1 skin ulcer, 1 reflux dx, 1 MI, 1 syncope + encephalitis; CG one pneumonia **Outcome ascertainment:** IIEF domains; SEP-Q2 and 3

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Nagao (2004) [103] **Funding source:** Bayer Yakuhin Ltd	**N screened =** 375 **N randomized =** 283 **IG1, n =** 67 **IG2, n =** 75 **IG3, n =** 66 **CG, n =** 71 **ITT analysis used for primary outcome:** Yes **Inclusion**: men 20-70 y, with ED for 6 mo or longer, willing to attempt at least 4 sexual intercourse during 4 wk run-in period, with no sign cardiac dx **Exclusion:** any medical, psychiatric, substance abuse disorder; any major clinically sign dx or condition; abnormal hormone profile; use of nitrates or nitric oxide donors, beta blockers; erythromycin, ketoconazole, anti-coagulants; antiandrogens, traxodone, investigational drugs in the previous 3 mo; sildenafil or other ED tx within 7 d; hypersensitivity to sildenafil or to $\geq$ 3 other drugs; unresponsiveness to sildenafil	**Age, mean (range):** 52 (21-70) y **Race (%)**: all Asian (Japanese) **Co-morbidities:** NR **Previous ED treatment, n (%)**: Sildenafil IG= 25 (12) vs. CG=4 (6) **Smoking status**: NR **Body weight, mean:** 68 kg **Other:** IIEF-EF Baseline score: mean (sd) 13.7 (5)	**Concomitant medications:** NR **Duration of ED, mean range:** 2- 3 y **Underlying disease:** NR **Psychogenic ED, n (%):** 183 (88) vs. 62 (87) **Physiologic ED, n (%):** 10 (5) vs. 4 (6) **Mixed ED, n (%):** 10 (5) vs. 5 (7)	**IG1-IG3:** Oral vardenafil **CG:** Placebo **IG1-3:** Dose: 5 mg (IG1); 10 mg (IG2); 20 mg (IG3) Duration: 12 wks Frequency: as required, no more than once/d Compliance (%): NR **CG:** Dose: 20 mg Duration: 12 wks Frequency: as required, no more than once/d Compliance (%): NR **Run In period:** 4 wk unmedicated **Wash out period:** NR **F/u duration:** 12 wks, every 4 wks for AE	**Primary outcome results:** Least square mean IG1- 2-3 vs. CG: IIEF Q3: baseline= 3; post: 4.1- 4.5- 4.6 vs. 3.2 IIEF Q4: baseline = 2; post: 3.5- 4.2- 4.3 vs. 2.3 IIEF EF: baseline= 13.7; post: 22.4- 25.6- 25.9 vs. 16.7 GAQ, % yes: 73, 85.3, 86.4 vs. 35.2 Successful intercourse, % yes, baseline vs. tx grp= IG1: 64 vs. 13; IG2: 79 vs. 8; IG3: 80 vs. 10; CG: 33 vs. 9 **Other outcomes assessed:** Fugl-Meyer quality of life questionnaire **Withdrawals/drop-outs/loss to F/u:** 7 (10) vs. 9 (12) vs. 6 (9) vs. 15 (21) **WDAE, n (%):** 2 (3) vs. 2 (2.7) vs. 3 (4.5) vs. 4 (6) **TAE, n (%):** Per-patient incidence 39 (57) vs. 47 (63) vs. 49 (74) vs. 37 (52); most frequently reported IG vs. CG: flushing 60 (28) vs. 6 (4); headache 21 (10) vs. 6 (4); rhinitis 14 (7) vs. 0 **SAE:** NR **Outcome ascertainment:** IIEF- Q3 & 4; GAQ; pts diary of sexual intercourse; Fugl-Meyer quality of life questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Nehra (2005) [104] [105] **Companion Brock (2003)** [105] **Funding source:** Bayer Pharmaceuticals Corp & Bayer Inc.	**N screened =** 567 **N randomized =** 440 **IG1, n =** 146 (ITT, n = 135) **IG2, n =** 149 (ITT, n = 145) **CG, n =** 145 (ITT, n = 134) **ITT analysis for primary outcome:** Yes **Inclusion:** men 18 or older, with ED due to nerve sparing-radical retro pubic prostatectomy, between 0.5 and 5 y prior to screening; localized tumours allowed; 4 attempts at sexual intercourse on 4 separate d with a 50% or higher chance of failure **Exclusion:** unstable CV; Gleason tumour score $\geq$ 8, hx of unresponsiveness to sildenafil due to lack of efficacy or sign. side effects leading to discontinuation, hypoactive SD, low serum T, DM; prostate cancer.	**Age, mean:** 60 y **Race, (%):** White 99 vs. 87 vs. 93 **Co-morbidities, n (%):** depressive disorder1 (<1) vs. 8 (6) vs. 10 (7); acute MI 12 (3); hypertension 130 (30); prostate hyperplasia 11 (3); hypercholesterolemia 91 (21); vasectomy 44 (10) **Previous ED treatment, n (%):** 338 (77) **BMI, mean:** 28 kg/m^2 **Smoking status, (%):** 46-55% previously smoked **Body weight:** NR **Other:** IIEF EF score, mean: pre-operation =23; baseline =9	**Concomitant medications:** NR **Duration of ED, mean:** 1.7 y (post surgery) **Underlying disease:** nerve sparing radial retro pubic prostatectomy (Mean Gleason tumour=6) **Psychogenic ED**: NR **Physiologic ED:** 100% **Mixed ED**: NR **Other:** neurovascular bundle sparing: n (% bilateral): 112 (76) vs. 101 (72) vs. 99 (71)	**IG1:** Oral Vardenafil **IG2:** Oral Vardenafil **CG:** placebo **IG1/IG2:** Dose: 10 mg (IG1), 20 mg (IG2) Duration: 12 wks Frequency: as needed but no more than 1x/day Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wk tx free **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** Last observation carried forward, mean IIEF- -Intercourse satisfaction, mean: Baseline, all =5; post tx: 8 vs. 7 vs. 5 IIEF-OF, mean: Baseline, all=5; post tx: 6 vs. 6 vs. 5 IIEF-OS: Baseline, all=5; post tx: 6 vs. 6 vs. 5 Hardness of erection, (mean per pts satisfaction rate %): 28 vs. 24 vs. 8 IIEF-EF score: Baseline, all =9; post tx 15 vs. 15 vs. 9 Mild-moderate ED: 26 vs. 25 vs. 16 Moderate ED: 23 vs. 19 vs. 13 Severe ED: 11 vs. 13 vs. 7 SEP-Q2, mean per pts success rate (%): baseline 21 vs. 18 vs. 14 Post tx: 47 vs. 48 vs. 22 SEP-Q3, mean per pts success rates (%): baseline 7 vs. 7 vs. 6; post tx 37 vs. 34 vs. 10 GAQ, % yes: 59 vs. 65 vs. 13 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE, (%):** 4 vs. 3 vs. < 1% **TAE, (%):** Tx emergent AEs 57 vs. 65 vs. 40; including headache 16 vs. 22 vs. 4; Vasodilation 19 vs. 21 vs. 0; Rhinitis 16 vs. 20 vs. 6; Sinusitis 6 vs. 7 vs. 1; dyspepsia 4 vs. 5 vs. 0; nausea 1 vs. 5 vs. <1 **SAE:** 1 (<1%) vs. 3 (2%) vs. 1 (<1%) cause NR **Outcome ascertainment:** IIEF; GAQ; SEP-Q2, and 2

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Porst (2001) [106] [107] **Companion study** [107] **Funding source:** Bayer	**N screened =** NR **N randomized =** 601 (data reported for n=590, pts who took at least one dose of study medication) **IG1, n =** 147 **IG2, n =** 141 **IG3, n =** 150 **CG, n =** 152 **ITT analysis used for primary outcome:** Y (n=580) **Inclusion**: age 21-70 y; in stable heterosexual relationship with ED for at least 6 mo; **Exclusion:** DM; SCI; radical prostatectomy; sign CAD; hx of hepatitis B and/or C; hypogonadal T levels; thyroid stimulating hormone level <0.28 mU/L; prior nonresponse to sildenafil No other ED tx, or nitrates were permitted Companion study reports on additional analysis in ITT population (n=580), for subgroups of various age and prior sildenafil use	**Age, mean (sd):** 53 (11) vs. 52 (11) vs. 52 (12) vs. 52 (11) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment, n (%):** Sildenafil 74 (51) vs. 67 (50) vs. 72 (49) vs.72 (49) **Smoking status**: NR **Body weight (sd):** 83 (16) vs. 85 (14) vs. 84 (14) vs. 85 (15) kg	**Concomitant medications:** NR **Duration of ED, mean (sd):** 3 (3) vs. 3 (4) vs. 3 (4) vs. 3 (3) y **Underlying disease:** NR **Psychogenic ED, n (%)**: 163 (27) **Physiologic ED, n (%):** 178 (30) **Mixed ED, n (%):** 245 (41) **Other:** Severity IIEF domain score, n (%): >25 (none)= 21 (4); 18-25 (mild)= 156 (26); 11-17 (moderate)= 204 (34); <11 (severe)= 195 (32)	**IG1-3:** vardenafil hydrochloride orally **CG:** placebo orally **IG1-3:** Dose: 5 (IG1), 10 (IG2) or 20 (IG3) mg Duration: 12 wk Frequency: once 1 hr before intercourse; max 1/d Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 13 wk **Other:** 11 (2%) did not take medication	**Primary outcome results:** Mean change from baseline (sd): IIEF-Q3: 1.2 (1.7) vs. 1.3 (1.5) vs. 1.5 (1.7) vs. 0.2 (1.7) IIEF-Q4: 1.4 (1.7) vs. 1.5 (2.0) vs. 1.7 (2.0) vs. 0.5 (1.7) IIEF- EF: 5.7 vs. 8 vs. 9 vs. 1.6 IIEF-IcS: 2.9 vs. 3.5 vs. 3.6 vs. 1 IIEF-OF: 1.9 vs. 1.6 vs. 1.8 vs. 0 IIEF-OS: 2.1 vs. 2.6 vs. 2.8 vs. 0.8 IIEF-SD: 0.5 vs. 0.4 vs. 0.6 vs. 0 GAQ, % improved: 66 vs. 76 vs. 80 vs. 30, IG vs. CG p<0.001 % of successful intercourse, mean %: baseline: 28.9 vs. 26.1 vs. 24.2 vs. 23.7 post tx: 71.1 vs. 70.9 vs. 74.6 vs. 39.5, IG vs. CG p<0.001 **Other outcomes assessed:** Fugl-Meyer Quality of Life Questionnaire **Withdrawals/drop-outs/loss to f/u:** 10 (0.2) **WDAE:** 7 (5) vs. 2 (1) vs. 1 (0.7) vs. 2 (1) (Not specified) **TAE, n (%):** pts with one or more AE 40 (27) vs. 38 (27) vs. 62 (41) vs. 14 (9); including headache, flushing, dyspepsia, rhinitis **SAE, n (%):** 4 (3) vs. 1 (<1) vs. 2 (1) vs. 4 (3) Not specified **Outcome ascertainment:** IIEF; SEP; GAQ; Fugl-Meyer QoL; pts diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Porst (2006) [108] **Funding source:** NR	**N screened =** 483 **N randomized =** 383 (International 31 centres) **IG, n =** 194 **CG, n =** 189 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older, with ED > 6 mo IIEF-EF score >5 or lower than 26, who failed on at least 50% of intercourse attempts **Exclusion:** penile abnormalities; hypoactive sexual dysfunction; surgical prostatectomy; retinitis pigmentosa; hx of hepatitis B surface antigen, hepatitis C, hepatic impairment, haematological disease; MI, stroke or serious arrhythmia in last 6 mo; uncontrolled atrial fibrillation, or DM; hypo/hypertension; heart failure; use of nitrates or nitric acid donors, antiandrogens, androgens, alpha blockers, anticoagulants; vardenafil in last 30 d; ED tx within 7 d	**Age, mean (sd):** 54.8 (9.3) vs. 56.6 (10.1) y **Race:** White 75%; Hispanic 11%; Black 8%; Asian 7%; other <1% **Co-morbidities, n (%):** NR **Previous ED treatment, %:** sildenafil 33%; tadalafil 28%; vardenafil 10% **Smoking status:** NR **Body weight:** NR **Other:** BMI, mean (sd): 28 (4.7) kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED, mean (sd):** since diagnosed 4.0 (3.2) vs. 3.9 (3.1) y **Underlying disease, n (%):** no specific cause **Psychogenic ED, n (%):** 42 (11) **Physiologic ED, n (%):** 165 (44) **Mixed ED, n (%):** 168 (45) **Other:** -ED severity, n (%): Mild 32 (9) Mild/moderate: 90 (24) Severe 134 (36) -IIEF-EF at baseline, mean (sd): 13.3 (5.5)	**IG:** Vardenafil **CG:** Placebo **IG:** Dose: starting dose 10 mg adjusted to 5, 10, or 20 mg; initial dose of 10 mg, titrated to 5 or 20 mg at wk 2 Duration: 10 wks Frequency: 8 hr before sexual activity Compliance: **CG:** Dose: NA Duration: 10 wks Frequency: as IG Compliance: **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 10 wks **Other:** Dose titration to 20 mg, %: 75 vs. 94	**Primary outcome results:** IIEF-EF, LS mean at 10 wks: 22.8 vs. 14.9 Success rate wk 2-6/ wk 0-10, LS mean, %: SEP-2: 81 vs. 51/ 79 vs. 50 SEP-3: 69 vs. 34/ 65 vs. 31 GAQ, %: 77 vs. 27 **Other outcomes assessed:** EQS superior scores IG vs. CG, p<0.001; primary efficacy data analysed for wk 2-10 (after dose titration) **Withdrawals/drop-outs/loss to f/u, n (%):** 17 (9) vs. 30 (16) **WDAE, n (%):** 1 (<1) vs. 1 (<1) **TAE, %:** pts with any tx emergent AE 39% vs. 22% **SAE, n (%):** 8 (4) vs. 0; inincluded flushing, headache, hypoaesthesia, hypotension, muscle cramp, arthralgia, back pain, diarrhoea, intervertebral disc protrusion and lethargy **Outcome ascertainment:** IIEF-EF; GAQ; SEP,2/3;Global Confidence Question (GCQ); Erection Quality Scale (EQS); SEP2, 3

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rosen (2006) [109] **Funding source:** Bayer, and GlaxoSmithKline	**N screened =** 488 **N randomized =** 280 **IG1, n =** 137 **CG, n =** 143 **ITT analysis used for primary outcome:** yes (also LOCF) **Inclusion:** men 18 or older with ED for 6 mo or longer; with diagnosed but untreated mild major depressive disorder; who were not in psychotherapy or taking antidepressants; in a stable heterosexual relationship for more than 6 mo with 50% or more failure rate on at least 4 attempts of sexual intercourse **Exclusion:** men medically unstable; hx of substance abuse, serious suicidal or homicidal risk, bipolar, schizophrenia, delusional, panic, or personality disorder, posttraumatic stress; penile anatomical abnormalities, primary hypoactive SD; SCI; or prior non-response to sildenafil.	**Age, mean (sd);** 54 (10) vs. 52 (12) **Race, (%):** Caucasian 75; Black 8; Asian 2; Hispanic <1; American Indian <1 **Co-morbidities:** NR **Previous ED treatment, %:** Sidenafil 59 **BMI, mean (sd):** 28 (4) vs. 27 (4) kg/m^2 **Smoking status, %:** 51 **Body weight mean (sd):** 85 (15) kg (overweight)	**Concomitant medications:** None **Duration of ED, mean (sd):** ≥6mo 3.5 (4) **Underlying disease, %:** Depression 100; DM 15; vvascular hypertensive 29; elevated cholesterol 12 **Psychogenic ED**, **n (%);** 32 (24) vs. 49 (37) **Physiologic ED:** 25 (19) vs. 15 (11) **Mixed ED, n (%):** 75 (57) vs. 69 (52) **Other, n (%):** 12% with elevated cholesterol	**IG:** Vardenafil **CG:** Placebo **IG1:** Dose: 10 mg (titrated to 5 or 20 mg at 4, or 8 wks) Duration: 12 wks Frequency: once/d Compliance, n (%): 118 (86) **CG:** Dose: NA (titration as IG) Duration: 12 wks Frequency: Once/d Compliance n, (%): 111 (78) **Run In period:** 4wk **Wash out period:** None **F/u duration** (on and off treatment)**:** wk 4, 8 12	**Primary outcome results:** IIEF Score, least square mean (LSM): IIEF-EF LS mean improved from baseline: 10 vs. 2, p<0.0001 Intercourse satisfaction: 10.9 vs. 7.8 OF: 7.7 vs. 5.9 OS: 7.1 vs. 4.9 SD: 7.3 vs. 6.4 Erectile hardness: 55.2 vs. 25 SEP-Q2: 76.7 vs. 52.4, p<0.0001 SEP-3: 66.4 vs. 38.1, p<0.0001 GAQ, % improved: (LOCF): 83% vs. 30%; p<0.0001 **Other outcomes assessed:** Remission of depressive symptoms **Withdrawals/drop-outs/loss to f/u, n (%):** 10 (7) vs. 29(20); including Insufficient therapeutic effect: 2 (1) vs. 10 (7) **WDAE, n (%):** 4 (3) vs. 2 (1); reason NR **TAE, n (%):** NR; AE in at least 2% of pts included headache: 15 (11) vs. 1 (1); flushing: 9 (7) vs. 1 (1); nasal congestion: 4 (3) vs. 0; insomnia: 0 vs. 4 (3) **SAE:** NR (no death occurred) **Outcome ascertainment:** IIEF domains, SEP-2/3;GAQ; Hamilton Depression rating scale (HAM-D) score, Rosenberg self-esteem scale.

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Stark (2001) [110] **Funding source:** NR	**N screened =** NR **N randomized =** 21 (3 way cross over) **IG1, n =** 21 **IG2 randomized =** 21 **CG randomized =** 21 **ITT analysis used for primary outcome:** NR/ or no **Inclusion**: men 18-60 y, normal body weight, mild to moderate ED for ≥ 6 mo or longer. Able to respond positively to visual sexual stimuli 4 wks. **Exclusion:** penile anatomical deformity, SCI, prostatectomy, neurological or endocrine causes of ED, major psychiatric illness, retinitis pigmentosa, DM, extreme hypo or hypertension, medications that might interact with PDE5 inhibitiors (nitrates), intolerance to medications, hypersensitivity and/or allergic reactions, excessive alcohol consumption, past failure to respond to Sildenafil	**Age, mean (sd):** 45 (10) y **Race (%):** 100% Caucasian **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status:** NR **Body weight, mean (sd):** 83 (10) kg **Other:** Mean Broca Index = 1 (0.09)	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR**:**	**IG1:** oral vardenafil hydrochloride solution **IG2:** oral vardenafil hydrochloride solution **CG:** oral placebo solution **IG1/ IG2:** Dose: 20 mg (IG1); 40 mg (IG2) Duration: 24 hrs Frequency: once Compliance: 100% **CG:** Dose: NR Duration: 24hrs Frequency: 1x Compliance: 99% **Run In period:** NR **Wash out period:** 5 d **F/u duration:** NR	**Primary outcome (EF)**: Base, % event rigidity, mean (sd): 59 (26) vs. 70 (17) vs. 42 (24) Base, average event tumescence, mean (sd): 10 (4) vs. 11 (3) vs. 8 (4) Tip, % Event rigidity, mean (sd): 50 (24) vs. 58 (19) vs. 34 (23) Tip, average event tumescence, mean (sd): 9 (4) vs. 9 (2) vs. 7 (4) Duration of erections with Rigidity >60% 58 vs. 64 vs. 14 min Mean individual ▲ in duration: 43 vs. 49 vs. NR (IG vs. CG, p <0.001) Duration of erections with Rigidity >80% 30 vs. 40 vs. 6 min pts with at least one erection: 18 (86) vs. 20 (95) vs. 16 (76) **Other outcomes assessed:** pharmacokinetic results **Withdrawals/drop-outs/loss to f/u, n:** 3 withdrew and were replaced **WDAE:** 0 **TAE, n (%):** 10 (48) vs. 14 (61) vs. 10 (48); including headache, flushing, nasal congestion, visual disturbance (1 event, 35 min post tx with 40 mg), in total 66 AE in 18 (85%) of patients **SAE:** 0 **Outcome ascertainment:** RigiScan device, venous blood samples, pts interview/self report

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Stief (2004) [111] **Funding source:** Bayer Vital GmbH, Leverkusen	**N screened =** NR **N randomized =** 1020 (n=755 completed 1st 12 mo; data provided for n=566 who continued 2nd 12 mo extension period) **IG1, n =** 272 **IG2, n** = 294 **CG, n =** NA **ITT analysis used for primary outcome:** Yes **Inclusion**: men 18 or older with ED (NIH Consensus Statement definition) in a steady heterosexual relationship for 6 mo or longer, had to complete the 1st 12-mo tx to be eligible to enter 2nd 12-mo tx period **Exclusion:** penile abnormalities, primary hypoactive SD, SCI-related ED, retinitis pigmentosa, angina pectoris, uncontrolled DM, resting hypo/hypertension, prior radical prostatectomy, prior use of vardenafil/sildenafil with poor tolerance or unresponsiveness within 6 mo	**Age, mean (sd):** 55 (22-89) y **Race (%)**: While (91), Black (4), others (5) **Co-morbidities:** hypertension (33%), diabetes (16%), prostate hyperplasia (18%) **Previous ED treatment:** Previous viagra use % = 56 vs. 65 **BMI, mean (sd):** 27 (4) vs. 28 (4) kg/m^2 **Body weight:** NR	**Concomitant medications:** NR **Duration of ED,** mean (sd): 2 (3) vs. 2 (4) y **Underlying disease:** NR **Psychogenic ED:** 17% **Physiologic ED:** 45% **Mixed ED:** 36%	**IG1:** Vardenafil **IG2:** Vardenafil **IG1:** Dose: 10 mg Duration: 24 mo Frequency: once/d Compliance: 85% **IG2:** Dose: 20 mg Duration: 24 mo Frequency: once/d Compliance: 84% **Run In period:** NR **Wash out period:** NR **F/u duration:** 2 y	**Primary outcome results:** Last observation carried forward (IG1 vs. IG2) IIEF-EF score, mean (sd): Baseline: 13 (5) vs. 14 (6) Post tx: 25 (7) vs. 26 (6) SEP-Q2, mean % with yes response: Baseline: 48 vs. 43; Post tx: 92 vs. 94 SEP-Q3 mean % with yes response: Baseline: 16 vs. 17; Post tx: 87 vs. 89 GAQ, % yes: 90 vs. 92% (sildenafil naïve 90.9 vs. 89.3; Sildenafil experienced 90.1 vs. 93.7) **Other outcomes assessed:** The Fugl-Meyer Life Satisfaction Checklist items 'sexual life' and 'sexual satisfaction' **Withdrawals/drop-outs/loss to f/u, n (%):** 41 (15) vs. 46 (16) **WDAE, n (%):** 5 (2) vs. 6 (2) **TAE, n (%):** NR; AEs=headache in 16 vs. 20%; flushing in 14 vs. 20%; rhinitis in 10 vs. 14%; nausea 2 vs. 2%; dyspepsia 4 vs. 9%; sinusitis 1 vs. 2%; conjunctivitis 2 vs. 1%; visual symptoms 5 (2) vs. 8 (3) **SAE, n (%):** 21 (8) vs. 13 (4); death 1 (0.4) vs. 3 (1) (unknown if the deaths are included in the 34 SAE) **Outcome ascertainment:** IIEF; SEP question 2, 3, Fugl-Meyer Life Satisfaction Checklist; and CESD scale

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Valiquette, (2005) [112 113] **Funding source:** GlaxoSmithKline, King of Prussia, Pa, and Bayer Healthcare Pharmaceutical Division	**N screened =** 600 (773 originally approached for 4 wk run-in) **N randomized =** 523 **IG1, n =** 260 (ITT, n = 255) **CG, n =** 263 (ITT, n = 254) **ITT analysis used for primary outcome:** Yes **Inclusion:** men 18 or older, heterosexual relationship, ED of 6 mo or longer (NIH Consensus Statement), no prior use of Vardenafil. At least 50% of sexual intercourse attempts during the 4 wk run in phase; IIEF-EF score $\leq$ 26 and $\geq$ 5, positive 1st time response to 10 mg challenge. **Exclusion:** evidence of unstable or chronic medical, psychiatric or substance abuse, penile abnormality, primary hypoactive SD, SCI, hx of radical prostatectomy, retinitis pigmentosa, unstable angina pectoris, hx of MI, stroke or life-threatening arrhythmia in last 6 mo (complete list can be found in full text article)	**Age, mean (sd):** 53.2 (11) vs. 54.5 (11) y **Race (%):** White 75; Asian 12; Black 5; Hispanic 4; Other <1 **Co-morbidities:** Hypertension: 155 (30); DM 72 (14); Benign prostatic hyperplasia 69 (14); Dyslipidemia 82 (16) **Previous ED treatment, n (%):** sildenafil 337 (64); tadalafil 104 (20) **BMI mean (sd):** 27 (4) kg/m^2 **Body Weight:** NR **Other:** IIEF-EF score, mean (sd)= 15 (5); severity of ED (%): no attempts ($\leq$5)= 1; severe 23; moderate 35; mild-moderate 30; mild 7; no ED (>25) < 1	**Concomitant medications**: NR **Duration of ED, mean (sd):** 6 (5); range 1-29 vs. 1-41 y **Underlying disease:** NR **Psychogenic ED: n (%):** 82 (16) **Physiologic ED: n (%):** 219 (42) **Mixed ED: n (%):** 208 (40)	**IG:** Vardenafil **CG:** placebo **IG:** Dose: 10 mg Duration: 12 wks Frequency: as needed, no more than once/ d Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wk run in period followed by 1 wk open label challenge phase **Wash out period:** NR **F/u duration:** 12 wks	**Primary outcome results:** IIEF-EF score, least square mean (se): 24 (0.4) vs. 16 (0.4) IIEF-EF score equal or more than 26, (% of pts): 50 vs. 16 SEP2-, (% yes): Baseline: 56 vs. 53 Post tx: 83 vs. 56 SEP-Q3, (% yes): Baseline: 22 vs. 21 Post tx: 77 vs. 42 GAQ, (% yes) according to last observation carried forward: 81 vs. 32 **Other outcomes assessed:** median # of doses/ pts= 32 vs. 20 **Withdrawals/drop-outs/lo to f/u, n (%):** 76 (30) vs. 43 (17) **WDAE, n:** 2 (0.8) vs. 4 (2) **TAE, n (%):** any event 72 (28) vs. 40 (15); including headache 13 (5) vs. 5 (2); flushing 14 (5) vs. 2 (0.8), dyspepsia 6 (2) vs. 1 (0.4) **SAE, n:** 2 (0.8) vs. 0; facial palsy, appendicitis **Outcome ascertainment:** SEP, Question 2 and 3; IIEF-EF, and GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
van Ahlen (2005) [114] **Funding source:** NR(5/6 authors are employees of Galxo-SmithKline/ Bayer producers of vardenafil)	**N screened =** NR **N randomized =** 388 (98 primary care sites in Germany**)** **IG, n =** 193 (ITT=178) **CG, n =** 195 (ITT= 176) **ITT analysis used:** yes (last observation carried forward) **Inclusion:** men 18 or older with ED of 6 mo or longer; arterial hypertension controlled with 1 or more medication; able to maintain 4 wk ED tx free (at least 4 intercourses) **Exclusion:** prior use of PED5 inhibitors; penile anatomical abnormalities; hypoactive SD; ED due to SCI or radical prostatectomy; retinitis pigmentosa; hepatitis B, C surface antigen or; unstable angina pectoris; MI, stroke, ischemia; DM; hypotension; use of anticoagulants, androgens, trazodone, antiandrogens, alpha1 antagonist, potent HIV protease inhibitor, nitrates, ketokonazole, erythromycin (more in full text)	**Age, mean (range):** **IG1:** mean 56 (range 22-78) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **BMI, mean:** 28 vs. 27 kg/m^2 **Smoking status**: NR **Body weight, mean (sd):** 88 (14) vs. 86 (12) kg	**Concomitant medications, n (%):** Antihypertensive medications: Diuretics: 24 (13) vs. 15 (8); Beta-blockers: 81 (42) vs. 82 (43); Calcium channel blockers: 36 (19) vs. 28 (15); Reninangiotensin acting agents: 136 (71) vs. 133 (70) Mean number of antihypertensives per patient: 1.5 vs. 1.4 **Duration of ED (yr):** NR **Underlying disease, (%):** Hypertension 100 vs. 99 **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Vardenafil **CG:** placebo **IG:** Dose: starting 10 mg (5 mg in pts 65 or older) one step titration to 5 or 20 mg at 4 & 8 wks Duration: 12 wks Frequency: 1/ d Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: 1/ d Compliance: NR **Run In period:** 4 wks tx free **Wash out period:** 4 wks ED tx free **F/u duration:** 12 wks (4, 8, and 12 wks measures) **Other:** Allowed a single dose per day (No use of nitrate or concurrent ED therapy ≤ 7 d of study or any investigational drugs < 30 d prior to screening; no use of alpha-blockers permitted**)**	**Primary outcome results:** SEP-Q2, % yes: 83 vs. 58, p< 0.0001 SEP- Q3, % yes: 67 vs. 35, p < 0.0001 IEEF-EF, mean score: baseline = 14 vs. 14.5; post tx= 25 vs. 18, p< 0.0001 (unaffected by the class of antihypertensive used) GAQ, % yes: 80 vs. 40, p < 0.0001 **Other outcomes assessed:** association of tx with clinical measures of BP, or HR **Withdrawals/drop-outs/loss to f/u:** 34 (8.7) **WDAE, n (%):** 4 (2) vs. 2 (1) **TAE, (%):** 21.2% vs. 16.4%; including headache: 6 (3) vs. 1 (0.5); flushing: 3 (2) vs. 1 (0.5) **SAE, n (%):** 6 (3) vs. 2 (1); no detail provided **Outcome ascertainment:** IIEF-EF, sum score of Q 1, 5 and 15, SEP question 2 and 3; and GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Ziegler (2006) [115]	**N screened =** NR **N randomized =** 318 (82 sites in Germany) **IG, n =** 163 **CG, n =** 155 **ITT analysis used for primary outcome:** yes (IG n=153, CG n=149) **Inclusion:** men 18 or older with ED (by NIH Consensus statement); established DM type I; PDE5i naïve **Exclusion:** penile abnormalities; hx or SCI, hepatitis B, C; MI; heart or liver conditions (explicitly reported); hypo/ hypertension; uncontrolled DM; hx of malignancy within past 5 y or serum creatinine levels > 2.5 mg/dL (pts were prohibited to take nitrates while in the trial); tx with anticoagulant drugs (except anti-platelets); androgens, alpha1-antagonists, potent HIV protease inhibitors, anti mycotic agents itraconazole and ketoconazole, and erythromycin; other ED tx within 7 d of trial entry	**Age, mean (sd):** 50.3 (9.7) y **Race:** NR **Co-morbidities (%):** CV 157 (51.8); nervous system 94 (31); eyes 90 (29.7); endocrine/ metabolic 83 (27.4); musculoskeletal system 49 (16.2); urinary tract 46 (15.2); other including allergies 28 (9.3) **Previous ED treatment:** NR **Smoking status:** NR **Body weight, mean (sd):** 85.8 (13.4) kg **Other:** BMI, mean (sd): 27.2 (3.8) vs. 26.9 (3.4) kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** DM **Psychogenic ED, n (%):** NA **Physiologic ED, n (%):** all, 100% **Mixed ED, n (%):** NR **Other:** Glycemic control, good (HbA_{1c} 7% or less) in 43 vs. 51%; moderate (HbA_{1c} 7-8%) in 58 vs. 47%; poor (HbA_{1c} >8%) 53 vs. 51%	**IG:** Vardenafil **CG:** Placebo **IG:** Dose: flexible dose starting with 10 mg (5 mg for pts 65 or older) titrated to 20 mg Duration: 12 wks Frequency: on demand 1 hr prior to intercourse, up to 1/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 4 wks no tx **Wash out period:** NA **F/u duration:** 12 wks Dosing at 12 wks: 87.7% on 20 mg vardenafil; 10.8% on 10 mg, and 1.5% on 5 mg	**Primary outcome results:** IIEF domains change in score from baseline, mean (sd): EF: 7.79 (7.9) vs. 2.05 (5.8); improvements unaffected by level of glycemic control IcS: 3.43 (3.6) vs. 0.72(2.45) OF: 1.99 (2.6) vs. 0.30 (2.7) SD: 0.67 (1.5) vs. 0.09 (1.4) OS: 2.32 (2.6) vs. 0.52 (2.0) SEP-2, mean % (sd); Baseline: 41 (38) vs. 47 (40) Post tx: 71 (35) vs. 52 (38) SEP-2, mean % (from graph): Baseline: 13 vs. 18 Post tx: 50 vs. 28 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 16 (5.3) with no efficacy evaluation at baseline or post tx **WDAE, n (%):** 3 (1.8) vs. 2 (1.3) **TAE, n (%):** 29.4 vs. 20.6; AE in 2% or more pts n= 14 vs. n= 8; headache 5 (3.1) vs. 0; flushing 4 (2.5) vs. 0; bronchitis 3 (1.84) vs. 4 (2.6); nasopharyngitis 2 (1.2) vs. 4 (2.96) **SAE, n (%):** 7 (4.6) vs. 3 (2), cause NR **Outcome ascertainment:** IIEF-EF; SEP2, and 3

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C3-Oral Tadalafil

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Aversa (2007) [116] **Funding source:** NR	**N screened =** NR **N randomized =** 20 (22 eligible at level II screening) **IG1/IG2, n =** 20 **CG, n =** NA **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 y or older with at least 3 mo hx of ED of any severity or etiology **Exclusion:** tx with nitrates, cancer chemotherapy or anti-androgens; CHF; hyper-homocysteinemia or other conditions or drugs impairing endothelium-dependent vaso-relaxation; (pts with past use of commercially available PDE-5i; and concurrent active drugs were not excluded) Data reported for organic vs. relational vs. Psychogenic pts	**Age, mean (sd):** 54 (8) y **Race:** NR **Co-morbidities, n (%):** hyper-cholesterolemia 6 (30); DM type II 4 (20); hypertension 4 (20); smoking 4 (20); Psychogenic 2 (10) **Previous ED treatment:** NR **Smoking status, n (%):** smokers 4 (20) **Body weight:** NR **Other:** BMI, mean (sd) 25.4 (3.6) kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** see co-morbidities **Psychogenic ED, n (%):** 2 (10) **Physiologic ED, n (%):** 18 (90) **Mixed ED, n (%)**: NR **Other:** semi structured interview for erectile dysfunction (SIEDY) score, median (quirtile)= organic 3.93 (0-9); relational 2.53 (0-9); Psychogenic 3.33 (0-5)	**IG1:** Tadalafil on dememand (OD) **IG2:** Tadalafil on schedule alternated days (AD) **IG1:** Dose: 20 mg Duration: Frequency: 4 wks Compliance: **IG2:** Dose: 20 mg Duration: 4 wks Frequency: OD Compliance: **Run In period:** 4 wks **Wash out period:** 2 wks **F/u duration:** 6 time point measurements at baseline and end of each tx period, and 2 wks after last dosing; SIEDY not measured at end point	**Primary outcome results:** Sexual intercourse/mo: 5.9 (0.4) vs. 6.0 (0.7) N of pills/ mo: 6.0 (1.9) vs. 15.2 (0.6), p<0.05 PSV (cm/s): Baseline: 9.3 (0.3) vs. 9.5 (0.4) Post tx: 10.4 (0.9) vs. 13.2 (0.1) FMD, %, mean (sd) Baseline: 3.3 (0.6) vs. 1.2 (0.6) Post tx: 2.1 (0.9) vs. 8.3 (0.3) Systolic pressure (variation in mmHg): -6.1 (2.2) vs. -4.0 (1.3) Diastolic pressure (variation in mmHg): -3.3 (1.3) vs. -2.3 (1.2) **Other outcomes assessed:** endothelial markers (VCAM; ICAM; ET-1; CRP; insulin); insulin levels ▲ sign in OD (IG1) compare to IG2 **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** 0 **TAE, n (%):** 2 (10); headache, back pain, pain and myalgia (no report of abnormal vision or priapism) **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** blood flow measures by laboratory analysis; sexual measures by pts logs/interviews

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Carrier (2005) [117] **Funding source:** NR (conflict of interest reported as Eli Lilly, or ICOS CO employed some investigators)	**N screened =** 283 **N randomized =** 253 **IG1, n =** 103 **IG2, n =** 100 **CG, n =** 50 **ITT analysis used for primary outcome:** yes, **Inclusion**: men 18 or older, with at least a 3 mo hx of ED (organic, psychogenic or mix) in a monogamous relationship, and no ED tx for at least 4 wk prior to randomization **Exclusion:** hx of radical prostatectomy or other pelvic surgery with subsequent failure to achieve erections, presence of clinically sign penile deformity, renal insufficiency, angina, unstable angina in last 6 mo, hx of MI, coronary artery bypass graft surgery or precutaneous coronary intervention within 90 d, HIV, current tx with nitrates, cancer chemotherapy or antiandrogens, or prior non-response to tx with sildenafil	**Age, mean (sd):** 59 (9) vs. 58 (11) vs. 59(10) y **Race**: 95% Caucasian **Co-morbidities, (%):** hypertension 23 vs. 32 vs. 18, arthritis 23 vs. 24 vs. 20; DM 23 vs. 24 vs. 16; allergic reaction 22 vs. 13 vs. 16; prostate dx 19 vs. 16 vs. 26; hypercholesteremia 13 vs. 18 vs. 8; hyperlipidemia 11 vs. 8 vs. 12, back pain 12 vs. 12 vs. 4, hernia 6 vs. 7 vs. 12; headache 7 vs. 5 vs. 10; pain 11 vs. 8 vs. 10 **Previous ED treatment, %**: sildenafil 68 vs. 54 vs. 62 **Smoking status, %**: 12 vs. 21 vs. 22 **Body weight, mean (sd):** 90 (15) vs. 88(10) vs. 84 (12) kg	**Concomitant medications:** for hypertension CAD, cardiac arrhythmias, congestive heart failure, hyperlipidemia, and DM, n (%)= 101 (98) vs. 28 (56) vs. 62 (62) Note: list of medications is provided in the full text article **Duration of ED, n (%):** 1 yr or more= 92 (92) vs. 92 (89) vs. 45 (90) **Underlying disease, %:** prostatic disorder 19 vs. 16 vs. 26 **Psychogenic ED**: NR **Physiologic ED:** most commonly present **Mixed ED**: NR	**IG1:** Tadalafil **IG2:** Tadalafil **CG:** placebo **IG1:** Dose: 20 mg Duration: 12 wks (three 4 wk periods, Frequency: once /d Compliance: NR **IG2:** Dose: 10 mg Duration: 12 wks Frequency: once/ d Compliance: NR **CG:** Dose: NR Duration: same as IG Frequency: same as IG Compliance: NR **Run In period: NR** **Wash out period:** NR **F/u duration:** 12 wk	**Primary outcome results:** Change in IG1 vs. IG2 vs. CG, mean (SE) IIEF EF domain (1-30): 8 (0.8) vs. 6.6 (0.8) vs. –0.9 (1.1) IIEF intercourse satisfaction (0-15): 3.2 (0.3) vs. 2.2 (0.3) vs. 0.4 (0.4) Successful penetration (SEP-Q2): 21.3 (3.6) vs. 21.3 (3.8) vs. –6.4 (4.1) Successful intercourse (SEP-Q3): 29 (3.7) vs. 32.8 (3.7) vs. 4.9 (4.3) End point Improved erection (GAQ), n (%): 79 (79) vs. 69 (67) vs. 11 (22) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** n=34 (4 vs. 14 vs. 6) Note: pts without both baseline and post-baseline data were excluded from analysis, 3 vs. 4 vs. 1 **WDAE:** n=5 (IG1 n=3, IG2 n=2) **TAE, n (%):** AE in >/= 5%= 94 (94) vs. 84 (82) vs. 31 (62) (% with dyspepsia: 22 vs. 10 vs. 2; headache: 17 vs. 15 vs. 8; infection: 11 vs. 19 vs. 22; pain: 8 vs. 10 vs. 2; back pain: 7 v. 5 vs. 2; vasodilatation 6 vs. 4 vs. 4; flu syndrome: 5 vs. 8 vs. 10; accidental injury: 5 vs. 1 vs. 4; rhinitis: 4 vs. 6 vs. 4; myalgia 4 vs. 5 vs. 4 **SAE:** NR **Ascertainment of outcomes assessed:** IIEF; SEP Q2 & 3 and GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Carson (2005) [118] **Funding source:** Lilly ICOS LLC	**N screened =** 241 **N randomized =** 195 **IG, n =** 146 **CG, n =** 49 **ITT analysis used for primary outcome:** Yes **Inclusion**: men 18 or older, with ED of at least 3-mo duration; in stable heterosexual relationship **Exclusion:** serious CV condition (e.g. MI, unstable angina, sign.ECG conduction deficit) within 90 days before screening; nitrate tx; congestive heart failure of New York Heart Association Class 2 or above; stroke in previous 6 mo; SBP >100 mm Hg or <90 mm Hg; DBP >100 mm Hg or <50 mm Hg; hx of radical prostatectomy or other pelvic surgery with subsequent failure to achieve an erection; prior ineffective txt with sildenafil	**Age, mean (sd):** 60 (11) vs. 60 (10) **Race (%)**: White: 119 (82) vs. 43 (88); African descent: 23 (16) vs. 6 (12); Hispanic: 3 (2) vs. 0; Asian: 1 (0.7) vs.0 **Co-morbidities, n (%):** Coronary artery disease: 15 (10) vs. 0; DM 32 (22) vs. 8 (16); Hyperlipidemia: I52 (36) vs. 19 (39); Hypertension: 59 (40) vs. 21 (43); Prostatic cancer: 17 (11) vs. 4 (8) **Previous ED treatment**: NR **Smoking status**: 24 (16.) vs. 8 (16.) **Body weight:** NR	**Concomitant medications:** More than one: 126 (86) vs. 40 (82); none 20 (14) vs. 9 (18) **Duration of ED, range:** 025 or less-1 y or more [≥0.25 to <0.5 y: 3 (2) vs. 0 ≥0.5 to <1.0 y: 11 (8) vs. 2 (4); ≥1 y: 132 (90) vs. 47 (96) **Underlying disease:** NR **Psychogenic ED, n (%)**: 4 (3) vs. 2 (4) **Physiologic ED, n (%):** 119 (82) vs. 41 (84) **Mixed ED, n (%)**: 23 (16) vs. 6 (12)	**IG:** tadalafil orally **CG:** placebo orally **IG1:** Dose: 20 mg Duration: 12 wk Frequency: 1 dose before sexual activity; max. 1/d Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: 1 dose before sexual activity; max. 1/d Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** IG vs. CG, mean change (SE) IIEF EF: 7 (0.8) vs. –0.2 (1), p<0.001 IIEF –Q3 (ability to penetrate): 1 (0.2) vs. 0.1 (0.3), p <0.001 IIEF-Q4 (maintaining erection): 1 (0.2) vs. 0 (0.2), p < 0.001 Intercourse satisfaction: 3 (0.3) vs. –0.2 (0.5), p <0.001 OS: 2 (0.3) vs. –0.3 (0.3), p<0.001 SEP- Q2 ability to penetrate (% yes): 26 (3) vs. 2 (4.2), p<0.001 SEP-Q3 OS (% yes): 34 (3) vs. 5 (4), p<0.001 **Other outcomes assessed:** partner SEP2 and 3 **Withdrawals/drop-outs/loss to f/u:** 48 (IG1 30 [20.5%], CG 18 [36.7%]) **WDAE, n:** 9 (5.5% vs. 2%) **TAE:** NR (AEs included headache in 9%, dyspepsia 5%, myalgia 3%; reported mild or moderate in 90% of cases) **SAE:** 4; 3 (2%, carotid artery bruit, esophageal spasm, brain neoplasm) vs. 1 (2%, angina pectoris) **Ascertainment of outcomes assessed:** IIEF- SEP; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Chen, KK (2004) [119] **Funding source:** NR	**N screened =** 222 **N randomized =** 196 **IG, n =** 65 **IG2, n =** 65 **CG, n =** 66 **ITT analysis used for primary outcome:** yes **Inclusion**: men at least 21 yrs, in a monogamous relationship, at least 3 mo hx of ED of any origin **Exclusion:** hx of radical prostatectomy or other pelvic surgery with subsequent ED, insufficiency in past 6 mo, hepatobiliary dx, angina occurring during sexual intercourse in last 6 mo, hx of MI, coronary artery bypass graft surgery, or percutaneous coronary intervention within 90 d prior to 1st visit, hx of HIV infection or current infection with any sexually transmitted dx, tx with nitrates, cancer chemotherapy, or anti-androgens, and prior no response to tx with sildenafil citrate	**Age, mean (sd):** 59 (11.8) vs. 60.4 (11.5) vs. 60.2 (12.9) yr **Race (%)**: NR **Co-morbidities, n (%):** prostatic dx 20 (31) vs. 25 (39) vs. 25 (38) hypertension 11 (17) vs. 22 (34) vs. 19 (29); CAD (NR); hyperlipidemia 8 (12) vs. 5 (8) vs. 5 (8), and DM 11 (17) vs. 20 (31) vs. 16 (25) **Previous ED treatment, n (%):** sildenafil 29 (45) vs. 39 (60) vs. 31 (47) **Smoking status, n (%):** 22 (34) vs. 24 (37) vs. 25 (38) **Body weight:** NR	**Concomitant medications:** medication for hypertension (20% vs. 37% vs. 36%), CAD; cardiac arrhythmias; congestive heart failure; hyperlipidemia; DM (14% vs. 25% vs. 18%) **Duration of ED, n (%):** > 1yr 59 (91) vs. 58 (89) vs. 61 (92) **Underlying disease:** prostatic disorder; hypertension (17% vs. 34% vs. 29%); DM (17) vs. 31% vs. 24%); hyperlipidemia **Psychogenic ED** (%): 6 vs. 9 vs. 11 **Physiologic ED (%):** 71 vs. 69 vs. 65 **Mixed ED (%)**: 23 vs. 22 vs. 24	**IG1:** Tadalafil 10 mg **IG2:** Tadalafil 20 mg **CG:** Placebo **IG1:** Dose: 10 mg Duration: 12 wks Frequency: as needed, max 1/d Compliance: NR **IG2:** Dose: 20 mg Duration: 12 wk Frequency: as needed, max 1/d Compliance: NR **CG:** Dose: NR Duration: 12 wk Frequency: as needed, max 1/d Compliance: NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** mean change in score from baseline; overall p value in IG1 vs. IG2 vs. CG: IIEF (1-30): 8 vs. 8 vs. 2.6; p<0.001 [IIEF (intercourse satisfaction domain): sign. ▲ in IG1 and IG2 vs. placebo % of pts with normal IIEF score at end point: 42 vs. 63 vs. 20 SEP (Q2): 34 vs. 35, vs. 10; p<0.001 SEP (Q3): 48, vs. 50, vs. 15; p<0.001 GAQ, % of pts improved erections at endpoint (%): 92 vs. 85 vs. 55 (p<0.001 for overall and pair wise comparison) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** n=13 (7); 4 (6) vs. 3 (5) vs. 6 (9) (personal, sponsor or physician decision to withdraw, n=4 vs. 2 vs. 2) **WDAE, n (%):** n=3 (1.5): IG2 1 (1.5) elevated serum transaminases vs. CG 2 (3), deafness and MI **TAE, n (%):** incidence in >/=5%= 37 (57) vs. 46 (71) vs. 29 (44); AE included back pain, dyspepsia, myalgia, infection, rhinitis, dizziness, headache, ▲ cough, arthritis, pharyngitis **SAE:** NR **Ascertainment of outcomes assessed:** IIEF at 4, 8 and 12 wks; SEP Q2 & 3 post each intercourse; GAQ at final visit

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Choi (2006) [120] **Funding source:** Lilly Research Laboratories	**N screened =** **N randomized =** 121(multi center in Korea) **IG, n =** 80 **CG, n =** 41 **ITT analysis used for primary outcome:** yes (LOCF) **Inclusion:** men 18 or older, in a monogamous relationship, with ED of at least 3 mo in duration; caused by Psychogenic, organic or mixed etiology **Exclusion:** hx of radical prostatectomy or other pelvic surgery with subsequent failure to achieve erection; sign renal insufficiency within last 6 mo; sign hepatobiliary disease; angina during sexual intercourse in the last 6 mo of study entry; hx of MI or coronary artery bypass graft or precuaneous coronary intervention within 90 d of study entry; HIV	**Age, mean (range):** 51.4 (24.7-74.4) y **Race:** 100% Asian **Co-morbidities, n (%):** benign prostatic hyperplasia 16 (20) vs. 9 (22); DM 16 (20) vs. 5 (12.2); hypertension 12 (15) vs. 5 (12.2); hyperlipidemia 5 (6.3) vs. 4 (9.8) **Previous ED treatment:** NR **Smoking status:** NR **Body weight, mean:** 70.7 kg	**Concomitant medications, n (%):** NR **Duration of ED:** NR; pts with ED of at least 1 y 71 (88.8) vs. 39 (95.1) **Underlying disease, n (%):** no specific condition **Psychogenic ED, n (%):** 15 (18.8) vs. 10 (24.4) **Physiologic ED, n (%):** 56 (70) vs. 27 (65.9) **Mixed ED, n (%):** 9 (11.3) vs. 4 (19.5) **Other:** ED severity, n (%): Mild 33 (41.3) vs. 17 (41.5) Moderate 33 (41.3) vs. 16 (39) Severe 14 (17.5) vs. 8 (19.5)	**IG:** Tadalafil **CG:** Placebo **IG:** Dose: 20 mg Duration: 12 wks Frequency: on demand, up to once/d (no restriction on food or timing) Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: **Run In period:** 4 wks **Wash out period:** **F/u duration:**	**Primary outcome results:** Change from baseline, mean: IIEF-EF: 7.8 vs. 0.1, p<0.001 EF by ED severity: Mild 4.8 (n=32) vs. –1.6 (n=17) Moderate 8.6 (32) vs. –0.8 (n=16) Severe 12.7(n=14) vs. 5.3 (n=8) IIEF-Q3: 0.9 vs. –0.2, p<0.001 IIEF-Q4: 1.6 vs. 0.2, <0.001 IIEF-IS: 4.4 vs. 1.5, p<0.001 IIEF-OS: 2.6 vs. 0.7, p<0.001 SEP-2, %: 17.1 vs. 0.5, p<0.001 SEP-3, %: 53.6 vs. 10.1, p<0.001 GAQ-1, %: 80 vs. 43.9 GAQ-2, %6: 80 vs. 43.9 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 6 (7.5) vs. 0 **WDAE, n (%):** 1 (1.3) vs. 0 **TAE, n (%):** 38 (47.5) vs. 11 (26.8) Headache, flushing eye pain (only in IG), arthralgia, palpitations, myalgia, pharyngitis, naso-pharyngitis, gastritis somnolence **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** IIEF, SEP, GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
De Rose (2005) [121] **Funding source:** NR	**N screened =** 134 **N randomized =** 120 **IG, n =** 60 **CG, n =** 60 **ITT analysis used for primary outcome:** NR **Inclusion**: at least 3-mo hx of ED; in a monogamous relationship **Exclusion:** failure to achieve erection after pelvic surgery; clinically sign. penile deformity; penile implant; stroke within previous 6 mo; spinal cord trauma within previous 6 mo; clinically sign. renal or hepatic insufficiency; treatment with nitrates, antiandrogens or cancer chemotherapy	**Age, mean (range):** 46 (25-66) vs. 46, (29-63) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status, n (%)**: Smoker: 16 (35) vs. 18 (39) **Body weight**: NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED, n (%)**: 5 (10) vs. 6 (13) **Physiologic ED, n (%):** 24 (52) vs. 22 (48) **Mixed ED, n (%)**: 17 (38) vs. 18 (39) Other: baseline IIEF, n (%): mild 18 (40) vs. 19 (41); moderate 12 (25) vs. 11 (24); severe 17 (35) in both grps	**IG1:** tadalafil oral **CG:** placebo oral **IG1:** Dose: 20 mg Duration: 3 mo Frequency: twice/wk Compliance: 98.3% **CG:** Dose: placebo Duration: 3 mo Frequency: as IG Compliance: 96.7% **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 3 mo	**Primary outcome results:** Mean change in IIEF EF: 12 vs. 3 Mean absolute change in positive response to SEP (%yes) SEP-Q1- (erection): 36 vs. 14 SEP-Q2 (penetration): 34 vs. 12 SEP-Q3 (intercourse completion): 57 vs. 11 SEP-Q4 (hardness of erection): 72 vs. 3 SEP-Q5 (sexual experience): 77 vs. 5 **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u, n:** 3 (1 vs. 2) **WDAE:** 0 **TAE, n of pts with at least one AE:** 14 vs. 5, included headache 6 vs.3; flushing 4 vs. 0; dyspepsia 2 vs. 2; myalgia and back pain 2 vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, SEP

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2004) [122] **Funding source:** Lilly ICOS LLC	**N screened =** 237 **N randomized =** 220 **IG1 screened =** NR **IG1 randomized =** 168 **IG2 screened =** NA **IG2 randomized =** NA **CG screened =** NR **CG randomized =** 52 **Inclusion**: age ≥18 yr; at least 3-mo hx of mild to severe ED; in stable heterosexual relationship **Exclusion:** hx of radical prostatectomy (except for bilateral nerve-sparing) or other pelvic surgery, with subsequent failure to achieve erection; hx of ineffective treatment with sildenafil; unstable cardiovascular disease (e.g. unstable angina, recent myocardial infarction or stroke, poorly controlled hypertension, and New York Heart Association Class II and above congestive heart failure); evidence of clinically sign. renal insufficiency or hepatic insufficiency (e.g. active symptomatic hepatobiliary disease or jaundice); treatment with nitrates, antiandrogens or chemotherapy	**Age, mean (sd):** IG1 53.6 (range 26-78), CG 52.9 (range 29-73) **Race (%)**: White: IG1 167 (99.4%), CG 52 (100%) **Co-morbidities (unrelated to disease):** Hypertension: IG1 42 (25.0%), CG 10 (19.2%) Diabetes: IG1 20 (11.9%), CG 5 (9.6%) Alcohol user: IG1 82 (48.8%), CG 30 (57.7%) **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: Sildenafil: IG1 81 (48.2%), CG 26 (50.0%) **BMI (kg/m^2)**: NR **Smoking status**: Smoker: IG1 39 (23.2%), CG 16 (30.8%) **Initial body weight:** IG1 84.5 kg (range 41-150), CG 83.2 kg (range 60-118)	**Concomitant medications:** NR **Duration of ED (yr):** 0.25-0.5: IG1 15 (8.9%), CG 7 (13.5%) 0.5-1: IG1 14 (8.3), CG 7 (13.5%) ≥1: IG1 139 (82.7%), CG 38 (73.1%) **Underlying disease (diagnosis) (N or % of diseased/grp):** NR **Psychogenic ED**: IG1 30.4%, CG 26.9% **Physiologic ED:** IG1 37.5%, CG 32.7% **Mixed ED**: IG1 32.1%, CG 40.4% **Other:** Mild ED: IG1 56 (33.3%), CG 16 (30.8%) Moderate ED: IG1 41 (24.4%), CG 13 (25.0%) Severe ED: IG1 68 (40.5%), CG 21 (40.4%)	**IG1:** tadalafil orally **IG2:** NA **CG:** placebo orally **IG1:** Dose: 20 mg Duration: 12 wk Frequency: as needed (max 1/day) Compliance (%): NR **IG2:** NA Dose: Duration: Frequency: Compliance (%): **CG:** Dose: placebo Duration: 12 wk Frequency: as needed (max 1/day) Compliance (%): NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration (both on and off treatment):** 12 wk **Other:** No	**Primary outcome results:** Change in EF domain of IIEF and in positive response to questions 2 ("Were you able to insert your penis into your partner's vagina?") and 3 ("Did your erection last long enough for you to have successful intercourse?") of Sexual Encounter Profile (SEP) diary Mean change in IIEF EF IG1 11.1 (SD 27.2), CG 0.4 (SD 6.6) Mean absolute change in positive response to SEP Q2: IG1 41.0%, CG 7.3% Q3: IG1 56.5%, CG 10.8% **List (narrative) other outcomes assessed:** Change in other IIEF domains; positive response to SEP questions 4 and 5; positive response to GAQ ("Has the treatment you have been taking during this study improved your erections?" and "If yes, has the treatment improved your ability to engage in sexual activity?") **AE (in ≥2% of patients in IG1):** Headache: IG1 30 (17.9%), CG 3 (5.8%). Dyspepsia: IG1 22 (13.1%), CG 0. Flushing: IG1 8 (4.8%), CG 1 (1.9%). Back pain: IG1 6 (3.6%), CG 0. Pain in limb: IG1 6 (3.6%), CG 0. Myalgia: IG1 4 (2.4%), CG 1 (1.9%). **ITT analysis used for primary outcome?** Y **Withdrawals/drop-outs/loss to f/u [N andor %]:** 25 (IG1 16, CG 9) **WDAE (N and/or %):** IG1 5 (3.0%), CG 1 (1.9%) **TAE:** NR **SAE:** IG1 3, CG 1; none judged to be related to study drug **Ascertainment of outcomes assessed:** NA

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2005) [24] **Funding source:** Lilly ICOS LLC	**N screened =** 411 **N randomized =** 367 **IG1, n =** 183 (first period) **IG2, n =** 184 (first period) **CG, n =** NA **ITT analysis used for primary outcome:** Yes **Inclusion**: Pts aged => 18 yrs with documented ED of any aetiology and severity, in a steady relationship with the same female partner naïve to treatment for ED with drugs inhibiting PDE5 **Exclusion:** Pts with endocrine dx, premature ejaculation, prostatectomy, pelvic surgery, penile deformity, sign renal or hepatic dx, CHF, Within 6 mo, MI, coronary artery bypass surgery, sudden cardiac arrest, sign.arrhythmia, SBP (< 90 - > 170 mmHg) or diastolic (< 50 - > 100 mmHg), malignant hypertension, retinitis pigmentosa, current tx with nitrates, cancer chemotherapy, HIV infection, substance/drug abuse in last 6 mo	**Age, mean (sd):** 54 (12) y **Race (%)**: Caucasian 92, Black 4, Asian 3, other 1.3 **Co-morbidities, (%):** hyperlipidemia 11, coronary artery dx 6.5, hypertension 26.4, DM 9.5, depression 4 **Previous ED treatment**: NR **Smoking status, (%)**: current = 24 **Body weight:** NR **Other:** current alcohol use (65%)	**Concomitant medications:** no other ED treatments **Duration of ED:** NR **(**pts with 1 y or more ED =74%) **Underlying disease:** NR **Psychogenic ED**: 12% **Physiologic ED:** 28% **Mixed ED**: 60% **Other:** ED defined as consistent change in the quality of erection that adversely affects subject's satisfaction with sexual intercourse **Other:** Mean IIEF (EF): 14 (6); Severity of ED: severe (IIEF1-10): 31%, moderate (IIEF 11-16): 30%, mild (IIEF 17-30): 39%	**IG1:** Sildenafil **IG2:** Tadalafil **IG1:** Sildenafil Dose: 25-100 mg Duration: 12 wks Frequency: NR Compliance: NR **IG2:** Tadalafil Dose: 10-20 mg Duration: 12 wks Frequency: NR Compliance: NR **Run In period:** 4 wks **Wash out period:** 7-10 d **F/u duration:** before and after crossover 24 wks (2 periods of 12 wks) **Other:** Dose was titrated up and down between 25-100 for Sildenafil and 10-20 mg for Tadalafil	**Primary outcome results:** Mean least squares change from baseline for IIEF domains and 95% CI (IG2 vs. IG1): EF: 0.5 (-0.07, 1.1) OF: 0.3 (0.02, 0.5) SD: 0.2 (0.02, 0.6) Intercourse satisfaction: 0.17 (-0.1, 0.42) Mean change in IIEF questions: erection firmness, intercourse satisfaction and enjoyment, desire level, OS, erection confidence: tadalafil > sildenafil OS: 0.3 (0.02, 0.5) SEP, mean change from baseline: SEP-Q2: 36 vs. 39 SEP-Q3: 53 vs. 58 **Other outcomes assessed:** mean scores of IIEF, drug preference **Withdrawals/drop-outs/loss to f/u:** IG1 (1^{st}) and IG2 (2^{nd}): n=42 IG1 (2^{nd}) and IG2 (1^{st}): n=39 **WDAE:** IG1 (1^{st}) and IG2 (2^{nd}): n=4 IG1 (2^{nd}) and IG2 (1^{st}): n=7 **TAE, n (%):** pts with 1 or more AE=125 (34) vs. 128 (35) **SAE, n:** 4 vs.5 **Ascertainment of outcomes assessed:** Questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Govier F (2003) [123] **Funding source:** NR (correspondence: Eli Lillly and Company)	**N screened =** NR **N randomized =** 215 (cross over) **IG1, n =** 109 (Tadalafil - Sildenafil) **IG2, n =** 106 (Sildenafil - Tadalafil) **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: Men with ED for => 3 mo, aged 18-65 yrs, in heterosexual relationship who had never received tadalafil or sildenafil **Exclusion:** Pts treated with nitrates, recent hx of MI or coronary revascularization, <= 6 mo hx of unstable angina, ED secondary to endocrine disorders, pelvic surgery, stroke or SCI within the last 6 mo, retinitis pigmentosa, HIV infection	**Age, mean (sd):** 50 (11) y **Race (%)**: White 87, African 9, Hispanic 3 **Co-morbidities:** NR **Previous ED treatment**: No tadalafil; sildenafil (15.3%) **Smoking status**: 23% current smokers **Body weight:** 90 (19.0) kg **Other:** height, mean (sd) = 179 (7) cm	**Concomitant medications:** CVD or diabetes (n = 54) **Duration of ED, %:** 75% with hx of 1 y or longer **Underlying disease:** NR **Psychogenic ED**: 18% **Physiologic ED:** 39% **Mixed ED**: 42% **Other:** severity of ED (based on clinical judgement) = mild (12%), moderate (60%), severe (27.5%)	**IG1:** tadalafil **IG2:** sildenafil **CG:** NA **IG1:** tadalafil Dose: 20 mg Duration: 4 wks Frequency: once/d Compliance: NR **IG2:** sildenafil Dose: 50 mg Duration: 4 wks Frequency: once/d Compliance: NR **Run In period:** 1 wk **Wash out period:** 1-2 wks **F/u duration:** 10 wks **(**per treatment = 4 wks)	**Primary outcome (EF)**: Treatment Preference Question ('which treatment did you prefer?') = N (%) pts preferring tadalafil (over sildenafil) vs. N (%) pts preferring sildenafil (over tadalafil) = 126 (66.3%) vs. 64 (33.7%), p < 0.001 Total N of attempts at sexual intercourse = IG1: 2334 vs. IG2: 2233, p = NR **Other outcomes assessed:** AE **Withdrawals/drop-outs/loss to f/u:** n=24 (11.2%), n=11 (lost to f/u) **WDAE, n:** 2 (each pt in IG1 vs. IG2) **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Guo (2006) [124] **Funding source:** Eli Lilly and Company	**N screened =** 399 **N randomized =** 367 **IG1, n =** 125 **IG2, n =** 120 **CG, n =** 122 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older in monogamous relationship, at least 3 mo hx of ED, with Psychogenic, organic or mixed cause **Exclusion:** hx of radical prostatectomy; or other pelvic surgery with subsequent failure to achieve erection; renal insufficiency, hepatobiliary disease, unstable angina within the last 6 mo; hx of MI; coronary artery bypass graft surgery, or precutaneous coronary intervention within 90 d prior to 1st visit; hx of HIV infection; tx with nitrates, cancer chemotherapy, or antiandrogens (discretionary criteria was ineffective tx with sildenafil)	**Age, mean (range):** 52 (24-82) y **Race:** East/ South-eastern 100% **Co-morbidities, n (%):** hypertension 77 (21); DM 42 (11.4); benign prostatic hyperplasia 14 (3.8); hyperlipidemia 9 (2.5) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **BMI, mean (range):** 24.8 (15.6-50.4) kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED:** pts with ED of 1 y or longer 341 (92.9) **Underlying disease, n (%):** no specific cause **Psychogenic ED, n (%):** 59 (16.1) **Physiologic ED, n (%):** 107 (29.2) **Mixed ED, n (%):** 201 (54.8) **Other:** IIEF severity, n (%) Normal 3 (0.8) Mild 23 (6.3) Mild/moderate 93 (25.3) Moderate 135 (36.8) Sever 113 (30.8) IIEF-EF baseline, mean: 13.6 vs. 13.6 vs. 14	**IG1:**Tadalafil low dose **IG2:** Tadalafil high dose **CG:** Placebo **IG1:** Dose: 10 mg Duration: 12 wks Frequency: on demand up to once/d Compliance: NR **IG2:** Dose: 20 mg Duration: 12 wks Frequency: as IG1 Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** Change in mean from baseline: IIEF-EF: 8.1 vs. 8.7 vs. 2.4 IIEF-Q3: 1.4 vs. 1.5 vs. 0.4 IIEF-Q4: 1.4 vs. 1.6 vs. 0.5 SEP-2, % yes: 33.5 vs. 34.8 vs. 7.7 SEP-3, % yes: 50.0 vs. 56.4 vs. 18.3 GAQ, %: 80.9 vs. 85.7 vs. 43.9 **Other outcomes assessed:** IIEF-EF based on severity of ED (% of pts in each grp), mean change in score: Mild (31 vs. 28 vs. 34) 24 vs. 23.5 vs. 21.9 Moderate (34.2 vs. 35.2 vs. 37.7) 22.3 vs. 23.0 vs. 15.6 Severe (30 vs. 30.4 vs. 30.2) 18.1 vs. 21.6 vs. 10.7 **Withdrawals/drop-outs/loss to f/u, n (%):** 10 (8.3) vs. 12 (9.6) vs. 8 (6.6) **WDAE, n (%):** 2 (1.7) vs. 2 (1.6) vs. 1 (0.8) **TAE, n (%):** in 2% or more 18 (15) vs. 17 (13.6) vs. 4 (3.3) including headache, back pain, dizziness, dyspepsia, chest pain, cough **SAE, n (%):** 1 death in IG2 **Ascertainment of outcomes assessed:** IIEF, GAQ, SEP

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Incrocci (2006) [125] **Funding source:** Lilly Icos	**N screened =** 632 medical records screened; 358 invited **N randomized =** 60 (cross over trial) **IG1/ CG, n =** 30/grp depending on the order of tx randomization (IG1 tadalafil first, CG placebo first) **ITT analysis used for primary outcome:** yes **Inclusion:** pts with histological proven prostate carcinoma treated by 3DCR at least 12 mo before study **Exclusion:** excluded prior to surgery: tx with chemotherapy or anti androgens, or hx of metastases; use of nitrates, CVD, coronary artery bypass graft within 90 d of entry, stroke, SCI within 6 mo of entry	**Age, mean (range):** 69 (53-84) y **Race:** NR **Co-morbidities, n (%):** hypertension 17 (28); DM 2 (3); both 3 (5) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** **Other:** tumor stages, and differentiation grade PSA, mean (range) 13.9 (1-86) µ/L	**Concomitant medications, n (%):** **Duration of ED:** NR (calculated from mean age at radiation-mean age at entry =4 y) **Underlying disease, n (%):** prostate carcinoma radiation tx **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG:** Tadalafil **CG:** Placebo **IG:** Dose: 20 mg Duration: 6 wks Frequency: on demand, at least once/wk, up to once/d (no restriction on alcohol or food) Compliance: 100% **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: 100% **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 12 wks; outcomes assessed at end each tx period	**Primary outcome results:** Mean (sd), tadalafil vs. placebo -IIEF- EF, baseline: 8.4 (3.1): Post tx: 17.7 (9.9) vs. 9.5 (5.9), p -IIEF-OF, baseline: 6.7 (3.0) Post tx: 7.4 (3.1) vs. 4.9 (3.5) -IIEF-SD, baseline: 8.0 (1.9) Post tx: 8.7 (1.7) vs. 7.9 (1.9) -IIEF-IS baseline: 5.9 (1.9) Post tx: 8.2 (3.5) vs. 5.6 (2.3) -IIEF-OS, baseline: 4.3 (2.4) Post tx: 6.5 (3.0) vs. 4.4 (2.6) SEP-2, %: 47 vs. 19, p<0.0001 SEP-3, %: 46 vs. 12 GAQ, %: 67 vs. 20 Successful intercourse, %: 48 vs. 9 **Other outcomes assessed:** **Withdrawals/drop-outs/loss to f/u, n (%):** 0 **WDAE, n (%):** 0 **TAE, n:** 56 vs. 10 AE included headache, flushing, and dyspepsia sign more in IG; myalgia, nasal congestion, back pain, dizziness not sign between grps **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** IIEF, SEP

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
McMahon (2005) [126] **Funding source:** Lilly ICOS LLC	**N screened =** 152 **N randomized =** 140 **IG1, n =** 93 **CG, n =** 47 **ITT analysis used for primary outcome:** Yes **Inclusion**: ≥18 yr; in monogamous relationship with female partner; at least 3-mo hx of ED **Exclusion:** premature ejaculation; penile implant; penile deformity; ED due to untreated endocrine condition; radical prostatectomy; pelvic surgery; sign central nervous system injury within 6 mo of screening; clinically sign renal insufficiency within previous 6 mo, hepatobiliary dx or uncontrolled DM; unstable angina; MI, coronary artery bypass grafting or percutaneous coronary arterial intervention within 90 days of screening; prior sildenafil treatment failure (for complete list of exclusions refer to full text article)	**Age, mean (sd):** IG1 58 (9), CG 61 (7) y **Race (%)**: 98% white in both grps **Co-morbidities, n (%):** hypertension: 15 (32) vs. 26 (28) hypercholesterolemia: 7 (15) vs. 17 (18) hyperlipidemia: 8 (17) vs. 12 (13) dyspepsia: 6 (13) vs. 12 (13); DM: 8 (17) vs. 9 (10) **Previous ED treatment**: NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** 1 yr (96% of pts) **Underlying disease:** NR **Psychogenic ED:** 2 (4) vs. 10 (11) **Physiologic ED:** 21 (45) vs. 37 (40) **Mixed ED:** 24 (51) vs. 46 (50) **Other:** No	**IG:** tadalafil orally **CG:** placebo **IG:** Dose: 20 mg Duration: 6 mo (24-26 wk) Frequency: 1 dose before sexual activity; max 1/d Compliance: NR **CG:** Dose: placebo Duration: 6 mo (24-26 wk) Frequency: 1 dose before sexual activity; max 1/d Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 24-26 wk + 96 h	**Primary outcome results:**IG vs. CG, mean change from baseline: IIEF EF: 6.8 vs. 1.6 IIEF- intercourse satisfaction (range 0-15): 2.6 vs. -0.1, p <0.001 IIEF OS (range 2-10): 2.5 vs. 2 GAQ, end point (%): 78 vs. 13 SEP, mean absolute change from baseline in positive response (%): SEP-Q2: 26.5 vs. −7.5 SEP-Q3: 40 vs. 0.9 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 15 vs. 4 **WDAE, n:** 4 (headache 2, dyspepsia 2) vs. 0 **TAE, n of events:** 142 vs. 39 (AEs reported: most common) included headache in 40 (43) vs. 4 (9); dyspepsia 20 (22) vs. 0; back pain 15 (16) vs. 7 (15); surgical procedure 15 (16) vs. 8 (17); infection 13 (14) vs. 5 (11); pain 11 (12) vs. 3 (7); accidental injury 10 (11) vs. 7 (15); diarrhea 9 (10) vs. 4 (9); myalgia 9 (10) vs. 1 (2); other included arthralgia, vasodilatation, abdominal pain, cough, flu symptoms, gout, nausea (n of events NR **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF- SEP, and GAQ questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
McMahon (2005) [127] **Funding source:** NR	**N screened =** NR **N randomized =** 145 (cross over) **IG1/IG2, n =** 145 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: heterosexual men age 18 or older with ED of 3 mo or longer; with 50% or greater failure rate in maintaining an erection sufficient for completion of sexual intercourse on at least four occasions during the 4 wk run in period **Exclusion:** penis anatomic abnormalities, hx of radical prostatectomy, ED due to SCI, severe chronic liver dx, renal failure, retinitis pigmentosa, unstable angina pectoris, uncontrolled atrial tachyarrhythmia or any MI, stroke, electrocardiography ischemia or life-threatening cardiac arrhythmia in last 6 mo	**Age, mean:** 57.6 vs. 57.3 mo **Race (%)**: NR **Co-morbidities, n:** Diabetes 18 vs. 15, CAD 9 vs. 7; hypertension 22 vs. 21; peripheral vascular disease 4 vs. 2; hyperlipidemia 24 vs. 26; obesity 12 vs. 10 **Previous ED treatment, n (%):** sildenafil in 94 (65), responders 61 (5) **Smoking status, n (%):** 43 (30) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean:** 21 vs. 22 mo **Underlying disease:** NR **Psychogenic ED, n (%):** 18 (12) **Physiologic ED, n (%):** 86 (59) **Mixed ED:** 41 (28) **Other:** baseline IIEF (ED domain) score, 15 vs. 14; baseline severity of ED in all pts, n (%): mild 23 (16); mild-moderate 33 (23); moderate 56 (39); severe 33 (23)	**IG1:** Tadalafil 10 mg **IG2:** Tadalafil 20 mg on demand **IG1:** Dose: 10 mg Duration: 12 wks Frequency: daily Compliance: NR **IG2:** Dose: 20 mg Duration: 12 wks Frequency: on demand, 2-3 hrs befoe sexual activity Compliance: NR **Run In period:** 4 wks **Wash out period:** 2 wks **F/u duration:** 12 wks after each intervention regiments	**Primary outcome results:** IIEF EF domain scores both grps: 26 vs. 23 (p<0.001 vs. baseline, p<0.05 for IG1 vs. IG2) SEP-Q2, mean rate (%): baseline= 36, at 12 wks 73 vs. 85 (p<0.001 vs. baseline, IG1 vs. IG2, p<0.05) SEP-Q3-, mean rate (%): baseline = 30; at 12 wks 80 vs. 67 (p<0.001 vs. baseline, IG1 vs. IG2, p<0.05) Return to normal IIEF score (>26), % of respondents: 73 vs. 57 (p<0.05) GAQ, proportion of yes responses: 88% vs. 73% (p<0.05) **Other outcomes assessed:** tx preference; severity of AE **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** total n=6 (4%), 4 vs. 2 **TAE, n (%):** incidence of >2%=35 (24) vs. 41 (28) headache 6 (8) vs. 12 (17); dyspepsia 8 (11) vs. 9 (13); facial flushing 6 (8), vs. 7 (10); nasal congestion 6 (8) vs. 5 (7.1); backache 5 (7) vs. 3 (4); myalgia 3 (4) vs. 3 (4); dizziness 1(1) vs. 2 (3) **SAE:** n=4 MI, 2 in each tx arms **Ascertainment of outcomes assessed:** IIEF ED domain; SEP (Q 2 and 3); GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
McVary (2007) [128] **Funding source:** Lilly ICOS L.L.C.	**N screened =** 479 **N randomized =** 281 (65% ED pts) **IG, n =** 138 **CG, n =** 133 **ITT analysis used for primary outcome:** yes **Inclusion:** men 45 y or older with hx of LUTS secondary to BPH of 6 mo **Exclusion:** PSA > 10 ng/ml; hx of any pelvic surgery; neurological condition affecting bladder function; recent LUTS; hx of urethral obstruction; intravesical obstruction 2nd to the prostate median lobe; prostate cancer; PVR 200 ml or more; certain CVD; unstable angina; recent MI; poorly controlled BP or DM; sign renal or hepatic insufficiency; stroke or SCI; use of nitrates, chemotherapy, antiandrogens or potent cytochrome P450 3A4 inhibitor	**Age, mean (range):** 62 (45-82.4) y **Race:** White 81%; Black 9.6%; Hispanic 6.8%; Other 2.5 **Co-morbidities, n (%):** LUTS **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** mean baseline I-PSS score post placebo run in=17.9 (range 3-53)	**Concomitant medications, n (%):** pts agreed not to use any other BPH medication during the study; alpha-blocker tx 24% **Duration of ED:** reported as pts with ED of 1 y or longer 61.6% vs. 52.1% **Underlying disease, n (%):** LUTS **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%)**: NR **Note:** reported pts with ED: 99 (71.1%) in Tadalafil vs. 84 (59.2%) in placebo	**IG:** Tadalafil **CG:** Placebo **IG:** Dose: 5 mg; titrated to 20 mg at 6 wks Duration: 12 wks Frequency: Compliance: 100% of all pts with data (3% NR) **CG:** Dose: NA Duration: 12 wks Frequency: as IG Compliance: as IG **Run In period:** 4 wks single blind placebo **Wash out period:** NA **F/u duration:** 16 wks	**Primary outcome results:** IIEF-EF: Baseline mean: 13.7 vs. 14.3 Change from baseline (post run in), mean (SE) 6 wks: 6.0 (0.9) vs. 0.6 (0.9) 12 wks: 7.7 (0.9) vs. 1.4 (1.0) **Other outcomes assessed:** change from baseline in I-PSS score, mean (95% CI)= 1.7 (0.5, 2.9) at 6 wks and 2.1 (0.9, 3.3) at 12 wks; more pts in IG improved in this score compare to CG (49% vs. 6.4%, p=0.03) **Withdrawals/drop-outs/loss to f/u, n (%):** 30 (10.67); 18 (6.8%) in first period, 12 (4.5%) in second period (wk 6-12) **WDAE, n (%):** 5 (3.6) vs. 2 (1.4) **TAE, n (%):** NR; AEs were ▲ erection; dyspepsia back pain, headache, naso-pharyngitis, upper respiratory tract infection all more in IG **SAE, n (%):** 0 vs. 1 (0.7) **Ascertainment of outcomes assessed:** IIEF-EF; I-PSS; GAQ (post hoc analysis to examine changes at 6 and 12 wks vs. visit 2 before the placebo run in)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Mirone (2005) [129 130] **Funding source:** Lilly ICOS LLC`	**N screened =** 4568 **N randomized =** 4262 (crossover design) **IG1/ IG2, n=** 4262 **CG, n =** NA **ITT analysis used for primary outcome:** y **Inclusion**: age ≥18; at least 3-mo hx of ED of any severity or etiology; must have same female partner during study **Exclusion:** treatment with nitrates, cancer chemotherapy or anti-androgens; symptomatic congestive heart failure	**Age, mean (sd):** 55 (11) y **Race (%)**: white 97%, African descent 0.7%, western Asian 0.1%, Hispanic 0.1%, east/southeast Asian 0.1%, other 0.2% **Co-morbidities:** NR **Previous ED treatment**: another phosphodiesterase type 5, 2513; other ED treatment, 316 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR pts with < 1 yr 14.8%, ≥1 yr 85.2% **Underlying disease (%):** cardiovascular dx 32.9; (hypertension in 27), DM 18, hyperlipidemia 12.5, LUTS 9.5, depression 5.2, bilateral-nerve-sparing prostatectomy 3.8 **Psychogenic ED**: 18.1% **Physiologic ED:** 34.5% **Mixed ED**: 47.5%	**IG1:** tadalafil orally **IG2:** tadalafil orally **IG1:** Dose: 20 mg Duration: 5-6 wk Frequency: on demand before sexual activity (max. 1/d) Compliance: NR **IG2:** Dose: 20 mg Duration: 5-6 wk Frequency: 3 times/wk Compliance: NR **Run In period:** 3-4 wk **Wash out period:** 1 wk **F/u duration:** on treatment: 10-12 wk; after treatment: at least 2 wk **Other:** n=2108 assigned to on-demand first, followed by set dosage; n=2154 vice versa	**Primary outcome results:** IIEF, mean score, IG1 vs. IG2: EF: pre=14.3; post: 24.6 vs. 24.8 (% with scores ≥26 =60% vs. 62%) IC s: pre= 6.9; post 11.6 vs. 11.5 OF: pre=2.9; post: 8.3 vs. 8.4 OS: pre= 4.5; post: 7.8 vs. 7.9 SD: pre=6.7; post 7.5 vs. 7.5 SEP (% of pts with positive response): Q1: 68.7; post 91.4 vs. 92.8 Q2: pre=47.8; post: 84.1 vs. 85.6 Q3: pre=21; post: 73 vs. 74 Q4: pre= 6.5; post: 62.9 vs. 65.4 Q5: pre=5.7; post 60.3 vs. 62.8 **Other outcomes assessed:** Subjects' treatment preference **Withdrawals/drop-outs/loss to f/u:** 535 **WDAE:** 4.8% (detail NR) **TAE:** 926 (22) vs. 1078 (25), AE with at least 2% incidence included headache: 311 (7) vs. 329 (8); dyspepsia: 258 (6) vs. 299 (7); back pain: 110 (3) vs. 125 (3); flushing: 95 (2) vs. 123 (3); myalgia: 88 (2) vs.128 (3); upper abdominal pain: 64 (1) vs. 74 (2); AE in at least 0.4% in extension phase also reported (headache, dyspepsia, back pain) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, Sexual Encounter Profile (SEP) diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Montorsi (2004) [131] **Funding source:** Lilly ICOS LLC	**N screened =** 351 **N randomized =** 303 **IG, n =** 201 **CG, n =** 102 **ITT analysis used for primary outcome:** Yes **Inclusion**: bilateral nerve-sparing retro pubic radical prostatectomy 12-48 mo before screening; 65 or younger at time of surgery; postoperative prostate cancer pathological stage pT3 or less; development of ED after surgery **Exclusion:** ED due to other causes; clinically sign penile deformity; other prior pelvic surgery; penile implant; clinically sign renal or active, symptomatic hepatic dx; uncontrolled diabetes; unstable CV condition; nitrate therapy; detectable PSA level; prior or planned radiation or hormonal therapy for prostate cancer, hx of HIV infection; sign CNS injury	**Age, mean (sd):** 60 (5) y **Race, n (%)**: White: 186 (93) vs. 95 (93) **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** severity of ED, n (%): Mild 51 (25) vs. 27 (27); moderate 44 (22) vs. 22 (22; severe 106 (23) vs. 53 (52)	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** tadalafil -oral **CG:** placebo -oral **IG1:** Dose: 20 mg Duration: 12 wk Frequency: 1 dose before sexual activity (max. 1/d) Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: 1 dose before sexual activity (max. 1/d) Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** IG vs. CG Change in IIEF EF, mean (SEM): 5 (0.5) vs. 1 (0.6), p<0.001 SEP- Q2, mean (SEM) absolute change in positive response: 22% (2.4) vs. 9% (2.5) SEP- Q3: 23% (2.3) vs. 4% (2.3) GAQ: NR **Other outcomes assessed:** Mean ED Inventory of Treatment Satisfaction scores; ED outcomes also reported for subgrp of pts **Withdrawals/drop-outs/loss to f/u, n (%):** 66 (33), n=40 vs. n=26 **WDAE, %:** 5.5 vs. 2 **TAE, n (%):** 13 (65) vs. 16 (16); headache 42 (21) vs. 6 (6); dyspepsia 27 (13) vs. 1 (1); myalgia 13 (7) vs. 0; pack pain 9 (5) vs. 6 (6); nasal congestion 9 (5) vs. 1 (1); fatigue 7 (4) vs. 1 (1); flushing 7 (4) vs. 0; sinus congestion 5 (3) vs. 0; cough 4 (2) vs. 1 (1); gastroesophageal reflux dx 4 (2) vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF- SEP questionnaire **Other**: a priori subgrp of n=201 with postoperative penile tumescence 50% or greater positive response to SEP-Q1

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Nagao (2006) [132] **Funding source:** Lilly Research Laboratories	**N screened =** 382 **N randomized =** 343 (34 Centres in Japan) **IG1, n =** 85 **IG2=IG3, n =** 86/ grp **CG, n =** 86 **ITT analysis used for primary outcome:** yes (LOCF) **Inclusion:** men 20 or older with ED of at least 3 mo in duration **Exclusion:** ED due to primary sexual disorders, hx of radical prostatectomy, pelvic surgery, penile implantation or clinically sign penile deformity; renal insufficiency, HIV infection, CHD, recent hx of MI or coronary artery bypass, malignant hypertension; stroke, angina, or serious arrhythmia, severe hepatobiliary disease; tx with nitrates, alpha-blockers, cancer chemotherapy, or antiandrogens, hx of sign CNS injuries, past unresponsiveness to sildenafil	**Age, mean:** 55.1 y **Race:** 100% Asian **Co-morbidities, n (%):** hypertension 66 (25.7); DM 53 (20.6); benign prostatic hyperplasia 35 (13.6); hyperlipidemia 34 (13.2) **Previous ED treatment:** sildenafil tx 194 (56.3) **Smoking status:** 136 (39.7) **Body weight, mean:** 68.8 kg **Other:** alcohol consumption 259 (75.5)	**Concomitant medications, n (%):** NR **Duration of ED:** pts with ED of at least 1 y 303 (88.3) **Underlying disease, n (%):** no specific condition **Psychogenic ED, n (%):** 98 (28.6) **Physiologic ED, n (%):** 111 (32.4) **Mixed ED, n (%):** 134 (39.1) **Other:** ED severity, n (%): Mild 128 (37.3) Moderate 83 (24.2) Severe 132 (38.5)	**IG1-3:** Tadalafil (various doses) **CG:** Placebo **IG1-3:** Dose: 5 mg (IG1), 10 mg (IG2), 20 mg (IG3) Duration: 12 wks Frequency: as needed, up to one tablet/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** IIEF-EF, mean baseline score: 13.9 Post tx: 21.0 vs. 23.2 vs. 23.5 vs. 16.0 IIEF-EF, LS mean by ED severity: Mild: 26.6 vs. 26.0 vs. 25.3 vs. 21.1 Moderate: 22.7 vs. 24 vs. 23.0 vs. 15.5 Severe: 15.8 vs. 20.2 vs. 21.9 vs. 11.2 SEP-2 mean % Baseline (from graph): 45 Post tx: 71.2 vs. 81.3 vs. 84.1 vs. 53.6 SEP-3 mean per pts%: Baseline (graph): 15 Post tx: 51.7 vs. 64.6 vs. 69.4 vs. 27.8 GAQ, %: 76.5 vs. 81.4 vs. 83.7 vs. 31.4 **Other outcomes assessed:** SEP-2/3 post hoc analysis for ED severity grps **Withdrawals/drop-outs/loss to f/u, n (%):** 8 (9.4) vs. 7 (8) vs. 7 (8) vs. 19 (22); total IG vs. CG 22 (8.6) vs. 19 (22) **WDAE, n (%):** 3 (1.2) vs. 0 **TAE, n (%):** pts with 3% or more AE 104 (40.5) vs. 24 (86) Ocular hyperemia 3 (3.5) only in IG3 **SAE, n (%):** 3 (1.2) vs. 0 including acute prostatitis and pyelonephritis (IG2); mental disorder (IG3); uretral calculus (IG1) **Ascertainment of outcomes assessed:** IIEF, SEP, GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Porst (2003) [133] **Funding source:** Lilly ICOS LLC	**N screened =** NR **N randomized =** 348 **IG, n =** 175 **CG, n =** 173 **ITT analysis used for primary outcome:** Y **Inclusion:** men 18 or older, minimum 3 mo ED (defined as consistent change in the quality of erection adversely affecting the pts satisfaction with intercourse), in a stable monogamous relationship **Exclusion:** penile implants or clinically sign penile deformities, failure to achieve erection after radical prostatectomy or pelvis surgery, hx of stroke or spinal cord trauma in the past 6 mo, unstable cardiac disease, and concomitant antiandrogen use or chemotherapy	**Age, mean (sd):** 57 (NR), range: IG 22-80, CG 28-87 yr **Race (%):** White 93 vs. 95; African 8 vs. 2; Hispanic 4 vs. 7; other 1 vs. 0 **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: current smoker 25% vs. 23 **Body weight:** NR **Other:** alcohol use 57% vs. 61%	**Concomitant medications:** NR **Duration of ED (yr):** more than 1 y (in majority of pts) **Underlying disease:** NR **Psychogenic ED, %:** 13 vs. 18 **Physiologic ED, %:** 45 vs. 53 **Mixed ED, %:** 42% vs. 36% **Other:** severity of ED (IG vs. CG) mild 70% vs. 69%, moderate 45% vs. 43%, severe 60% vs. 61% (based on erectile domain of IIEF)	**IG1:** Tadalafil **CG:** Placebo **IG1:** Dose: 4 x 20 mg Duration: 8 wks (two 4 wk period, intercourse 24 hrs and 36 hrs after each dose in 1st and 2nd period respectively) Frequency: twice/ 4 wks Compliance: 98% **CG:** Dose: placebo Duration: same as IG Frequency: same as IG Compliance: 99.5% **Run In period:** **Wash out period**: 8-10 d between two doses in each 4 wk period **F/u duration:** 8 wks	**Primary outcome results:** Successful intercourse attempts, n (%): 24 hr: 120/227 (53) vs. 72/247 (29.), p<0.001 36 hr: 132/223 (59) vs. 60/212 (28), p<0.001 Patients with successful intercourse attempts, (%): 24 hr: 61 vs. 37, p<0.001 36 hr 64 vs. 35, p<0.001 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** n=21 **WDAE, n (%):** n=4, 3 (2) vs. 1 (0.5) **TAE, n (%):** 89 vs. 2; Headache 14 (8) vs. 2 (1), p=0.003, Flushing 10 (6) vs. 0, p=0.002 Dyspepsia 59 (34) vs. 0, p=0.004 Myalgia 6 (3) vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** Pts self report on Sexual Encounter Profile (SEP-Q3)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rajfer (2006) [134] **Funding source:** Lilly ICOS LLS.	**N screened =** 314 **N randomized =** 287(15 US Centres) **IG1, n =** 96 **IG2, n =** 97 **CG, n =** 94 **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 y or older, with ED at least 3 mo in duration caused by psychological, organic or mixed factors **Exclusion:** ED due to premature ejaculation or untreated endocrine disease, radical prostatectomy or pelvic surgery; penile implant or penile deformity; clinically sign renal or hepatic insufficiency; unstable angina; MI; coronary artery intervention; hx of heart problems; SBP > 170 or <90 mmHg, DBP >100 or <50 mmHg; hx of stroke, SCI; HIV infection	**Age, mean (range):** 60 (25.5-82.3) y **Race:** Caucasian 86%; Hispanic 5.6%; African decent 5.6%; Western Asian 1%; Other 1% **Co-morbidities, n (%):** CAD 30 (10.4); depression 22 (7.6); DM 40 (14); hyper-lipidemia 64(22.3); hypertension 123 (42.8) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** ED severity at baseline, % by IIEF: mild 35%; moderate 26%; sever 39%.	**Concomitant medications, n (%):** **Duration of ED:** 96.3% with ED of 12 mo or longer **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** 5 (5) vs. 2 (2) vs. 5 (5) **Physiologic ED, n (%):** 67 (70) vs. 67 (69) vs. 62 (66) **Mixed ED, n (%)**: 24 (25) vs. 28 (29) vs. 27 (29) **Other:** baseline ED defined as: consistent change in erection quality adversely affecting satisfaction with sexual intercourse)	**IG1:**Tadalafil low dose **IG2:**Tadalafil high dose **CG:** placebo **IG1:** Dose: 2.5 mg Duration: 24 wks Frequency: once/d Compliance: 94.8%* **IG2:** Dose: 5 mg Duration: 24 wks Frequency: once/d Compliance: 94.8%* **CG:** Dose: Duration: 24 wks Frequency: once/d Compliance: 94.8%* **Run In period:** 4 wks **Wash out period:** **F/u duration:** *Note: compliance met if >70% of doses were administered	**Primary outcome results:** IIEF-EF, mean baseline: 13.4 (1-28) all pts at 24 wks: 19.1 vs. 20.8 vs. 14.6 In mild ED: 24.3 vs. 26.2 vs. 20.8 In moderate ED: 21 vs. 21.9 vs. 14.3 In sever ED: 13.8 vs. 15.5 vs. 8.9 SEP-2, %: All pts at 24 wks: 65.3 vs. 70.7 vs. 51.1 Mild ED: 90.0 vs. 91.9 vs. 79.9 Moderate ED: 74.8 vs. 82.2 vs. 55.7 Severe ED: 38.9 vs. 44.9 vs. 20.1 SEP-3, %: All pts at 24 wks: 50.0 vs. 56.9 vs. 31.3 Mild ED: 72.5 vs. 82.2 vs. 56.7 Moderate ED: 56.3 vs. 61.3 vs. 27.3 Severe ED: 27.4 vs. 32.6 vs. 9.2 GAQ-1, % yes: 62.8 vs. 72.8 vs. 26.1 GAQ-2, % yes: 58.5 vs. 70.7 vs. 23.9 **Other outcomes assessed:** IIEF, IS domain; IIEF Q3, 4 **Withdrawals/drop-outs/loss to f/u, n (%):** 15 (15.6) vs. 16 (16.5) vs. 18(19) **WDAE, n (%):** 6(6.3) vs. 4(4.1) vs. 2(2.1) **TAE, n (%):** AE occurring in 3% or more 40 (42) vs. 35 (36) vs. 22 (23) **SAE:** pts with >/=1 SAE 2 vs. 3 vs. 2 including MI, fractures, an road traffic accident **Ascertainment of outcomes assessed:** IIEF-EF; SEP-2, 3;GAQ; PAIRS

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rodriguez (2006) [135] **Funding source:** NR (medication was not provided to pts)	**N screened =** NR **N randomized =** 132 (open label randomized) **IG1-6, n =** 22 per grp (each grp randomized to particular sequence in which they took the three tx) **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older, with heterosexual relations, mild to moderate ED of at least 6 mo in duration; naïve to PDE-5i **Exclusion:** hx of MI; or unstable angina; resting SBP >170 or <90; or DBP >110; retinitis pigmentosa or hx of hepatitis B or C; tx with androgens, cytochrome P-450-3 A4 inhibitors, or alpha blockers	**Age, mean (sd):** NR **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG1:** sildenafil **IG2:** vardenafil **IG3:** tadalafil **IG1:** Dose: 100 mg Duration: 45-60 d Frequency: at least 6 doses Compliance: NR **IG2:** Dose: 20 mg Duration: as IG1 Frequency: as IG1 Compliance: NR **IG3:** Dose: 20 mg Duration: as IG1 Frequency: as IG1 Compliance: NR **Run In period: NR** **Wash out period: 7 d** **F/u duration:** 3 mo (f/u at end of each tx period)	**Primary outcome results:** IIEF, median (percentile 10-90) Baseline: 17 (11-23) Sildenafil post tx: 29 (25-30) Vardenafil post tx: 28 (23.10-30) Tadalafil post tx: 30 (25-30) (baseline vs. post tx, p<0.0001) **Other outcomes assessed:** tx preference: Sildenafil 25 (28%) vardenafil 18 (20%) tadalafil 47 (52.22) **Withdrawals/drop-outs/loss to f/u, n (%):** 42 (31.8) **WDAE, n (%):** 5 (3.8) vs. 5 (3.8) vs. 2 (1.5) [pts stating they would not continue after study due to AE: 7(5.3%) vs. 2 (1.5%) vs. 4 (3)] **TAE:** NR AE reported, %: headache 11 vs. 12 vs. 9; flushing 8 vs. 3.3 vs. 4.4; dyspepsia 4.4 vs. 5.5 vs. 2.3; myalgia 0 vs. 0 vs. 4.4; nasal congestion 1.1 vs. 1.1 vs. 2.2; tachycardia 4.4 vs. 1.1 vs. 2.2; vision disorders 4.4 vs. 3.3 vs. 3.3 **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF, EDITS

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rosano (2005) [136] **Funding source:** Pfizer	**N screened =** 49 **N randomized =** 32 (Parallel double-blinded) **IG, n =** 16 **CG, n =** 16 **ITT analysis used for primary outcome:** NR **Inclusion**: men aged 59-71 y, with presence of more than 2 risk factors for coronary artery dx (CAD) regardless the degree of their ED; **Exclusion:** clinically sign findings on physical exam or presence of know clinically sign dx that would prejudice the completion of the study or contraindicate tadalafil assumptions; Recent acute MI, primary valvular, congenital heart dx; myocardial, pericardial or endocardial dx; congestive heart failure	**Age, mean (sd):** 65 (6) y **Race:** NR **Co-morbidities:** NR **Blood glucose, mean (sd):** sub grp (n=8) with type 2 diabetes 7 (0.5) HbA1C **Previous ED treatment**: NR **BMI (kg/m^2); mean (sd):** 25.4 (3.2) **Smoking status, n (%)**: 10 (31) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease, n (%):** Diabetes: 8 (25) Hypertension: 9 (28) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** only 16 (50%) had presence of ED	**IG:** Tadalafil (TAD) **CG:** Placebo **IG1:** Dose: 20mg Duration: 4 wks Frequency: every other d Compliance: 100% **CG:** Dose: Duration: 4 wks Frequency: every other d Compliance: 100% **Run In period:** 4wks **Wash out period:** None **F/u duration:** Baseline, end of each treatment, 2 wks after last tx	**Primary outcome results:** IG vs. CG, mean (sd) GAQ, (yes %) in IG, n=9; CG, n = 7: 8 (88) vs. 1 (14) Brachial artery diameter, baseline to 4 and 6 wks: basal-1, basal 2, nitroglycerine & hyperemia (mm): no sign change from baseline in either grps FMD, %: (sign▲ from baseline in IG only)= 4 (0.6) to 9 (0.3) vs. 4 (0.6) to 4 (0.9) **Other outcomes assessed**: endothelial marker, mean (sd): Serum nitrogen oxides 38 (12) to 53 (12) vs.36.5 (12) to 39 (8) µmol/l; endothelin-1: sign ▼ from baseline -12% vs. 20% p/ml Nitrite levels, (sign ▲ from baseline in IG only) 38% vs. 7% **Withdrawals/drop-outs/loss to f/u:** None **WDAE:** None **TAE, n (%):** IG, 2 (12) Dyspepsia, headache, back pain, pain, myalgia, spontaneous erection nasal congestion and infection **SAE:** None **Ascertainment of outcomes assessed:** GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rosen (2004) [137] **Funding source:** NR (Eli Lilly and company, and ICOS corporation were involved in editorial and critical review of manuscript)	**N screened =** NR **N randomized =** 233 **IG, n =** 74 **IG2, n =** 75 **CG, n =** 74 **ITT analysis used for primary outcome:** Y **Inclusion**: heterosexual men age 21 or older, with hx of ED for 3 mo or longer who were not using any other ED therapy during the study **Exclusion:** ED caused by untreated endocrine disorders, hx of penile implant or sign penile deformities, hx of radical prostatectomy, hepatic, renal, cardiovascular, or central nervous system disorders/injuries, treatment with nitrates, cancer chemotherapy or antiandrogens, current infection with any sexually transmitted disease, hx of drug, alcohol, or substance abuse within the past 6 mo, previous use of tadalafil	**Age, mean (sd):** 58 (11) vs. 59 (12) vs. 59 (11) yr **Race (%)**: White 87; African decent, 7; Asian, 2; Hispanic, 4 **Co-morbidities, n (%):** Hypertension, 24 (32) vs. 25 (33) vs. 35 (47) DM, 20 (27) vs. 23 (31) vs. 17 (23) Depression, 5 (67) vs. 11 (15) vs. 5 (7) Hyperlipidemia, 3 (4) vs. 4 (5) vs. 7 (10) **Previous ED treatment, n (%):** sildenafil 7 (10) vs. 5 (7) vs. 7 (10) **Smoking status:** NR **Body weight, mean (sd):** 94 (17) vs. 92 (18) vs. 91 (17) kg	**Concomitant medications:** NR **Duration of ED, n (%):** 3 mo or longer: 3 (4) vs. 0 vs. 1 (1) 6 mo or longer: 5 (7) vs. 8 (11) vs. 4 (5) 1 yr or longer: 66 (89) vs. 67 (89) vs. 69 (93) **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Tadalafil low dose- oral **IG2:** Tadalafil high dose- oral **CG:** placebo **IG1:** Dose: 10 mg (total=292 doses) Duration: 4-5 wks Frequency: 4 doses once every 8-10 d Compliance: NR **IG2:** Dose: 20 mg (total=300 doses) Duration: as IG1 Frequency: as IG1 Compliance: NR **CG:** Dose: Placebo (total=284 doses) Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 28 d no tx **Wash out period:** NR **F/u duration:** 30 min after dosing	**Primary outcome results:** SEP (Q3) yes response (mean %) - at 30 min: 25 vs. 34 vs. 18, (IG1 vs. CG p=0.054, IG2 vs. CG p=0.002) - at 16 min: 9 vs. 47 (16) vs. 22 (8) , (IG1 vs. CG p=0.05, IG2 vs. CG 0.012) **Other outcomes assessed:** minimum time to effect; post hoc analysis for dosing and ED severity **Withdrawals/drop-outs/loss to f/u, n (%):** 2 (2.7) vs. 1 (1.3) vs. 6 (8.1) **WDAE, n (%):** 1(1) vs. 1 (1) vs. 2 (3) **TAE, n (%):** incidence in 11 (15) vs. 13 (17) vs. 1 (1); AE included headache, 3 (4) vs. 6 (8) vs. 0; Myalgia 3 (4) vs. 1 (1) vs. 0; Dyspepsia = nausea = vasodialation1 (1) vs. 2 (3) vs. s0 Back pain, 2 (3) vs. 0 vs. 1 (1) **SAE:** NR **Ascertainment of outcomes assessed:** SEP (Q3) and patient diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sáenz de TeJada (2002) [138] **Funding source:** Lilly ICOS LLC	**N screened =** NR **N randomized =** 216 **IG1, n =** 73 IG2, n = 72 **CG, n =** 71 **ITT analysis used for primary outcome:** yes **Inclusion**: men 18 or older; clinical diagnosis of type 1 or 2 DM; mild to severe ED for ≥3 mo; in stable monogamous relationship with female partner **Exclusion:** pts with HbA1C > 13%recent hx of diabetic ketoacidosis; hypoglycaemia requiting assistance; angina during intercourse, unstable angina, dx of coronary artery dx, poorly controlled BP(for complete list of exclusion criteria refer to full text)	**Age, mean (sd):** 55.7 (9) y **Race, n (%):** White 215 (99.5); Black 1 (0.5) **Co-morbidities, n (%):** type I diabetes IG1 = CG 8 (11.3) vs. IG2 4 (5.6); type II DM 65 (89) vs. 68 (94.4) vs. 63 (88.7) Hypertension 80 (37); hypercholesterolemia 38 (18); micro-vascular complications in all grps 48 (22.2) **Previous ED treatment:** NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications, (%):** insulin only 36 vs. 28 vs. 45; oral only 44 vs. 54 vs. 41; mix 12 vs. 8 vs. 10 **Duration of ED, n (%):** > 1y: 201 (93) **Underlying disease:** diabetes; hypertension **Psychogenic ED:** NR **Physiologic ED:** all **Mixed ED**: NR **Other:** IIEF score overall, mean (sd)= 12.2 (6.2) **Other:** subgroup defined based on HbA1C levels: poor (>9.5%)= 40 (18.5), fair (7-9.5%)= 136 (63), good (<7%)= 40 (18.5)	**IG1:** Tadalafil oral **CG:** placebo oral **IG1:** Dose: 10 (IG1) or 20 (IG2) mg Duration: 12 wk Frequency: 1 dose before anticipated sexual activity; max. 1/d Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: 1 dose before anticipated sexual activity; max. 1/d Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 13-14 wk	**Primary outcome results:** IG1 vs. IG2 vs. CG Change (▲) in mean EF domain of IIEF: 6.4, vs. 7.3 vs. 0.1 (% of pts with more than 5 positive points in IIEF EF domain: 44% vs. 56% vs. 13%, p <0.001) Change (▲) in mean % of "yes" response: SEP-Q2: 22 vs. 23 vs. - 4.1 SEP-Q3: 28 vs. 29 vs. 2 GAQ, proportion of positive responses, (%): 56 vs. 64 vs. 25, p < 0.001 **Other outcomes assessed:** IIEFQ 3 and 4; OS, and OF (all sign post tx, values NR) **Withdrawals/drop-outs/loss to f/u:** 25 **WDAE:** 6 (3%); 5 in IG and 1 in CG; 2 MI one in each grp; moderate myalgia, pain, headache & flushing **TAE, n (%):** AE in > 3% of pts= 29 (40) vs. 32 (44) vs. 22 (31); dyspepsia 8 (11) vs. 8 (11) vs. 0; headache 9 (10) vs. 6 (8) vs. 2 (3), myalgia 4 (6) vs. 3 (4) vs. 1 (1), flu symptoms, IG=CG 3(4), back pain 1 (1) vs. 4 (6) vs. 1 (1), flushing 2 (3) vs. 3 (4) vs. 0 **SAE:** 2 (MI) (1 in either grp; however, patient in IG1 never took study drug) **Ascertainment of outcomes assessed:** IIEF, SEP, GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Saylan (2006) [139] **Funding source:** Lilly ICOS LLC	**N screened =** 139 **N randomized =** 132 (Egypt and Turkey) **IG, n =** 101 **CG, n =** 31 **ITT analysis used for primary outcome:** yes (LOCF) **Inclusion:** men at least 18 y, with ED of at least 3 mo in duration and any kind of severity and etiology **Exclusion:** ED caused by premature ejaculation or untreated endocrine disease, or after pelvic surgery or pts receiving nitrates, antiandrogens or chemotherapy, sign penile deformity or penile implant, clinically sign renal or hepatic insufficiency, poorly controlled DM; stroke, MI, or SCI, unstable cardiovascular disease; prior ineffective tx with sildenafil (physician discretion)	**Age, mean (range):** 48.7 (26.6-67.7) vs. 51.7 (27.8-66.1) y **Race:** Caucasians **Co-morbidities, n (%):** DM 21 (20.8) vs. 8 (25.8); hypertension 10 (9.9) vs. 7 (22.6); benign prostatic hyperplasia 4 (4.0) vs. 2 (6.5); hypercholesterolaemia 3 (3.0) vs. 1 (3.2); hyperlipidemia 1 (1.0) vs. 2 (6.5) UTI 1 (1.0) vs. 2 (6.5) **Previous ED treatment:** NR **Smoking status:** 25.6 vs. 32.3% **Body weight:** 82.35 kg **Other:** alcohol consumption <7%	**Concomitant medications, n (%):** **Duration of ED:** <6 mo: 14% >/=6 mo: 10 vs. 22.6% >/= 1 y: 75.2 vs. 64.5% **Underlying disease, n (%):** no specific condition **Psychogenic ED, n (%):** 11 (10.9) vs. 2 (6.5) **Physiologic ED, n (%):** 31 (30.7) vs. 9 (29) **Mixed ED, n (%):** 59 (58.4) vs. 20 (64.5) **Other:** ED severity, n (%): Mild 35 (34.7) vs. 11 (35.5) Moderate 38 (37.6) vs. 12 (38.7) Sever 28 (27.7) vs. 8 (25.8)	**IG:** Tadalafil **CG:** Placebo **IG:** Dose: 20 mg Duration: 12 wks Frequency: on demand, up to once/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks (3 visits)	**Primary outcome results:** Mean change from baseline (SE): IIEF-EF: 9.3 (0.8) vs. 2.3 (1.6) -By ED severity: Mild: 6.3 (n=32) vs. 0.2 (n=9) Moderate: 8.2 (n=37) vs. 0.3 (n=11) Severe: 14.8 (n=27) vs. 7.5 (n=8) IIEF-Q3: 1.5 (0.2) vs. 0.2 (0.3) IIEF-Q4: 2.0 (0.2) vs. 0.8 (0.3) IIEF-IS: 4.8 (0.3) vs. 2.3 (0.7) IIEF-OS: 3.6 (0.3) vs. 1.1 (0.6) SEP-2, %: 34.5 (4.1) vs. –4.6 (8.1) SEP-3, %: 52.2 (3.8) vs. 16.8 (7.8) GAQ-1, %: 81.2 vs. 41.9 GAQ-2, %: 76.2 vs. 41.9 **Other outcomes assessed:** SEP Q4-5 **Withdrawals/drop-outs/loss to f/u, n (%):** 17 (16.8) vs. 6 (19.4) **WDAE, n (%):** 4 (3.9) vs. 0 **TAE, n (%): NR** Most commonly reported, %: Headache 16.8 vs. 9.7; back pain 6.9 vs. 0; dyspepsia 2 vs. 6.5 **SAE, n (%):** 1 (1) vs. 0 (death cardiac arrest in a pts with multiple diseases) **Ascertainment of outcomes assessed:** IIEF, SEP, GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Seftel (2004) [140] **Funding source:** Lilly ICO LLC	**N screened =** 239 **N randomized =** 207 **IG1, n =** 159 **CG, n =** 48 **ITT analysis used for primary outcome:** Yes **Inclusion**: men 18 or older; at least 3-mo hx of mild to severe ED; stable relationship with female partner **Exclusion:** clinically sign penile deformity or penile implant; recent hx of stroke of SCI; hx of unstable CV dx in last 90 d; SBP >170 mm Hg or <90 mm Hg, or DPB>100 mm Hg or <50 mm Hg; clinically sign renal or hepatic insufficiency; failure to achieve erection after radical prostatectomy or pelvic surgery; tx with nitrates, antiandrogens or chemotherapy; prior ineffective tx with sildenafil	**Age, mean (sd):** **Race, n (%)**: White: 151 (73) African descent: 26 (16); 26 (16); Asian: 3 (1); Other: 1 (0.6) **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, n (%):** ≥1 y in duration148 (93) vs. 47 (98) **Underlying disease:** hypertension 75 (36); bbenign prostatic hyperplasia 58 (28); diabetes 36 (17); hyperlipidemia 37 (18); depression 13 (6); CAD 10 (0.5); peripheral vascular disease 1 (2) **Psychogenic ED, n (%)**: 16 (10) vs. 4 (8) **Physiologic ED, n (%):** 94 (59) vs. 24 (50) **Mixed ED, n (%):** 49 (31) vs. 20 (42) **Other:** baseline severity of ED= mild 43 (27) vs. 15 (31); moderate 42 (26) vs. 12 (25); severe 69 (43) vs. 20 (41)	**IG:** Tadalafil oral **CG:** placebo oral **IG:** Dose: 20 mg Duration: 12 wk Frequency: 1 dose before sexual intercourse (max. 1/day) Compliance: NR **CG:** Dose: placebo Duration: 12 wk Frequency: same as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** Change in IIEF, mean (sd): IIEF-EF: 9.3 (0.6) vs. 0.3 (0.9) Intercourse satisfaction: 4 (0.3) vs. 0.8 (0.4), OS: 3 (0.2) vs. 0 (0.3) Mean (sd) absolute change in positive response: SEP-Q2: 31.6% (2.5) vs. 2% (5.5) SEP-Q3: 43.6% (2.7) vs. 3.5% (4.2) SEP- Q4: 44 (3) vs. 6 (3) GAQ (improved erection), mean (sd) at 12 wk: 125 (83) vs. 9 (20) -Sign improvement in all IG vs. CG, p <0.001 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 31 (23 vs. 8) **WDAE:** 9; 8 (5.0%) vs. 1 (2) **TAE:** NR (AE (%)=headache: 16 vs. 6; back pain: 9 vs. 0; dyspepsia 8 vs. 0) **SAE, n:** 2 (chest pain) vs. 0 **Ascertainment of outcomes assessed:** IIEF- SEP (Q2 and 3)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Skoumal (2004) [141] **Funding source:** Eli Lilly and Company	**N screened =** NR **N randomized =** 409 **IG1, n =** 305 **CG, n =** 104 **ITT analysis used for primary outcome:** Yes **Inclusion**: men 18 or older, with at least 3-mo hx of mild to severe ED; same female partner throughout study **Exclusion:** ED due to premature ejaculation or untreated endocrine dx; failure to achieve erection after pelvic surgery, including radical prostatectomy (except bilateral nerve-sparing); sign penile deformity or penile implant; clinically sign renal or hepatic insufficiency; poorly controlled diabetes; unstable CA dx; recent hx of sign CNS injury; hx of HIV infection; exclusion of pts with prior ineffective tx with sildenafil was at discretion of investigators	**Age, mean (95% confidence interval):** 52 (51-53) vs. 52 (49-54) y **Race (%)**: NR **Co-morbidities, n (%):** hypertension 98 (32) vs. 31 (30); Diabetes 43 (14) vs. 9 (9); Prostatic hyperplasia/ hypertrophy 19 (6) vs. 11 (11); hypercholesterolemia 31 (10) vs. 9 (9); hyperlipidemia: 16 (5) vs. 3 (3) **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** less than 0.25 y - equal or more than 1 y (majority, 78 vs. 80% with 1 y or longer) **Underlying disease:** NR **Psychogenic ED, n (%):** 46 (15) vs. 19 (18) **Physiologic ED, n (%):** 89 (29) vs. 29 (28) **Mixed ED, n (%)**: 170 (56) vs. 56 (54) **Other:** baseline IIEF EF severity class, n (%)= mild 145 (48) vs. 49 (47); moderate 89 (29) vs. 31 (30); severe 71 (23) vs. 24 (23)	**IG1:** Tadalafil (Cialis$^{(R)}$) oral **CG:** placebo- oral **IG1:** Dose: 20 mg Duration: 12 wk Frequency: as needed (max. 1/day) Compliance (%): NR **CG:** Dose: placebo Duration: 12 wk Frequency: as needed (max. 1/day) Compliance (%): NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 12 wk	**Primary outcome results:** Mean change in IIEF score (and 95% confidence interval) EF: 10 (9-10.6) vs.1.4 (0.1-2.8) Intercourse satisfaction: 5 (4.4-5.1) vs. 1.4 (0.8-2.1) OF: 2 (1.9-2.6) vs. 0.2 (−0.4-0.8) SD: 1 (0.9-1.3) vs. 0 (−0.3-0.4) OS: 4 (3.4-4.0) vs. 0.7 (0.2-1.2) Mean absolute change SEP-Q2 (yes): approx. 2% vs. 35% SEP-Q3: IG1 approx. 53%, CG approx. 13% GAQ-1: 86% vs. 33% GAQ-2: 97% vs. 94% **Other outcomes assessed:** ED Inventory of Treatment Satisfaction scores **Withdrawals/drop-outs/loss to f/u, n (%):** 23 (6) **WDAE:** 1 vs. 0 **TAE, n (%):** >/= 2 events= 55 (18) vs. 3 (3); headache, back pain in 10 vs. 3%; flushing, influenza, and nasal congestion only in IG (9%) **SAE:** 2 (pulmonary embolism, subarachnoid hemorrhage) vs. 0 **Ascertainment of outcomes assessed:** IIEF ED domain, SEP (Q2, and 3); GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Staab (2004) [142] **Funding source:** Eli Lilly and Company	**N screened =** NR **N randomized =** 212 **IG, n =** 171 (2 mg =42, 5 mg= 44, 10 mg= 42, 25 mg =43) **CG, n=** 41 **ITT analysis used for primary outcome:** NR **Inclusion**: men18 or older; with ED for 3 mo or longer; in stable, monogamous, heterosexual relationship **Exclusion:** ED due to untreated endocrine disorder; hx of radical prostatectomy, with failure to achieve any erection; pelvic surgery; sign penile curvature; prior unsuccessful tx with phosphodiesterase type 5 inhibitors; hx of human immunodeficiency virus infection; poorly controlled diabetes; clinically sign hepatic, renal, cardiovascular or central nervous system dx during prior 6 mo	**Age, mean (sd):** 58 (10) y **Race, n (%)**: White 194 (92), African descent 10 (5), Asian 7 (3), other 1 (0.5) **Co-morbidities, n (%):** currently active cardiovascular condition 85 (40), hx of cardiovascular condition 8 (4), diabetes 44 (21) **Previous ED treatment**: NR **Smoking status, n (%):** Current smoker 40 (19) **Body weight, mean (sd):** 87 (14.5) kg	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** ED severity: mild 93 (44%); moderate 52 (25%); severe 67 (31%); no sign difference between IG	**IG1:** tadalafil -oral **CG:** placebo -oral **IG1:** Dose: 2, 5, 10 or 25 mg Duration: 8 wk Frequency: max. 1/day (1 dose before sexual intercourse) Compliance: NR **CG:** Dose: placebo Duration: 8 wk Frequency: as IG Compliance: NR **Run In period:** 4 wk **Wash out period:** NA **F/u duration:** 8 wk	**Primary outcome results:** IG (only reported for 25 mg grp) vs. CG: IIEF Q3, approximate % with score of 5: 75% vs. 20% IIEF Q4, approximate % with score of 5: 62% vs. 10% IIEF EF, mean score: 24 vs. 14 SEP Q3 - % positive response: 82% vs. 52% SEP Q4 - % positive response: 78% vs. 40% **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n:** 10 **WDAE, n:** 2 **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** IIEF questions 3 and 4: scored from 0 (no intercourse) to 5 (best performance) IIEF EF domain: sum of scores for questions 1-5 and 15 **Other**: results are shown in probability tables

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Von Keitz (2004) [143] **Funding source:** Lilly ICOS LLC	**N screened =** 299 **N randomized =** 219 (cross over drug preference) **IG1, n =** 105 **IG2, n** = 114 **CG, n =** NA **ITT analysis used for primary outcome:** No **Inclusion**: men 18-65, with ED for at least3 mo (consistent change in the quality of erection hat adversely affected the patient's satisfaction with sexual intercourse), in heterosexual relationship; also pts non-responsive to previous tx with sildenafil **Exclusion:** Pts treated with nitrates, recent hx of MI or coronary revascularization (within 90 d), rapid ejaculation, 6 mo or longer hx of unstable angina, ED secondary to endocrine disorders, pelvic surgery, stroke or SCI within the last 6 mo, retinitis pigmentosa, HIV infection	**Age, mean (sd):** 52.5 (9.3) y **Race (%)**: White 89, African 7, Hispanic 2, Asian 2 **Co-morbidities, (%):** hypertension 26, DM 17, depression 4, CAD 3 **Previous ED treatment:** sildenafil (66%) **Smoking status, (%):** current smokers= 29 **Body weight:** NR	**Concomitant medications:** CVD or diabetes (n = 54) **Duration of ED (yr):** => 1 yr (94%) **Underlying disease:** NR **Psychogenic ED**: 7% **Physiologic ED:** 42% **Mixed ED**: 51% **Other:** severity of ED (based on clinical judgement; %) = mild (18%), moderate (56%), severe (26%)	**IG1:** Tadalafil+ Tadalafil instruction 1st; Sildenafil + sildenafil instruction 2nd **IG2:** Sildenafil+ Sildenafil instruction 1st; Tadalafil + Sildenafil instruction 2nd **IG1:** Dose: 20 mg Duration: 12 wks/ period Frequency: once/d Compliance: NR **IG2:** Dose: 50 mg Duration: 12 wks/period Frequency: once/d Compliance: NR **Run In period:** 1 wk **Wash out period:** 1-2 wks (1st washout), 96 hrs 92nd washout post 24 wks prior to 12 wks extension period) **F/u duration:** 38 wks (2 x12 wks tx + 1-2 wks washout + 96 hrs no tx at end +12 wks extension **Other:** preference of dosing instructions also in two additional arms (n=36)	**Primary outcome (EF)**: No ED outcomes reported N (%) pts preferring tadalafil (over sildenafil) vs. N (%) pts preferring sildenafil (over tadalafil) = 132 (73) vs. 49 (27), p < 0.001 **Other outcomes assessed:** treatment preference by subgroups, AE **Withdrawals/drop-outs/loss to f/u, n (%):** 24 (23) vs. 28 (25); including total withdrawals17 (16) vs. 21 (18); lost to f/u 7 (7) vs. 7 (6) **WDAE, n (%):** 4 (4) vs. 3 (3) **TAE, n (%):** pts with 2 or more AE= 73 (70) vs. 57 (50); AE included headache 26 (12) vs. 17 (8); dyspepsia 14 (6) vs. 10 (5); back pain 9 (4) vs. 4 (2); myalgia 9 (4) vs. 1 (0.5); flushing 6 (3) vs. 8 (4); nasal congestion 6 (3) vs. 10 (5); influenza-like illness 3 (1) vs. 7 (3) **SAE:** NR **Ascertainment of outcomes assessed:** questionnaires to determine pts preference of tx

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Yip (2006) [144] **Funding source:** Lilly Research Laboratories	**N screened =** **N randomized =** 242 (17 centres across China) **IG1, n =** 159 **CG, n =** 83 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older with ED of at least 3 mo in duration of Psychogenic, organic or mixed causes **Exclusion:** ED caused by premature ejaculation, or untreated endocrine disease; pelvic surgery, including radical prostatectomy; penile deformity, or penile implant, renal or hepatic insufficiency, uncontrolled DM, unstable CVD, hx of central nervous system injury, HIV infection (discretionary criteria: prior ineffective tx with sildenafil)	**Age, mean (range):** 54 (28-78) y **Race:** East/Southeast Asian 97% **Co-morbidities, n (%):** DM 31%; hypertension 30%; benign prostatic hyperplasia 22.9% vs. 17.6; hypercholeserolemia 6% vs. 11% **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** 70.3 (9.4) vs.68.6 (9.5) kg	**Concomitant medications, n (%):** NR **Duration of ED:** pts with ED longer than 1 y, n (%) 131 (82.4) vs. 76 (91.6) **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** 22 (13.8) vs. 19 (22.9) **Physiologic ED, n (%):** 94 (59.1) vs. 54 (65.1) **Mixed ED, n (%):** 43 (27) vs. 10 (12) **ED severity, n (%):** severe 26%; moderate 33%; mild 41% Baseline IIEF-EF, mean: 14.9 vs. 14.8	**IG:** Tadalafil **CG:** placebo **IG1:** Dose: 20 mg Duration: 12 wks Frequency: on demand, up to once/d Compliance: NR **CG:** Dose: NA Duration: 12 wks Frequency: on demand, up to once/d Compliance: **Run In period:** 4 wks **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** Change in mean from baseline: IIEF-EF: 8.5 vs. 2.1, P<0.001 IIEF-Q3: 1.3 vs. 0.2, P<0.001 IIEF-Q4: 1.7 vs. 0.5, P<0.001 SEP-2, % yes: 30.1 vs. –1.2, P<0.001 SEP-3, % yes: 46.7 vs. 8.9, P<0.001 GAQ-1, % improved: 86.2 vs. 30.1 GAQ-2, % improved: 80.5 vs. 28.9 **Other outcomes assessed:** IIEF-EF based on severity of ED (% of pts in each grp), mean change in score: Mild (39% vs. 42%) 5.3 vs. –0.3 Moderate (35% vs. 30) 9.1 vs. 2.7 Severe (25.8% vs. 26.5%) 12.5 vs. 5.2 **Withdrawals/drop-outs/loss to f/u, n (%):** 12 (5) [5 (3) vs. 7 (8)] **WDAE, n (%):** 2 (<1) vs. 1 (<1) **TAE, n (%):** AE in 3% or more46 (28.9) vs. 6 (7.2); included headache, back pain, dizziness, dyspepsia, and myalgia **SAE, n (%):** 3 (1.8) vs. 1 (1.2) including a worsening of CAD, fractures and dengue fever in IG; DM & sepsis in CG **Ascertainment of outcomes assessed:** IIEF, GAQ, SEP

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Young (2005) [145] **Funding source:** Lilly ICOS LLC (Bothell, Wash and Indianapolis)	**N screened =** NR **N randomized =** 483 (phase III) **IG1, n =** 161 **IG2, n =** 161 **CC, n =** 161 Note: pts further sub-divided for efficacy analyses at 24 hr post dosing (n= 80) & 36 hr (n= 81) for all grps **ITT analysis used for primary outcome:** y **Inclusion**: at least 18 y of age, reported minimum of 3 mo hx of ED **Exclusion:** clinically sign. penile deformities or penile implants, a recent hx of stroke or spinal cord trauma, unstable cardiovascular status (e.g. unstable angina, myocardial infarction, or myocardial revascularization within 90 days), use of nitrates, cancer chemotherapy, or antiandrogens, failure to achieve erection following radical prostatectomy or pelvic surgery.	**Age, mean (range):** 57.4 (33-82) vs.58 (26-75) vs. 58(37-78) y **Race (%)**: Caucasian 80 vs. 87 vs. 83; African descent 10 vs. 8 vs. 14; Hispanic 8 vs. 5 vs. 2; other 2 vs. 0.6 vs. 2 **Co-morbidities, (%):** DM 8 (11) vs. 11 (7) vs.15 (9); hypertension 64 (40) vs. 64(40) vs. 60 (37); coronary artery disease 5 (3) vs. 8(5) vs. (5) **Previous ED treatment**: NR **Smoking status, n (%):** current smoker 27(17) vs. 26 (16) vs. 21(13) **Body weight**: NR	**Concomitant medications:** testosterone (total = 22 pts) during post baseline period **Duration of ED:** 3 mo **Underlying disease:** NR **Psychogenic ED, n (%):** 16 (10) vs. 14 (9) vs.16 (10) **Organic ED, n (%):** 109 (68) vs. 115 (71) vs.100 (62) **Mixed ED, n (%):** 36 (22) vs. 32 (20) vs. 45 (28)	**IG:** tadalafil, 10 mg, oral **IG2:** tadalafil, 20 mg, oral **CG:** oral placebo **IG** Dose: 10 mg Duration: 4-6 wks Frequency: 4 diff. times at 24 or 36 hrs post dosing, 7 d between each dose Compliance: NR **IG2** Dose: 20 mg Duration: 4-6 wks Frequency: as IG1 Compliance: NR **CG:** Dose: placebo Duration: 4-6 wks Frequency: as IG Compliance: NR **Run in period:** 4 wks + 2-4 wks equilibration phase **Wash out period:** 7 d **F/u duration:** 4-6 wks for efficacy6 mos open-label active medication extension – results NR)	**Primary outcome results:** SEP3, mean per pt % "yes" responses, % change): 24-hrs IG (55.8%, ▲ 25.5%, p = 0.038), IG2 (67.3%, ▲ 46.3%, p < 0.001) sign superior vs. CG (41.8%, ▲9.4%) 36-hrs IG (56.2%, ▲ 23.9%, p< 0.001), IG2 (61.9%, ▲28.7%, p<0.001) sign successful vs. CG (32.8%, ▲1.9%) **Other outcomes assessed:** SEP-Q1, 2,4,5 **Withdrawals/drop-outs/loss to f/u, n (%):** 23 (4.8%) **WDAE (%):** IG= 2, vs. CG= 0.6 **TAE** n (%)**:** AE in 2% or more= 37 (23) vs. 55 (34) vs. 9 (5.6); AE included headache 9 (6) vs. 17 (11) vs. 1 (0.6); back pain 11 (7) vs. 10 (6) vs. 1 (1); dyspepsia 6 (4) vs. 8 (5) vs. 1 (0.6); nasopharyngitis 8 (5) vs. 5 (3) vs. 5 (3); nasal congestion 3 (2) vs. 6 (4) vs. 0; upper respiratory tract infection 4 (3) vs. 5 (3) vs. 3 (2); myalgia 2 (1) vs. 5 (3) vs. 0; influenza 2(1) vs. 4 (3) vs. 3 (2). **SAE:** n=3, 1 death in IG2; 2 (NR) in CG **Ascertainment of outcomes assessed:** SEP3: "Did your erection last long enough for you to have successful intercourse?" [yes/no]

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

F4-Apomorphine (sublingual)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Dula (2000) [146] **Funding source:** TAP Holdings Inc.	**N screened =** NR **N randomized =** 569 **IG1, n =** 242 **IG2, n =** 119 **IG3, n =** 89 **CC, n =** 119 **ITT analysis used for primary outcome:** NR **Inclusion**: age 21-73; in stable heterosexual relationship for ≥6 mo; failed to achieve and maintain firm erections for satisfactory intercourse in ≥50% of attempts in last 3 mo **Exclusion:** MS; SCI; Parkinson's disease; hypogonadism; hyperprolactinemia; uncontrolled diabetes or hypertension; radical prostatectomy; major penile deformity or penile prosthesis; ED tx in preceding 3 mo; hx of drug or alcohol abuse within past 2 yr; AIDS or positive HIV test; hx of cancer; allergy to opiates; partner breast-feeding, pregnant or with hx of major affective disorder (IG1 vs. IG2 vs. IG3 vs. CG)	**Age, mean (range):** 55 (21-72) vs. 55 (37-71) vs. 55 (26-73) vs. 56 (25-71) y **Race,(range %)**: White 90-92%; African-American 1-7%; other 2-7% **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** % of pts with one or more of following hypertension 29%; diabetes 6%; benign prostatic hyperplasia 16%; CAD 12% **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** ED severity, (%): severe 35%; moderate 37%; mild 28% (determined by IIEF)	**IG1/2/3:** apomorphine - sublingually **CG:** placebo-sublingually **IG1/2/3:** Dose: IG1=2, 4, 5, 6 mg (dose optimizing grp); IG2= 5 mg; IG3=6 mg Duration: 8 wk (4 wk, dose adjustment + 4 wks steady dosefor IG1) Frequency: wk 1-4: 2-5 doses/wk; wk 5-8: ≥2 doses/wk Compliance: NR **CG:** Dose: placebo Duration: 8 wk Frequency: wk 1-4: 2-5 doses/wk; wk 5-8: ≥2 doses/wk Compliance: NR **Run In period:** None **Wash out period:** NA **F/u duration:** 8 wk	**Primary outcome results:** Erection firm enough for intercourse, (%): Baseline: 26 vs. 21 vs. 28 vs. 24 Post tx: 53 vs. 53 vs. 53 vs. 35 (▲ in %=27 vs. 32 vs. 25 vs. 11) Attempts resulting in erection firm enough for intercourse, (%): Baseline: 26 vs. 21 vs. 26 vs. 23 Post tx: 50 vs. 51 vs. 50 vs. 33 (▲ in %=24 vs. 34 v. 30 vs. 10) **Other outcomes assessed:** Partner rated erection; time to erection **Withdrawals/drop-outs/loss to f/u:** IG 111 (25), CG 14 (12) **WDAE:** 25 (10) vs. 8 (7) vs. 8 (9) vs. 1 (1) **TAE:** NR AE in 10% or more of pts, (%), [1st 4 wks; 2nd 4 wks]: nausea [25; 12] vs. [34; 12] vs. [44; 17] vs. [3; 0]; headaches [16; 6] vs. [12; 2] vs. [19; 6] vs. [10; 4] dizziness [11; 4] vs. [14; 4] vs. [16; 6] vs. [0; 0]; sweating [10; 5] vs. [10; 0] vs. 16; 1] vs. 1; 0]; yawning [10; 3] vs. [14; 0] vs. [16; 0] vs. [6; 0]; somnolence [7; 2] vs. 15; 4] vs. [11; 0]; [2; 1] Note: AE data reported for n=197 vs. n=94 vs. n=70 vs. n=105) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF; partners brief Sexual Functional Inventory

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Dula (2001) [147] **Study a** **Funding source:** TAP Pharmaceuticals Inc.	**N screened =** NR **N randomized =** 194 (cross over) **IG/CG, n =** 194 **ITT analysis used for primary outcome:** No **Inclusion**: male with ED 3 mo or longer, in stable sexual relationship 6 mo or longer; controlled diabetes, hypertension, benign prostate hypertrophy, and CAD **Exclusion:** unable to achieve at least 55% base rigidity for 10 min on at least once/ two nights; sign neurological dx, endocrine, genito/urinary or psychiatric dx, HIV, AIDS, cancer in remission; drug abuse, hypersensitivity to morphine, recent tx for ED, use of metoclopramide Introduction of or dose changes in anxiolytics, serotonin reuptake inhibitors, beta-blockers, thiazide diuretics, alpha-methyl dopa, clonidine; penile fibrosis; severe pyronie's dx, or prior penile prosthesis	**Age, mean (range):** 56.7 (27-72) y **Race n (%):** Caucasian: 166 (86) African-American: 13 (7) Hispanic: 13 (7) Other: 2 (1) **Co-morbidities, n (%):** Hypertension: 85 (44) Diabetes: 30 (16) Benign prostatic hypotrophy: 49 (25) CAD: 19 (10) None: 79 (41) **Previous ED treatment**: NR **Smoking status**: NR **Body weight mean, (range):** 179 (155-198) kg	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** severity of ED, n (%)= severe 62 (32), moderate 56 (29), mild 52 (27), none 1 (0.5), not specified 23 (12)	**IG:** sublingual formulation of apomorphine **CG:** placebo formulation **IG:** Dose: 3 mg Duration: 4 wks Frequency: minimum twice /wk with at least 8 hr in between doses Compliance: 84% **CG:** Dose: NA Duration: 4 wks Frequency: as IG Compliance: 84% **Run In period:** 2-4 wks **Wash out period:** 24-96 hrs **F/u duration:** NR	**Primary outcome results:** Percentage attempts resulting in erection firm enough for intercourse IG1: 46.9% CG: 32.3% IG1 significantly superior to CG across all severities of ED **Other outcomes assessed:** Time to erection **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE, n (%):** AE reported by 5% or more of pts= 61/185 (33) vs. 24/177 (14); including: nausea 13 (7) vs. 2 (1); yawning 15 (8) vs. 1 (0.6); dizziness 12 (7), vs. 6 (3); somnolence 9 (5) vs. 3 (2), headache 4 (2) vs. 8 (5); vasodilatation 4 (2) vs. 4 (2) **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan, home diaries, Brief Sexual Function Inventory, IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Dula (2001) [147] **Study b** **Funding source:** TAP Pharmaceuticals Inc.	**N screened =** NR **N randomized =** 102 (cross over) **IG1/IG2, n =** 102 **ITT analysis used for primary outcome:** No **Inclusion**: male with ED 3 mo or longer, in stable sexual relationship 6 mo or longer; controlled diabetes, hypertension, benign prostate hypertrophy, and CAD **Exclusion:** unable to achieve at least 55% base rigidity for 10 min on at least once/ 2 nights; sign neurological dx, endocrine, genito/urinary or psychiatric dx, HIV, AIDS, cancer in remission; drug abuse, hypersensitivity to morphine, recent tx for ED, use of metoclopramide Introduction of or dose changes in anxiolytics, serotonin reuptake inhibitors, beta-blockers, thiazide diuretics, alpha-methyl dopa, clonidine; penile fibrosis; severe pyronie's dx, or prior penile prosthesis	**Age, mean (range):** 57 (32-71) y **Race n (%)**: Caucasian: 87 (85) African-American: 9 (9) Hispanic: 5 (5) Other: 1 (1) **Co-morbidities, n (%):** hypertension: 35 (34) Diabetes: 12 (12) Benign prostatic hypertrophy: 20 (20) Coronary artery disease: 12 (12) None: 46 (45) **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (range):** 178 (155 – 199) kg	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** severity of ED, n (%)= severe 32 (31); moderate 35 (34); mild 20 (20); not specified 15 (14)	**IG1:** apomorphine-sublingual **IG2:** apomorphine-sublingual **IG1:** Dose: 3 mg Duration: 4 wks Frequency: minimum twice /wk with at least 8 hr in between doses Compliance: 78% **IG2:** Dose: 4 mg Duration: 4wks Frequency: as IG1 Compliance: 78% **Run In period:** 2-4 wks **Wash out period:** 24-96 hrs **F/u duration:** NR	**Primary outcome results:** Percentage of attempts resulting in erection firm enough for intercourse 49% vs. 50% **Other outcomes assessed:** Proportion of attempts culminating in successful intercourse **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE, n (%):** AE reported by 5% or more of pts= 23/90 (26) vs. 51/92 (55); included nausea 3 (3) vs. 13 (14); yawning 8 (9) vs. 12 (13); dizziness 2 (2) vs. 5 (5); somnolence 5 (6) vs. 9 (10); headache 4 (4) vs. 6 (7); vasodilatation 1 (1) vs. 6 (7) **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan, pts diaries, IIEF, Brief Sexual Function Inventory

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Eardley (2004) [148] **Funding source:** NR	**N screened =** NR **N randomized =** 139 (cross over open label) **IG1, n =** 66 (sildenafil - apomorphine) **IG2, n =** 65 (apomorphine - sildenafil) **CG randomized =** NA **ITT analysis used for primary outcome:** Yes (n=118) **Inclusion**: male pts with ED (Sexual Health Inventory-Male score <= 21) aged > 18 yrs, in a stable relationship **Exclusion**: pts taking concomitant nitrates, hypersensitivity to morphine, previous treatment for ED, concurrent dosing with the inhibitor of the CYP3A4 enzyme system, unstable CVD, hx of retinitis pigmentosa, and other major hepatic renal or haematological abnormalities	**Age, mean (range):** 57.6 (39-77) vs. 54.7 (28-82) y **Race**: White 92%; other 8% **Co-morbidities:** NR **Previous ED treatment**: None **Smoking status**: NR **Body weight, mean (sd):** 86 (17) vs. 87 (16) kg **Other:** mean height= 177 vs. 175 cm	**Concomitant medications:** None **Duration of ED, mean (range):** 4.7 (0.2-25) vs.3.3 (0.2-17) y **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** sildenafil (1st period)/ apomorphine (2nd) **IG2:** apomorphine (1st)/ sildenafil (2nd) **IG1:** Dose: NR Duration: 8 wks (given in 1st or 2nd period) Frequency: NR Compliance: n=5 pts did not take sildenafil **IG2:** Dose: NR Duration: 8 wks (given in 1st or 2nd period) Frequency: NR Compliance: n=8 pts did not take apomorphine **Run In period:** 2 wks **Wash out period:** 2 wks **F/u duration:** 8 wks for each drug; chronological = 18 wks (2 periods and wash out period combined)	**Primary outcome results:** Sildenafil vs. apomorphine, adjusted mean (95% CI): IIEF-EF score: Post tx: 25 (24-27) vs. 16 (14-17) Tx 9.3 (7.6-11) OS: Post tx: 8.5 (8- 9) vs. 6 (5.4-6.3) Tx difference: 2.7 (2- 3) EDITS 'successful intercourse attempts (% of pts): Post tx: 75 (69, 81) vs. 35 (29- 41) Tx difference: 40 (33, 46.5) EDTS, total score: Post tx: 82.5 (78-87) vs. 47 (42-52) Tx difference: 36 (30-41) **Other outcomes assessed:** OF, sexual desire; **Withdrawals/drop-outs/loss to f/u:** n = 21 **WDAE, n (%):** 5 (8); including n=2 (sildenafil), MI; postural hypotension, dizziness, & shortness of breath; n=3 (apomorphine), suspected MI; headache and blurred vision; nausea) **TAE:** 110 (in n=62) vs. 53 (in n=42) **SAE:** n=5, suspected MI, Dupuytren's contracture (apomorphine) vs. deterioration of an arthritic shoulder and MI, atrial fibrillation (sildenafil), one atrial fibrillation 30 d post end of tx **Ascertainment of outcomes assessed:** IIEF, EDITS

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gontero (2005) [149] **Funding source:** NR	**N screened =** 154 **N randomized =** 130 **IG, n =** 65 **CG, n =** 65 **ITT analysis used for primary outcome:** no **Inclusion**: diabetic men (type I and II) with hx of ED, lasting at least 3 mo. for which never received treatment **Exclusion:** any major psychiatric disorder, absence of stable partner, penile deformities, concomitant presence of a neurological disease (other than diabetes)	**Age, mean (sd):** IG 56.58(10.25), CG 56.05(9.65) **Race (%)**: NR **Co-morbidities:** ischemic heart disease 17 vs. 21; nitrates 5 vs. 7; hypertension 44 vs. 38; cholesterol (> 200) 22 vs. 21 **Blood glucose, mean (sd):** 8 (2) vs. 8(1.7) HbA1C **Previous ED treatment**: NA **Smoking status (%):** 34% vs. 38 **Body weight:** NR **Other:** diabetes (%): type I**=** 15 vs. 15; type II (insulin)= 47 vs. 41	**Concomitant medications:** NR **Duration of ED, mean. (sd):** 25 (26) vs. 23(19) mo **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** duration of diabetes, mean (sd): 12 (9) vs. 11 (8) y; Baseline IIEF-ER, mean (sd): responders=13 (6) vs. 13 (5); non-responders 13 (6) vs. 13 (6); pts with Erection grade 3 or higher, (%): responders 73 vs. 67; non-responders= 40 vs. 38	**IG:** apomorphine SL, oral **CG:** placebo, oral **IG:** Dose: 3 mg Duration: 4 wks Frequency: X1, 15 min before sexual intercourse, max= once in 8-hr period Compliance (%): non-responders= 45%; responders= 10% did not take all tablets **CG:** Dose: 3 mg Duration: 4 wks Frequency: as IG Compliance (%): non-responders= 50%; responders= 12% did not take all tablets **Run In period:** NA **Wash out period:** NA **F/u duration:** NA	**Primary outcome results:** IIEF- EF domain: 13.8(6) vs. 13.2 (6) IIEF- Q3 (erection sufficient for intercourse): 2 (1) vs. 2 (1) IIEF-Q4 (ability to maintain erection): 2 (1) vs. 2 (1) = no sign. differences for all variables p > 0.05 IIEF-GEQ: affirmation responses 25 %, vs. 21% (P=0.65) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** 9% vs. 5% (nausea) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF-questionnaire; GEQ, 1 item (yes or no), IIEF-EF domain was considered sign. if improved by 5 point

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Hagemann (2003) [150] **Funding source:** NR	**N screened =** NR **N randomized =** 12 **IG, n =** 6 **CG, n =** 6 **ITT analysis used for primary outcome:** NR **Inclusion**: Men with ED based on documentation of less than 50% successful attempts to attain and/or maintain an erection firm enough for intercourse with partner for a min of 90 d prior to study or if no attempts were made **Exclusion:** Men without ED	**Age, mean (range):** 35 (24-41) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status, n (%):** 6 (50) **Body weight, mean (range):** 82 (65-93) kg, **Other:** consumed alcohol, n (%)= 9 (75)	**Concomitant medications:** None **Duration of ED:** Min 90 d prior to study **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Apomorphine SL **CG:** Placebo **IG:** Dose: 4 mg Duration: 70 min Frequency: during Positron emission tomography (PET) procedures Compliance: 100% **CG:** Dose: placebo Duration: 70 min Frequency: as IG Compliance: 100% **Run In period:** None **Wash out period:** None **F/u duration:** NR	**Primary outcome results:** IG vs. CG n (%) RigiScan positive response 4 (67) vs. 0 (0) **Other outcomes assessed:** PET scan: ▲ cerebral activity post administration of apomorphine, associated with penile rigidity. **Withdrawals/drop-outs/loss to f/u:** None **WDAE:** None **TAE, n (%):** 0 vs. 2 (33) headache **SAE:** None **Ascertainment of outcomes assessed:** RigiScan monitoring penile rigidity during all PET procedures. (40%=positive response, below 40%=non-responsive) PET scan, 4 were performed in each pts following a 30 s video

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Lammers (2002) [151] **Funding source:** NR	**N screened =** 68 **N randomized =** 43 (4 way cross over) **IG1-4, n =** 43 **CG, n** = NA **ITT analysis used for primary outcome:** NR **Inclusion**: ED of ≥ 6mo, moderate to severe, in a stable monogamous heterosexual relationship, provided informed consent, informed partners of study participation **Exclusion:** ED caused by untreated endocrine dx, postural hypotension or uncontrolled hypotension, sign. penile pathology, hx of sign. hepatic or renal dx, CAD, nervous system dx, radical prostatectomy, uncontrolled psychiatric condition, known intolerance to study medications, concomitant use of organic nitrates, regular use of sympathetic-CNS depressors, blood donations (pts with ▼of >30% SBP, or DBP or ▲ of >30% HR after in office drug administration were withdrawn)	**Age, range:** 40-75 y **Race:** NR **Co-morbidities:** NR **Previous ED treatment:** many had used sildenafil, (and other study medications) **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (mo):** ≥ 6 mo **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** phentolamine + apomorphine **IG2:** phentolamin + papaverine **IG3:** phentolamine + papaverine + apomorphine **IG4:** sildenafil **IG1:** Dose: 40 mg + 6 mg Duration: NA Frequency: once (in office) **IG2:** Dose: 40 mg +150 mg Duration: NA Frequency: as IG1 **IG3:** 40 mg+150 mg +6 mg Duration: NA Frequency: as IG1 **IG4:** Dose: 100 mg (not blinded) Duration: NA Frequency: as IG1 Compliance (all): 100% **Run In period:** 4 wks placebo **Wash out period:** NA **F/u duration:** 60 min post tx	**Primary outcome results:** SEP, mean ▲ from baseline: 1.9 vs. 1.6 vs. 1.7 vs. 1.8 Successful vaginal penetrations, mean proportion: Baseline: 0.13 Post tx: 0.5 vs. 0.4 vs. 0.5 vs. 0.4 GAQ (1-5), mean score: 2.9 vs. 2.9 vs. 2.9 vs. 2.5 Rigidity by VAS (baseline = 17): 45 vs. 44 vs. 45 vs. 46 **Other outcomes assessed:** Tx preference, duration and satisfaction; vaginal intercourse leading to orgasm **Withdrawals/drop-outs/loss to f/u:** 1 **WDAE:** 0 **TAE:** 150 (in 19 pts) including CV events 2 (5) in IG3, and 2 (5%) in IG4 Most frequent AEs: rhinitis 4 (10) vs. 2 (5) vs. 6 (15) vs. 3 (8); headache 2 (5) vs. 1 (2) vs. 1(2) vs. 3 (8); dyspepsia 2 (5) only in IG3; nausea 2 (5) only in IG2 **SAE:** 1 hospitalization for right nephrectomy, (grp NR) **Ascertainment of outcomes assessed:** SEP; visual analogue scale of 0-100 (VAS), GAE, reports of AE

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Perimenis (2004) [152] **Funding source:** NR	**N screened** = NR **N randomized =** 40 **IG1, n =** 20 (apomorphine-sildenafil) **IG2, n =** 20 (sildenafil-apomorphine) **CG, n =** NA **ITT analysis used for primary outcome?** NR **Inclusion**: male outpatients with non-arteriogenic ED (repeated PSV 25 cm/s or higher), with a stable relationship of 6 mo or longer, age 18-80 yrs **Exclusion:** penile or testicular deformity, SCI, severe neurological dx, hormonal deficiency, severe BP abnormality or hx of retinitis pigmentosa, tx with vacuum devices, IC injections, testosterone or nitrates	**Age, mean:** 56. y, 95% CI= 53.9, 57.6 **Race:** NR **Co-morbidities, (%):** DM (17.5), hypertension (50), Ischemic cardiac disease (12.5), dyslipidaemia (37.5) **Previous ED treatment:** NR **Smoking status**: smokers (95%) **Body weight:** NR **Other:** mean IIEF-5 score = 17, 95%CI: 16.1, 18.4; mean PSV: 31.5 cm/s, 95% CI: 28.8, 33.1	**Concomitant medications:** pts were receiving medications to control comorbidities during trial (not specified) **Duration of ED, mean:** 9.2 mo, 95%CI: 7.1, 11.3 **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** non-arteriogenic 100% **Mixed ED**: NR	**IG1:** apomorphine **IG2:** sildenafil **IG1:** apomorphine Dose: 2-3 mg Duration: 6 wks (given in 1st or 2nd period) Frequency: once/d Compliance: NR **IG2:** sildenafil Dose:50-100 mg Duration: 6 wks (given in 1st or 2nd period) Frequency: once/d Compliance: NR **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** 6 wks for each drug; chronological = 13 wks (1,st 2nd periods, and wash out period combined) **Other:** for apomorphine and sildenafil the dose was titrated 2-3 mg and 50-100 mg respectively if the patient was not satisfied with the effectiveness	**Primary outcome results:** of successful intercourse attempts, n/N (%) = IG1: 326/520 (63%) IG2: 373/510 (73%), $p < 0.0004$ (two periods combined) **Other outcomes assessed:** tx satisfaction **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Questionnaires **Other**: the pts' response to 2 mg apomorphine & 50 mg sildenafil was age-related ($p < 0.05$), but not related to ED duration, PSV, or IIEF score

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Perimenis (2004) [153] **Funding source:** NR	**N screened =** NR **N randomized =** 43 **IG1 randomized =** 24 (apomorphine 1st period; sildenafil 2nd) **IG2 randomized =** 19 (sildenafil 1st, apomorphine 2nd) **CG randomized =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: male outpatients with ED with a stable relationship of 6 mo or longer, repeated PSV lower than 25 cm/s **Exclusion:** penile or testicular deformity, SCI, hormonal deficiency, severe blood pressure abnormality or hx of retinitis pigmentosa, tx with vacuum devices, IC injections, T or nitrates tx	**Age, mean (sd):** 59.2, 95%CI: 57.3, 61.2 **Race (%)**: NR **Co-morbidities, (%):** DM (17), hypertension (47), CVD (9), respiratory obstruction (5), transurethral prostatectomy (5), depression (2), heart failure (2) **Previous ED treatment**: NR **Smoking status**: smokers (95%) **Body weight:** NR **Other:** mean IIEF-5 score = 7.9, 95%CI: 7.07-8.74; mean penile PSV: 20.7 cm/s, 95%CI: 19.5, 21.9	**Concomitant medications:** pts were receiving medications to control co-morbidities during trial **Duration of ED, mean:** 19.3 mo, 95%CI: 13.1, 25.4 **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** arteriogenic 100% **Mixed ED**: NR	**IG1:** apomorphine **IG2:** sildenafil **IG1:** Dose: 2-3 mg Duration: 6 wks (given in 1st or 2nd period) Frequency: once/d Compliance: NR **IG2:** Dose:50-100 mg Duration: 6 wks (given in 1st or 2nd period) Frequency: once/d Compliance: NR **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** chronological = 13 wks (1, st 2nd periods, and wash out period combined) **Other:** for apomorphine and sildenafil the dose was titrated 2-3 mg and 50-100 mg respectively if not satisfied	**Primary outcome results:** Apomorphine vs. sildenafil of successful intercourse attempts, n/N (%) 1st + 2nd period= 189/588 (32%) vs. 375/589 (64%), p < 0.01 1st period= 31.3% vs. 62.6% 2nd period= 32.9% vs. 64.8% n/N (%) of successful intercourse attempts= **Other outcomes assessed:** satisfaction with tx **Withdrawals/drop-outs/loss to f/u:** n=2 (apomorphine) **WDAE:** n=2 (apomorphine) due to repeated nausea, syncope episode (in a pt who consumed alcohol) **TAE:** apomorphine: 6 (14%) including nausea, headache, dizziness and syncope vs. sildenafil: 3 (7%) including headache, dyspepsia **SAE:** NR **Ascertainment of outcomes assessed:** Questionnaires (event log)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Porst (2007) [154] **Funding source:** NR	**N screened =** NR **N randomized =** 131 (cross over) **IG1, IG2 n =** 131 (1:1 to either arms: IG1sildenafil then apomorphine n=68 vs. IG2 apomorphine then sildenafil, n=63) **CG:** NA **ITT analysis used for primary outcome:** yes (n=116) **Inclusion:** men with ED, IIEF-5 of 21 or lower, in stable relationship **Exclusion:** hypersensitivity or any components of study medication or to opiates, major genital deformities leading to difficulties in performing intercourse, serious CV conditions, ED tx known to induce side effects, alcohol or drug abuse within last 30 d also excluded	**Age, mean (sd):** 53 (12) y, range 22-77 y **Race:** White 98% Black 1%; other 1% **Co-morbidities, n (%):** hypertension 27.9%; DM 9.3%; dyslipidemia 7%; CAD 4.6%; **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** 85 (11.7) kg	**Concomitant medications, n (%):** NR **Duration of ED, mean (range):** 4.2 (0.2-30.6) vs. 3.5 (0.1-13.8) y **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** 18 (26.5) vs. 23 (37.7) **Physiologic ED, n (%):** 19 (27.9) vs. 17 (27.9) **Mixed ED, n (%)**: 31 (45.6) vs. 21 (34.4)	**IG1:** Sildenafil **IG2:** Apomorphine **IG1:** Dose: initial 50 mg (adjusted to 25-100 based on efficacy and tolerability after 4 wks; 55% titrated up and 5% titrated down) Duration: 8 wks Frequency: on demand Compliance: see dropouts **IG2:** Dose: initial 2 mg (adjusted to 2-3 afer 4 wks; 88% of pts titrated up) Duration: 8 wks Frequency: as IG Compliance: as IG **Run In period:** 2 wks **Wash out period:** 2 wks **F/u duration:** f/u measures at end of each 8 wks tx period	**Primary outcome results:** IIEF, mean sum score: EF: 23.6 vs. 12.8, P<0.0001 IS: 12 vs. 9.2, P<0.0001 OS: 8.2 vs. 5.7, P<0.0001 Individual IIEF questions mean difference from baseline (sd): Q2: 1.9 (1.5) vs. 0.6 (1.3) Q3: 1.8 (1.5) vs. 0.7 (1.2) Q4: 1.8 (1.6) vs. 0.6 (1.2) Successful intercourse attempts: 62.7% vs. 28.3% GEQ, % improved: 88.7% vs. 43.1% **Other outcomes assessed:** adjusted mean tx difference between grps **Withdrawals/drop-outs/loss to f/u, n (%):** 11 (8.4) did not complete the study; 15 (11) excluded from analysis; 8 completed one phase **WDAE, n (%):** 1 (0.8) **TAE, n:** 65 vs. 35; pts with AE= 45 (35.7) vs. 27 (21.8) most common were headache, flushing, dyspepsia and rhinitis vs. headache and nausea **SAE, n (%):** 2 (1.6) vs. 1 (0.8); including 1 death **Ascertainment of outcomes assessed:** IIEF, EDITS and GEQ, Q1 and Q2

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
von Keitz (2002) [155] **Funding source:** NR	**N screened =** NR **N randomized =** 507 **IG1, n =** 254 **CG, n =** 253 **ITT analysis used for primary outcome:** Y **Inclusion**: heterosexual; in stable health; aged 18-70; hx of ED; some intrinsic penile function; in stable sexual relationship for ≥6 mo **Exclusion:** MS, or SCI; hypogonadism; serum T < 8.3 nmol/L; uncontrolled diabetes; HbA_{1C} >10%; episode of ketoacidosis in last 3 mo; radical prostatectomy; penile prosthesis; penile deformity; pelvic surgery; uncontrolled hyper or hypotension; MI within last 6 mo; unstable angina; any major CV impairment; hx of drug of alcohol abuse; positive HIV or hepatitis B surface antigen; cancer with dx-free interval <5 yr; ED medication within last 2 wk prior to randomization; hx of allergic reaction to opiates	**Age, mean (range):** 55 (22-70) y **Race (%)**: white 99 **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications, (%):** used at least one medication, 63 vs. 51 **Duration of ED:** NR **Underlying disease, (%):** Hypertension 24 vs. 19 CAD 1 vs. 10 Diabetes 10 vs. 8 Benign prostatic hyperplasia 5.5 vs. 6 **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** apomorphine SL-sublingually **CG:** placebo sublingually **IG:** Dose: 2 mg initially, ▲ by 1 mg at 2 and 4 wk (forced dose escalation regimen) Duration: 8 wk Frequency: once/ 8 hrs 1/8 hrs Compliance: NR **CG:** Dose: placebo Duration: 8 wk Frequency: as IG Compliance: NR **Run In period:** None **Wash out period:** NA **F/u duration:** 8 wk	**Primary outcome results:** Erections sufficient for intercourse (%): 62 vs. 55 (p=0.021) Successful attempts resulting in sexual intercourse (%): Overall: 38 vs. 28 3 mg apomorphine vs. CG: 35 vs. 26 **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u, n (%):** 33 (13) vs. 33 (13) **WDAE, n (%):** 12 (5) vs. 4 (2) **TAE:** 400 (in n=158) vs. 131 (in n= 62) **SAE:** 9 in n=6; 3 events considered related to study drug: IG1: syncope and vomiting in n=1 CG: angina pectoris of moderate intensity in n=1 **Ascertainment of outcomes assessed:** diary card

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y=yes, N=no, NR=not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C5-Intracavernousal Injection Trials

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Allen (1992) [156] **Funding source:** NR	**N screened =** NR **N randomized =** 7 Cross over design **IG1/IG2/IG3, n =** 7 **CC, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: men with organic ED, abnormal nocturnal penile tumescence **Exclusion:** NR	**Age, mean (sd):** NR **Co-morbidities:** NR **Previous ED treatment:** Effective Papaverine + phentolamine IC ≥1 mo before **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** 0 **Physiologic ED:** 7 (100%) **Mixed ED**: 0	**IG1:** Papaverine + Phentolamine **IG2:** Papaverine + Phentolamine + PgE_1 **IG3:** Papaverine + PgE_1 **IG1:** Dose: Papaverine 30 mg/ml + phentolamine 5 mg/ml **IG2:** Dose: a + PgE_1 5 µg/ml **IG3:** Dose: Papaverine 30 mg/ml + PgE_1 5 µg/ml Frequency: two injections/d (a+ either b or c) Compliance, all: 86% **Run In period:** NR **Wash out period:** time to de-tumescence to be (<5 mm from baseline) at each test d; 1 wk between two test d, NR **F/u duration:** NA tumescene between injections	**Primary outcome results:** Duration: mean valued longer than a in IG3 (p=0.002), and trimix (p=0.001) Mean max rigidity: both combination of PgE1 better than (no sign) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 1 drop-out, post single intervention of 2 injections **WDAE:** NR **TAE:** NR **(**no pain observed) **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan for penile rigidity Erection duration timed: started when > 80% of max and stopped < 80% for ≥ 20 min

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Aversa (1996)[157] **A: (single-blind trial)** **Funding source:** NR	**N screened =** NR **N randomized =** 24 (cross over) **IG1/IG2, n =** 24 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: pts 20-45 yrs with non-organic ED => 6 mo duration (inability t achieve or maintain adequate erection for successful coitus), normal testicular size, no concomitant disease, no recent hx of drug abuse, normal cella turcica roentgenograms, normal results of neurological, vascular and clinical chemistry (3h glucose tolerance, liver and renal function tests), and normal basal serum levels (PRL < 25 ng/ml, testosterone> 653 nmol/l) **Exclusion**: NR	**Age, range:** NR (20-45) yrs (based on total sample from 2 separate trials (study a and b) **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: n=18 (total in 2 separate trials **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** => 6 mo **Underlying disease:** NR **Psychogenic ED**: 100% **Physiologic ED:** None **Mixed ED**: NR	**IG1:** PgE1 **IG2:** PgE1 + phentolamine **IG1:** Dose: 20 μg/ml Duration: NA Frequency: once Compliance: NR **IG2:** Dose: 20 μg/ml (PgE1) 0.5 μg/ml (phentolamine) Duration: NA Frequency: once Compliance: NR **Run In period:** 12 hr (no smoke, no coffee) **Wash out period:** 7 d **F/u duration:** 7 d (assessments done 15 min after the injections)	**Primary outcome results:** N (%) pts with full response (IG1 vs. IG2) = 5 (21%) vs. 13 (54%), p < 0.05 N (%) pts with partial response (IG1 vs. IG2) = 10 (42%) vs. 8 (33%), p = NR % pts with a valid-for-intromission erection (IG1 vs. IG2) = 63% vs. 87%, p < 0.05 Mean duration of erection (IG1 vs. IG2) = 112 (7.9) vs. 130 (8.5), p = NR **Other outcomes assessed:** level of anxiety **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** mild to moderate discomfort in 21%; prolonged erection in 2: 1 IG1 (4%); 1 in IG2 (4%) Note: % of pts reported for combined data, n=34 **SAE:** NR **Ascertainment of outcomes assessed:** questionnaires; axial rigidity by tonometer, and radial rigidity by RigiScan

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Aversa (1996) [157] **B:(single-blind trial)** **Funding source:** NR	**N screened =** NR **N randomized =** 10 (cross over) **IG1/ IG2, n=** 10 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: pts 20-45 y with non-organic ED => 6 mo duration (inability t achieve or maintain adequate erection for successful coitus), normal testicular size, no concomitant disease, no recent hx of drug abuse, normal cella turcica roentgenograms, normal results of neurological, vascular and clinical chemistry (3h glucose tolerance, liver and renal function tests), and normal basal serum levels (PRL < 25 ng/ml, testosterone> 653 nmol/l) **Exclusion**: NR	**Age, range:** (20-45) y (based on total sample from 2 separate trials **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: n=18 (total in 2 separate trials **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** => 6 mo **Underlying disease (diagnosis) (N or % of diseased/ grp):** NR **Psychogenic ED**: 100% **Physiologic ED:** None **Mixed ED**: NR	**IG1:** PgE1 **IG2:** PgE1 + phentolamine **IG1:** Dose: 25 μg/ml Duration: 7 d Frequency: NR Compliance: NR **IG2:** Dose: 25 μg/ml (PgE1) 0.5 μg/ml (phentolamine) Duration: 7 d Frequency: NR Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 7 d (assessments done 15 min after the injections)	**Primary outcome results:** N (%) pts with full response (IG1 vs. IG2) = 3 (30%) vs. 6 (60%), p < 0.05 N (%) pts with partial response (IG1 vs. IG2) = 3 (30%) vs. 3 (30%), p = NR % pts with a valid-for-intromission erection (IG1 vs. IG2) = 60% vs. 90%, p < 0.05 Mean duration of erection (IG1 vs. IG2) = 115 (8.5) vs. 135 (10.5), p = NR **Other outcomes assessed:** level of anxiety **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Baum (2000) [158] **Funding source:** Upjohn Pharmaceutical Company	**N screened =** 50 **N randomized =** 50 (parallel) **IG, n=** 25 **CG, n=** 25 **ITT analysis used for primary outcome:** No **Inclusion**: psychogenic ED, assessed by preservation of full, rigid morning or nocturnal erection and rigid erection with self-stimulation or masturbation **Exclusion:** endocrin cause of ED Data reported for IG vs. CG	**Age, mean:** 49.6 vs. 50.1 **Race (%)**: 64% White; 32% Black; 2% Hispanic; 2% Oriental **Co-morbidities:** NR **Previous ED treatment (n)**: IG1 vs. CG None 22 vs. 24 Oral medications 2 vs. 1 Vacuum or other device 1 vs. 0 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean:** 3.5 vs. 4.4 y **Underlying disease:** NR **Psychogenic ED:** 50 (100%) **Physiologic ED:** NR **Mixed ED:** NR	**IG:** Low dose PgE1 + information + instructional video **CG:** standard sex therapy **IG:** Dose: 2.5-5.0 µg (initial 2.5 µg + 2.5 µg after 60 min if erection <75% of pts normal erection, Optimum dose:produced erection lasting 60 min or more with rigidity adequate for intercourse) Duration: 12 wks Frequency: up to 3x/wk with at least 24 hr between doses Compliance: 52 % **CG:** Dose: up to 12 Duration: NR Frequency: 1x/wk Compliance: 64 **Run In period: NR** **Wash out period: NR** **F/u duration:** assessment at wks 4,8,12	**Primary outcome results:**IG vs. CG Improvement in obtain un-aid erection: 47% vs. 58% Duration of erection: 35 vs. 10 min sex situations producing erection: 63% vs. 82% Extremely satisfied with treatment: 69% vs. 75% Improvement in Sexual Life Quality Questionnaire Subscale: 74 vs. 71 points Frequency of intercourse: 20.5 vs. 20 **Other outcomes assessed:** Prediction of ability to perform 6 mo in future, cost comparison of treatment arms **Withdrawals/drop-outs/loss to f/u:** 12 (48%) vs. 9 (36%) **WDAE:** 0 **TAE:** penile bleeding & pain, n=1 in IG, n=1 report of ecchymosis also in IG **SAE:** NR **Ascertainment of outcomes assessed:** Sexuel Life Quality Questionnaire (SLQQ), RigiScan device

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Bechara (1996) [159] **Funding source:** NR	**N screened =** NR **N randomized =** 32 (crossover design) **IG1/IG2, n=** 32 **CG randomized =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: lack of response to 2 consecutive tests with papaverine plus phentolamine **Exclusion:** NR	**Age, mean (range):** 61 (26-71) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** 2.56, range 0.5-4.25 **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** PgE_1 + visual and manual stimulation **IG2:**Trimix + visual and manual sexual stimulation **CG:** NA **IG1:** Dose: 40 µg Duration: NR Frequency: 1 dose Compliance: NR **IG2:** Dose: 17.64 mg papaverine, 0.58 mg phentolamine, 5.8 µg PgE_1 Duration: NR Frequency: 1 dose Compliance: NR **Run In period:** NR **Wash out period:** ≥ 1 wk **F/u duration:** NR	**Primary outcome results:**examiner assessment of response on 5-point scale from E0 (no tumescence) to E5 (full rigidity) 15 min after injection Grade 4 or 5 erection IG1: 7 (22%) IG2: 16 (50%) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 15 **WDAE:** NR **TAE:** NR (Pain 41% vs. 12.5%) **SAE:** NR **Ascertainment of outcomes assessed:** NR **Other**: NA

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Bechara (1997) [160] **Funding source:** drugs by Farmacica	**N screened =** NR **N randomized =** 60 (cross over design) **IG/CG =** 60 (randomized into 6 grps, details of these grps NR) **ITT analysis used for primary outcome:** NR **Inclusion**: pts with hx of ED longer than 6 mo **Exclusion:** major neurological impairment secondary to SCI or radical pelvic surgery; previous use of self injected vasoactive drugs, or previous pharmacological erection test	**Age, mean (range):** 58 (22-6-78) y **Co-morbidities:** NR **Previous ED treatment:** NA **Smoking status**: NR **Body Weight** NR	**Concomitant medications:** NR **Duration of ED:** More than 6 mo **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Papaverine + phentolamine; **IG2:** PgE1 **CG:** placebo **IG1:** Dose: 30 mg/ml papaverine + 0.5 mg/ml phentolamine (1 ml solution) Duration: NA Frequency: once/ wkl Compliance: 100% **IG2:** Dose: 30 µg/ml prostaglandine (1 ml solution) Duration: NA Frequency: once/ wkl Compliance: 100% **CG:** Dose: placebo: 1 ml isotonic sodium chloride solution Duration: NA Frequency: once/ wkl Compliance: 100% **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** NR **Other:** Data provided for 3 intervetion type	**Primary outcome results:** Erection response (IG1 vs. IG2 vs. CG) [N erectile response (%)]: Grade 4: 20 (33) vs. 16 (27) vs. 0 Grade 5: 14 (23) vs. 14 (23) vs. 0 Grade 4+5: 34 (56) vs.30 (50) vs. 0 **Other outcomes assessed:** Systemic effects: No effects were noted **Withdrawals/drop-outs/loss to f/u:** n=0 **WDAE:** n=0 **TAE:** Total pts with AE: NR Prolonged erection lasting more than 3 hr, n (%): 11 (18) vs. 9 (15) vs. 0 Pain: 9 (15) vs. 21 (35) vs. 0 **SAE:** NR **Ascertainment of outcomes assessed:** Manual & visual sexual stimulation at 10, 20 and 30 min post injection-erectile responses classified as E0 = no tumefaction to E5=full rigidity (E4-5= positive, E0-3 = negative)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Buvat (1998) [161] **Funding source:** Schwarz Pharma A.G., Mannheim, Germany	**N screened =** 186 **N randomized =** 156 **IG1, n=** 81 **IG2, n=** 75 **CG, n=** NA **ITT analysis used for primary outcome:** NR **Inclusion**: Age 18-70 y; with ED of 6 mo or longer in duration **Exclusion:** Drug/alcohol addiction; presence of other severe disease (e.g. unstable angina, MI) within 3 mo before study start; urological pathology responsible for ED (e.g. hypospadias); ED of hormonal origin; concomitant treatment with other vasoactive agents; hx of Peyronie's disease' anatomical deformation of penis	**Age, mean (sd):** 53.7 (10.8) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (sd):** 4.5 (5.2) y **Underlying disease:** NR **Psychogenic ED, n (%)**: 73 (46%) **Physiologic ED:** 41 (26%) **Mixed ED, n (%):** 43 (28%) **Other:** NA	**IG1:** moxisylyte chlorhydrate **IG2:** PgE1 (alprostadil α-cyclodextrin) **IG1:** Dose: 10–20 mg Duration: 6 wk Frequency: up to 6 injections/ 6 wks Compliance: NR **IG2:** Dose: 10–20 µg Duration: 6 wk Frequency: up to 6 injections/ 6 wks Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 wk	**Primary outcome results:** IG 1 vs. IG2 Penile buckling test with axial loading force of 1 kg, (clinic): ≥ 1 positive test: 32 (40%) vs. 56 (75%) Occurrence of rigid erection after self-injection, (home): ≥1 positive test: 37/61 (61%) vs. 58/68 (85%) **Other outcomes assessed:** positive buckling test by subgroups of psychogenic s. physiologic vs. mixed Successful injections; patient & partner opinion of tx **Withdrawals/drop-outs/loss to f/u:** NR **WDAE** NR **TAE:**IG1 vs. IG2, (%): Pain during injection: clinic 15 vs. 15; home 13 vs. 25 Pain during erection: clinic 3 vs. 35; home 17 vs. 24 Pain after erection: clinic 0 vs. 5; home 7 vs. 19 Bleeding: clinic 3 vs. 5; home 3 vs. 15 Erection > 2 hr: clinic 0 vs. 2; home 5 vs. 4 Dizziness/hypotension: home 8 vs.1 **SAE:** 0 **Ascertainment of outcomes assessed:** NA

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Colli (1996)[162] **Funding source:**	**N screened =** NR **N randomized =** 45 (cross over) **IG1-3/ CG, n=** 45 **ITT analysis used for primary outcome?** No **Inclusion**: Men aged 18-65 yrs with ED of probable vascular, neurological and/or psychological origin of => 6 mo duration **Exclusion:** penile anatomical deformation, priapism or corporeal fibrosis, endocrine ED (serum testosterone < 120 ng/dl and PRL > 20 ng/ml), sickle cell anemia, hematologic diseases, systematic or psychiatric dx of recent onset, uncontrolled DM (fasting blood sugar > 300 mg/dl), uncontrolled hypertension (systolic > 150 and diastolic > 100 mmHg), hypotension (systolic < 100 mmHg), smokers (> 40 cigarettes/d), present use of PgE1	**Age, mean (sd):** NR (NR); 20% (< 40 yrs), 33.3% (40-49 yrs), 37.7% (50-59 yrs), 8.8% (=> 60 yrs) **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** <= 1 yr (22.2%) 1-2 yrs (31.1%) 2-5 yrs (22.2%) 5-10 yrs (20%) > 10 yrs (4.4%) **Underlying disease (diagnosis) (N or % of diseased/ grp):** diabetes 2 (4.4%) **Psychogenic ED**: 24 (53.3%) **Physiologic ED:** vascular 12 (26.6%), neurologic 2 (4.4%) **Mixed ED**: Mixed 5 (11.1%)	**IG1-3:** PgE1 (alprostadil) **CG:** placebo **IG1:** PgE1 Dose: 5 μg (IG1), 10 μg (IG2), 20 μg (IG3) Duration: NA Frequency: one/wk Compliance (%): NR **CG:** placebo Dose: NR Duration: NA Frequency: one/wk Compliance (%): NR **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** NR (assessments done 5-120 min after injection)	**Primary outcome results:** IG1 vs. IG2 vs. IG3 vs. CG 'Full' erection as assessed by clinical manual palpation (n): 12 vs. 23 vs. 4 vs. 0, p < 0.001 (likelihood ratio test for the treatment effect) 'No' erection as assessed by clinical manual palpation (n): 11 vs. 5 vs. 2 vs. 41, p < 0.001 (likelihood ratio test for the treatment effect) 'Excellent' erection- pts assessment (n): 5 vs. 9 vs. NR, vs. 0, p < 0.001 (likelihood ratio test for the treatment effect) 'Full' erection (70% or more rigidity at tip or base for 10 min), n: 17 vs. 25 vs. 7 vs. 0, p < 0.001 (likelihood ratio test for rigidity) **Other outcomes assessed:** latency of erection **Withdrawals/drop-outs/loss to f/u** NR **WDAE:** NR **TAE:** NR; AE reported as treatment-related n=3 (IG2) vs. n=1 (IG1) **SAE:** NR **Ascertainment of outcomes assessed:** manual palpation; RigiScan, questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Costa (1993) [163] **Funding source:** NR	**N screened** = NR **N randomized =**64 (cross over design: this grp received 3 single dose of active intervention a, b, c, & placebo **IG1/2/3/CG, n =** 64 **Inclusion**: Diagnosis of ED **ITT analysis used for primary outcome?** No **Exclusion:** Peyronie's disease; endocrine impotence; cardiac; renal; hepatic; ventilatory failure; systolic BP < 100 mm/Hg; neoplasm *Note: only values of IG3 is reported for outcome, since very similar to all other doses	**Age, mean (range):** 30 (20-50) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight**: NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: IG2=32 **Physiologic ED:** Neurogenic 12 (34%) **Mixed ED**: NR Other: neither psychogenic or hormonal in 50%	**IG1-3:** Moxisylyte in 3 dosages, tourniquet at penis base **CG:** Placebo (Lyophilized Mannitol) IC (tourniquet used) **IG1/IG2/IG3:** Dose: 10, 20 and 30 mg (2 ml volume) Duration: NA Frequency: single **CG:** Dose: 2 ml placebo Duration: NA Frequency: single Compliance all: 95% (n=61) **Run In period:** 1 mo **Wash out period:** 7-15 d **F/u duration:** 2 wks post last IC	**Primary outcome results:**IG3* vs. CG (Max at 15 min for all parameters) Penile length/ circumference, mean (SE): At 0 min: 113 (3) vs. 113 (3) mm/ 93 (2) vs. 91(2) mm At 30 min post tx: 135 (3) vs. 133 (3) mm/ 110 (3) vs. 98 (3) mm Erection sufficient for intercourse, n (%): 53 (87) vs. 17 (28) Duration of erection, mean (range): 2 hrs (50 min – 4 hr) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** N=3 **WDAE:** NR **TAE, n (%):** mild pain during injection 4(5); hypotension + nausea 1 (1.4); prolonged erection (24h) 1 (1.4); faintness + normal BP 2 (2.8); drowsiness with all dose 1(1.4); sharp pain at injection1 (1.4); Hot flushes 1 (1.4); Rhinorrhea 4 (5) **SAE:** 1 sustained erection (24h) 10cc aspirated at 6hr to avoid priapism **Ascertainment of outcomes assessed:** Patient & clinician evaluated erection rigidity/ parameters

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Dinsmore (1999) [164] **Funding source:** Senetek plc	**IG screened =** 236 **IG randomized =** 171 (parallel) **IG1/ CG, n=** 107 (ITT) **IG2/ CG, n =** 29 (ITT) **ITT analysis used for primary outcome:** Yes (per protocol analysis also reported) **Inclusion**: en 18 y or older, with ED of 1 y or longer in duration in stable heterosexual relationship **Exclusion:** overt psychogenic aetiology, ability to perform intercourse without medication or physical aid, hypoactive sexual dx, nocturnal or early morning erections, systemic dx, sickle-cell trait or dx; surgery, hormonal imbalance requiring treatment (except diabetes mellitus), angina pectoris, uncompensated congestive heart failure, hx of drug abuse (other exclusion lists could be found in the article) **Note:** Dose assessment phase: vasoactive intestinal polypeptide given by auto injector IC	**Age, mean (range):** 56.5 (25-81) y **Co-morbidities:** NR **Previous ED treatment (n)**: IC PgE-1 n=96; papaverine/PM n=64; Other (yohimbine, vacuum devices) n=19 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED (%):** 61% (arteriogenic 16%; DM 16%; neurogenic 16%; venous leakage 13%) Other 2% **Mixed ED**: 37%	**IG:** vasoactive intestinal polypeptide (VIP) + phentolamine meyslate (PM) **IG1/IG2:** Dose: 25 µg VIP, + 1mg (G1) or 2 mg (G2) phentolamine (dose of MP was established for each pts in the initial non-randomized dose assessment phase) in .35 mL volume Duration: 6 o Frequency: 10 injections in 6mo Compliance (96.5%) (n/grp): 136/141 **CG:** Dose: 35 mL solution Duration: as IG Frequency: two injections in 6 mo Compliance: as IG **Run In period:** NR **Wash out period:** at least 36hrs between injections **F/u duration (both on and off treatment):** NR	**Primary outcome results:** Erection suitable for intercourse (% of injections): IG1 75% vs. CG 12% IG2 66% vs. CG 18% Duration of erection, median in all grps: 56 min (range from 26 min in pts with venous leakage to 92 min in min in neurogenic pts) OS with drug (%) 88% (108/136) Satisfaction with auto-injector (%) 92% (111/136 participants) **Other outcomes assessed:** response of patients previously treated with one or more alternative therapies **Withdrawals/drop-outs/loss to f/u, n (%):** n=35 (30 never used injections and were removed) **WDAE, n (%):** 6 (4) **TAE: reported for dose assessment + RCT phase:** % of injections with at least one AE 65 vs. 68 vs. 27 (flushing 47 vs. 50 vs. 9; bruising in less than 8% of injections and pain experienced only on injection in 8% in CG alone; priapism in n=1 IG1 equal to 0.1% of 962 injections); AE experienced in 91% vs. 93% vs. 65% of pts **SAE:** 0 **Ascertainment of outcomes assessed:** Diary entries, F/u questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Earle (1990) [165] **Funding source:** NR	**N screened =** NR **N randomized =** 205 crossover design (1 & 2) **IG1/IG2, n=** 205 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: men with ED, (also included low testosterone men) **Exclusion:** NR Data reported for n=129 who completed the 1st injection	**Age, mean range:** 52-59 y **Co-morbidities:** Alcohol >420 gm/wk: 20 **Blood glucose:** ▲ glucose in diabetics n=6, & normal glucose n=15 **Previous ED treatment**: NR **Smoking status**: 18 smokers 55 ex-smokers **Body weight:** NR	**Concomitant medications:** 80/129 (33 on hypotensive/ cardio-active medication) **Duration of ED:** NR **Underlying disease:** Low testosterone (<11nmol/L) n=11 **Psychogenic ED**: Affective psychosis 1 **Physiologic ED:** n=80 Vascular 51; Lower back injury: 2; Diabetes 26; Bowel tumor resection: 1 **Mixed ED**: NR **Other: also** other causes of ED, idiopathic n=35	**IG1:** PgE_1 , Compressed base , massaged penis **IG2:** Papaverine, Compressed base, massaged penis **IG1:** Dose: 5 µg Duration: 5-10 s Frequency: once every mo for 2 mo Compliance: 83% for 1st injection; 100/129 (78%) for 2nd injection **IG2:** Dose: 18 mg Duration: as a Frequency: as a Compliance: as IG a **Run In period:** NR **Wash out period**: 1 mo **F/u duration:** 10-20 min post injection	**Primary outcome results:**Quality of erection, n (%): IG1 vs. IG2 No response: 0 vs. 5 (39) Partial erection: 95 (74) vs. 107 (83) Full erection: 34 (26) vs. 17 (13) (chi-square = 6.26, p<0.025) Attempts to intercourse on intervention, a vs. b Successful intercourse (4 wks): 40 (31%) vs. 43 (33%), chi-square = 0.077, (p > 0.05) **Other outcomes assessed:** self reported observations **Withdrawals/drop-outs/loss to f/u:** 76 (37% post initial IC); 29 (22%) dropout following 2nd intervention **WDAE:** NR **TAE:** NR [AE Pain during injection: IG1: 11 (8.5%) IG2 6 (4.7%) Prolonged erection: < 8 hrs: 1in IG2 (no event in IG1)] **SAE:** NR **Ascertainment of outcomes assessed:** patient report

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
El-Saleh (1995) [166] **Funding source:** NR	**N screened =** NR **N randomized =** 16 (cross over) **IG1/IG2/IG3, n =** 16 **ITT analysis used for primary outcome:** No **Inclusion**: Use of PGE1 to obtain erection suitable for intercourse **Exclusion:** NR Result of this study is presented in graphs. The data could not be extracted for this table.	**Age, mean (sd):** 59 (7.7) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (sd):** 82.73 (11.29), kg	**Concomitant Medications, n:** hypotensive drugs: 4 vitamins: 4 10 patients were on undisclosed prescribed medications **Duration of ED, mean (range):** 6.7 (2-16) y **Underlying disease, n:** Diabetes: 1 Multiple sclerosis: 1 Thyroidectomy: 1 Hx of musculoskeletal back injuries: 3 **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** PgE1 + digital compression by penile clamp **IG2:** PgE1 + hand compressin **IG3:** PgE1 with no compression **IG1/IG3:** Dose: mean (sd) 17.5 (16.5), range 2.5 to 50 µg (according to the dose used pre-trail) Duration: 3-5 s Frequency: total 3, once/d /tx Compliance: 100% **IG2:** Dose: NA (pressure = 100 mm Hg) Duration: 3.8-4.5 min Frequency: once Compliance: 100% **Run In period:** NR **Wash out period: NR (min** 3 d between any injections at home & clinic injection) **F/u duration:** NR	**Primary outcome results:**Erection (at least some degree of tumescence): 100% of pts; only 7/15 (47%) had response comparable to home injection result Presence of erection: no consistent evidence in favour of use of clamping or compression of any sort to obtain better erection Rating of erection in laboratory compared to erections at home: no consistent indication that clamp was more useful than being at home **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** n=1 (excluded from analysis due to withdrawal in IG1) **WDAE** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Patient perception, clinical palpation, RigiScan, pulse, BP

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Floth A (1991) [167] **Funding source:** NR	**N screened =** NR **N randomized** = 87 (two cross over design studies) **IG1 n =** 49 **IG2, n=** 38 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: NR **Exclusion:** NR Data reported for IG1 (a vs. b) vs. IG2 (a vs. b)	**Age, mean (sd):** 51(13) vs. 53 (12) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** Diabetes in 9 (18.9 %) **Psychogenic ED, n (%)**: 6 (12.3) vs. 4 (10.5) **Physiologic ED:** Arterial restriction: 32 (65.3) vs. 26 (68.4); venous leak: 8 (16.3) vs. 5 (13.2); neurogenic: 3 (6.1) vs. 3 (7.9); DM: 8 (16.3) vs. 1 (2.5) **Mixed ED**: Acknowledged but NR	**IG1** **a:** Papaverine + phentolamine **b:** Papaverine + PgE_1 **IG2:** **a:** PgE_1 alone **b:** same as IG1b **IG1 a:** Dose: papaverine 7.5 mg + phentolamine 0.25 mg Duration: NA Frequency: once **IG1 b/IG2 b:** Dose: papaverine 7.5 mg + PgE1 5 µg Duration: NA Frequency: once **IG2 a:** Dose: PgE1 10 µg + papaverine 7.5 mg Du ration: NA Frequency: once **Run In period:** NR **Wash out period:** 2 d **F/u duration:** NR	**Primary outcome:** a vs. b Time to erection, mean (sd): IG1: 8.6 (4) vs. 8.2 (5) min IG2: 7.3 (3) vs. 8.3 (5) min Duration of erection, mean (sd): IG1: 178.5 (133) vs. 146.6 (131) min IG2: 109.3 (61) vs. 124.3 (111) min Quality of erection (objective), n (%): IG1, between arms p< 0.01 score 1-2: 12 (25) vs. 6 (12) score 3: 9 (18) vs. 5 (10) score 4-5: 28 (57) vs. 38 (78) IG2, between arms, p= 0.03 score 1-2: 3 (8) vs. 2 (5) score 3: 12 (32) vs. 8 (21) score 4-5: 23 (61) vs. 28 (74) (b more effective than a) **Other outcomes assessed:** Duplex Ultrasound Peak velocity flow (no data) **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** 0 **TAE:** NR (AE Prolonged erection: > 5 hrs IG1: 4 vs. 4; IG2: 0 vs. 4 Pain: IG1: 0 vs. 8 (16.3%); IG2: 13 (34.2%) vs. 7 (18.4%) **SAE:** NR **Ascertainment of outcomes assessed:** Researcher observed erection scale 1-5:

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Fu (2004) [168] **Funding source:** NR	**N screened =** NR **N randomized =** 42 cross over **IG1/IG2, n=**42 **CG, n=** NA **ITT analysis used for primary outcome:** No **Inclusion**: normal range of serum testosterone, PRL, estradiol, FSH, LH and glucose **Exclusion:** neurogenic or endocrinopathic ED	**Age, mean (range):** 43.5 (27-65) yr **Race:** 100% Chinese **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** sodium nitroprusside IC **IG2:** papaverine + phentolamine by IC **IG1:** Dose: sodium nitroprusside 300 micrograms Duration: NA Frequency: once Compliance: NR **IG1:** Dose: papaverine 30 mg + phentolamine 1mg Duration: NA Frequency: once Compliance: NR **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** NR **Other:** *N of pts reported slightly different in the report*	**Primary outcome results:**Erection characteristics: in IG1: Length: ▲ 4.75 (1.45) cm Circumference ▲ 2.59 (1.65) cm Rigidity: all patients scored >10, with 25 >100 Duration of erection (scores >100): 24.23(7.96), range 15-45 min IG2: Length ▲ 4.00 (1.80) cm Circumference ▲ 2.71 (2.05) cm Rigidity: all patients scored >10, with 28 >100 Duration of erection (scores >100): 37.68 (15.36), range 20-55 min **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to follow:** NR **WDAE:** 0 **TAE:** IG1: 0; IG2: 3 had priapism, 15 had local pain **SAE:** 0 **Ascertainment of outcomes assessed:** physician assessment of outcomes

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Garceau (1996) [169] **Funding source:** NR	**N screened =** NR **N randomized =** 54 **IG/CG, n =** 54 **ITT analysis used for primary outcome:** Y **Inclusion:** men with ED, previous PgE1 treatment **Exclusion:** Hx priapism; Sickle Cell anemia or trait, Untreated endocrine disorders, Cavernosal fibrosis; anatomical deformation of penis, Peyronie's disease, thyroid condition causing ED; onset of acute illness, hx of Sexually Transmitted dx ≤ 6 mo, using hormonal or investigational medications, Previous use of IC to tx ED Note: baseline pts data reported for pooled data (n=365) of this RCT (n=54) and a dose titration study of n=294	**Age, mean (range):** 48.9 (21-75) y **Co-morbidities:** NR **Previous ED treatment:** 100% PgE_1 users **Smoking status:** NR **Body weight:** mean: 71 (range: 45 - 121) kg	**Concomitant medications:** NR **Duration of ED, mean (range):** 3.8 y (2 – 35 mo) **Underlying disease:** NR **Psychogenic ED:** 101 (27.7%) **Physiologic ED:** Vascular: 150 (41.1%) Neurogenic: 10 (2.7%) **Mixed ED:** 74 (20.3%) **Other:** 30 (8.2%) other causes	**IG1:** PgE_1 (in three formulation: aqueous injection, sterile powder, or Prostin VR $^{(R)}$) **CG:** placebo **IG:** Dose: 2.5, 5, 10 or 20 µg (randomized based on past dose, <10 mg to 2.5 or 5 µg; >10 µg to either Duration: NR Frequency: 3 (one injection of each formulation at assigned dose if randomized to IG) Compliance: NR **CG:** Dose: NR Duration: NR Frequency: once (?) Compliance all: NR **Run In period:** 3 wks (no PgE1 injections) **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** Optimal erectile response, n/N (%): 2.5 µg: 2/13 (15%) 5 µg: 10/16 (63%) 10 µg: 4/10 (40%) 20 µg: 10/15 (67%) CG: NR **Other outcomes assessed:** Optimal erectile response, latency of erection, duration of erection, time to complete de-tumescence, also reported for pooled population **Withdrawals/drop-outs/loss to f/u:** 1in due to pain post IC injection **WDAE:** NR **TAE: NR** AE: NR [Pooled data (n=365): 45 (12%) of pts experience drug related (as reported by authors) events; pain: 53 episodes in 39 (11%) pts] **SAE:** 0 **Ascertainment of outcomes assessed:** a five-point scale ranging from 0 ("not effective") to 4 ("very effective")

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gherchiu (1996) [170] **Funding source:** NR	**N screened =** NR **N randomized =** 11 (cross over) **IG1/IG2, n =** 11 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: pts with previous self injection of PGE1 at home **Exclusion:** NR	**Age, range:** 44-72 y **Co-morbidities:** NR **Previous ED treatment**: PGE1 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** fast injection of Pg E1 at **IG2:** slow injeciton of PgE1 **IG1/2:** Dose: NR (same does as at home use); injected in 5 s in IG1, and in 60 s in IG2 Duration: NA Frequency: single injection Compliance (%): 100% **Run In period:** NR **Wash out period:** 7 d **F/u duration:** NR	**Primary outcome results:** IG1 vs. IG2, mean (sd): Intensity of pain: 1.5 (1.8) vs. 0.6 (1.5), p = 0.04 Duration of pain: 29 (70.5) vs. 11 (27.5), p = 0.11 Note: n=1 experienced pain for 250 min (IG1), and 65 min (IG2); n=10 experienced pain for 25 min or less) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR **(AE** pain, n (%): n=8: 26(55%) vs. 2 (18%) **SAE:** NR **Ascertainment of outcomes assessed:** Intensity of pain by 10 point Likert scale (0 =no pain; 10 =worse pain)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Godschalk (1994)[171] **Funding source:** NR	**N screened =** 28 **N randomized =** 15 **IG/CG, n =** 15 (crossover design; 3 phases: phase I double blind; phase II and III nonblind. Non responders from phase I moved to phase II, responders of phase &II move to phase III) **ITT analysis used for primary outcome:** NR **Inclusion**: ED of all causes **Exclusion:** major illness within previous 6 mo; uncontrolled diabetes or hypertension; hypogonadism; laboratory value ≥ 25% above or below normal range; previous IC injections for treatment of ED Phase II / III may not be randomized	**Age, mean (sd):** 55.8 (9.2) **Race (%)**: white 7, black 7, Hispanic 1 **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** mean number of pts (sd) 2.7 (1.3) **Duration of ED (yr):** 7.61 (SD 9.85) **Underlying disease:** NR **Psychogenic ED**: 0 **Physiologic ED:** 15 **Mixed ED**: 0	**IG1:** PgE_1 **CG:** placebo **IG:/CG** Dose: Phase I: 0 (placebo) 2.5, 5, 7.5 and 10 µg Phase II: 12.5 (15-50) µg Phase III: mainenance dose Duration: 8 wks [4 wks (I & II); 4 wks (III)] Frequency: 2/wk; total Phase I=II: 10 doses **Run In period:** NR **Wash out period:** 0.5 wk **F/u duration:** 120 min post dosing	**Primary outcome results:**All means approximate Penile rigidity (%), from scale of 0-100%, phase I: IG, 2.5 µg 30%; 5 µg 47%, 7.5 µg 38%; 10 µg 43%(Overall in 5-10 µg dose: 40%) vs. CG: 7% Full erection (60% rigidity) or experienced intolerance in phase I, n: 6/15 (moved to phase III) Phase II, (n=8): Adequate erection, n: 4/8 (entered phase III) Phase III, (n=10): Partial or full erection, in 85% **Other outcomes assessed:** Rigidity (absent, partial or full) as assessed by palpation **Withdrawals/drop-outs/loss to f/u:** n=1 in phase II **WDAE:** 0 **TAE:** NR **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Godschalk (1996)[172] **Funding source:** NR	**N screened =** 13 **N randomized =** 10 (cross over) **IG1/IG2, n =** 10 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: 18-75 yr with ED who had experienced penile pain after at least 70% of IC PgE1 self injections at home **Exclusion:** recent major illness, uncontrolled hypertension, or diabetes, a hx of priapism, Peyronie's plaques or laboratory abnormalities greater than 25% above or below accepted normal ranges, use of analgesics	**Age, range:** 18-75 yr **Co-morbidities:** NR **Previous ED treatment**: Pg E1 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED:** NR	**IG1:** PgE1 + sodium bicarbonate (alkaline) **IG2:** PgE1 alone (acidic) **IG1:** Dose:PgE1 20 µg+ 42 mg/ml sodium bicarbonate, to reach PH of > 7 Duration: 2 d Frequency: single dose Compliance: 100% **IG2:** Dose: PgE1 20 µg Duration: as IG1 Frequecy: single dose Compliance: 100% **Run In period:** NR **Wash out period:** at least 1 d **F/u duration:** NR	**Primary outcome results:** IG1 vs. IG2, mean (sd): Degree of pain: 3.4 (2.9) vs. 2.7 (1.9), (p = 0.27) Duration of penile pain: 50.9 (45.3) vs. 56.9 (59.5) min, NS (p=0.37) Frequency of pain: ▼in in IG1 (not sign.) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** n=0 **WDAE** n=0 **TAE:** NR [AE, n (%): pain, IG1 vs. IG2, 70% vs. 80%; n=6 experienced pain with both injections] **SAE:** NR **Ascertainment of outcomes assessed:** Pain and its duration by pts filled questionnaire Severity of pain by 10 point Likert scale (0=no pain to 10=- worst pain)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gontero (2003) [173] **Funding source:** NR	**N screened =** 95 **N randomized =** 79 (parallel) **IG1, n =** 36 **IG2, n=** 37 **CG, n=** NA **ITT analysis used for primary outcome:** No **Inclusion**: Non-nerve sparing radical prostatectomy, diagnosis of localized prostate cancer, completion of IIEF **Exclusion:** NR	**Age, mean:** 65 y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications, n (%)** Adjuvant hormones; IG13 (8) vs. IG2 4 (11) Radiotherapy; IG1= IG2 4 (11) **Duration of ED:** NR **Underlying disease:** 100% Prostate cancer (palpable tumor) **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** PgE1 (early intervention) **IG2:** PgE1 (delayed intervention) **IG1:** Dose: 20 mg Duration: NA Frequency: once, 1-3 mo post operative Compliance: 100% **IG2:** Dose: 20 mg PgE1 Duration:NA Frequency: once, 4-12 mo post operative Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:**IG1 vs. IG2 Grade 3-4 erection post operatively, (%): IG1 80% vs. IG2 37% Mean visual analog scale (rating of discomfort with 0 = no pain and 10 maximal pain): 3.58 vs. 2.58 **Other outcomes assessed:** Pathological stage, Gleason score, concomitant adjuvant treatment; Peak systolic velocity < 30 cm/s (n/grp): 8/36 (22.2%) vs. 19/37 (51.3%) **Withdrawals/drop-outs/loss to f/u:** n=6 (2 excluded for high scores on IIEF, 4 refused to undergo Doppler ultrasound) **WDAE:** 0 **TAE: NR** **[**AE prolonged erection, in n=3 (IG1)] **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, Dynamic colour Doppler ultrasound, Grading of erection (0-4: 3=suboptimal rigidity, sufficient for penetration; 4= full rigidity for at least 20 min), Visual Analog Scale Score

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kattan (1991) [174] **Funding source:** NR	**N screened =** 54 **N randomized =** 50 Crossover design **IG1/IG2, n =** 50 split in two grps (1 & 2) of 25 to receive 1st intervention and then switched to the 2nd intervention **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: men with vasculogenic impotence who failed Papaverine **Exclusion:** NR	**Age, mean (sd):** 57.08 (7.41) **y** **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease (diagnosis) (N or % of diseased/grp):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** PgE_1 **IG2:** Papaverine **IG1:** Dose: 20 µg in 2 ml volume Duration: NA Frequency: Single Compliance: 100% **IG2:** Dose: 60 mg in 2 ml volume Duration: NA Frequency: single Compliance: 100 % **Run In period:** NR **Wash out period:** 1 wk= half life of drug **F/u duration:** NR	**Primary outcome results:**Researcher observed quality of erection, IG1 vs. IG2 Positive response: 34% vs. 2% (12% responded to both treatments) Satisfactory erection, (%): 46% vs. 14% **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 4 drop outs post first IC **WDAE:** 0 **TAE:** NR (Aepainat IC site < 10 min, (% of pts): 47% vs. 6%; Dizziness + headache: 2% vs. 4%) **SAE:** NR **Ascertainment of outcomes assessed:** Researcher observed quality of erection Partial or complete response vs. no response

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kattan (1995) [175] **Funding source:** NR	**N screened =** NR **N randomized =** 25 (crossover design) **IG1/IG2, n =** 25 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion:** NR **Exclusion:** Hx of MI; uncontrolled BP	**Age, mean (sd):** 53, range 40-60 **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease, n:** diabetes 17, heavy smoking (> 1 pack/day) 9, on antihypertensives 2, low serum testosterone levels 3, Peyronie's disease 1 **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** PgE_1 IC **IG2:** PgE_1 plus lidocaine hydrochloride IC **IG1:** Dose: 20 µg (+ manual sexual stimulation for 10 min after injection) Duration: NR Frequency: 1 dose Compliance: NR **IG2:** Dose: 20 µg PgE_1 + 1 cc lidocaine 1% (+ manual sexual stimulation for 10 min after injection) Duration: NR Frequency: 1 dose Compliance: NR **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** NR	**Primary outcome results:**Erection assessed by investigator on 4-point scale from 0 (none) to 3 (normal), (n) Grade 0: 2 vs. 2 Grade 1: 14 vs. 6 Grade 2 (adequate): 6 vs. 11 Grade 3: 0 vs. 3 Adequate erection, (% of pts): 27% vs. 64% **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** n=3 (2 due to AE) **WDAE:** 3 **TAE:** NR, (AE: pain in 22 (86% vs. 10 (45%); local edema at site of injection 1(5%) vs. 0) **SAE:** NR **Ascertainment of outcomes assessed:** NA

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kunelius (1998) [176] **Funding source:** NR	**N screened =** 30 **N randomized =** 30 (cross over) **IG1-3/CG, n =** 30 **ITT analysis used for primary outcome:** No **Inclusion**: NR **Exclusion:** NR	**Age, mean:** 55 (21-71) y **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: NR **Body weight:** NR	**Concomitant Medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Physiologic ED:** NR **Psychogenic ED:** NR **Mixed ED**: NR	**IG1:** papaverine **IG2:** PgE1 **IG 3:** moxisylyte **CG:** placebo **IG1:** Dose: 40 mg (1 mL) Duration: NA Frequency: once /visit Compliance: 100% **IG2:** Dose: 20 µg Duration: NA Frequency: once /visit Compliance: 100% **IG3:** Dose: 20 mg Duration: NA Frequency: once /visit Compliance: 100% **CG:** Dose: 1 mL saline Duration: NA Frequency: once /visit Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** 15 min post injection	**Primary outcome results:**IG1 vs. IG2 vs. IG3 vs. CG Tumescence: no difference between the agents Rigidity (maximal at tip (%▲): I20.7 vs. 33.9 vs. 14.2 vs. 0 Rigidity (maximal at base (%▲): 16.8 vs. 34 vs. 14.2 vs. 0 Clinician rating of erection, patients with grade 4/5, (%): 10 vs. 40 vs. 7 vs. NR Mean Duration of Erection (min) 13.4 vs. 40.2 vs. 6.5 vs. 0 **Other outcomes assessed:** BP, pulse rate, patient satisfaction with erections **Withdrawals/drop-outs/loss to f/u:** 0 **WAED:** 0 **TAE: NR** (AE: prolonged erection of > 2 hrs: 6 (20%); IG1 n=2, IG2 n=3; IG3 n=1 **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan device; pts filled questionnaire; degree of erection 0-5 (4 &5 sufficient for penetration)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Linet (1996) [177] **Funding source:** Upjohn Company	**N screened =** NR **N randomized =** 296 (parallel design) **IG1 n=**57 **IG2, n =** 60 **IG3, n=** 62 **IG4, n =** 58 **CG n =** 59 **ITT analysis used for primary outcome:** Y **Inclusion**: ED ≥ 4 mo **Exclusion:** penile deformity (including fibrosis); hx of priapism; sickle-cell trait; recent major illness; uncontrolled DM or hypertension; major psychiatric disorder; human immunodeficiency virus infection or other transmittable disease; heavy smoking (> 40 cigarettes/day); endocrine causes of ED	**Age, mean (range):** 54, (21-74) y **Co-morbidities:** NR **Previous ED treatment**: IC treatment 7 (2%) **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** 39 (13%) **Physiologic ED:** Vasculogenic 130 (44%) Neurogenic 39 (13%) **Mixed ED**: 86 (29%)	**IG1-4:** PgE1 (alprostadil) **CG:** placebo **IG1-4:** Dose: 2.5 (IG1), 5 (IG2), 10 (IG3) or 20 (IG4) µg Duration: NA Frequency: 1 dose Compliance: 100% **CG:** Dose: placebo Duration: NA Frequency: 1 dose Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** % of pts with Radial rigidity clinician assessment) (RigiScan data: / ≥ 70% rigidity at tip or base of penis lasting ≥ 10 min) IG: 2.5 µg approx. 17% (21%) 5 µg approx. 27% (31%) 10 µg approx. 45% (27%) 20 µg approx. 50% (48%) CG: 0 (0) Note: above numbers extracted from bar graph Duration of erection (mean) 2.5 µg, 12 min; 20 µg, 44 min, p<0.025 **Other outcomes assessed:** % of patients with satisfactory sexual activity (masturbation, and intercourse); **Withdrawals/drop-outs/loss to f/u:**0 **WDAE** 0 **TAE:** NR (AE: IG only: Penile pain 54 (23%); priapism 6 (**SAE:** n=1 death (reported to be unrelated to study drug) **Ascertainment of outcomes assessed:** RigiScan™ Ambulatory Rigidity and Tumescence System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Mahmoud (1992)[178] **Funding source:** NR	**N screened =** NR **N randomized** = 52 Cross over design (intervention a & b) **IG1/IG2, n =** 52 **CG, n =** NR **ITT analysis used for primary outcome:** NR **Inclusion**: pts who consulted clinic for erectile failure **Exclusion:** NR Notes 1-on eligibility: to compare drug safety 8 patients with hx of priapism with Papaverine IC were included in PgE1 arm & excluded from Papaverine arm 2-This trial includes n=2 with SCI 3- pts were categorized by subgroups according to probable cause of ED dx at baseline	**Age, mean (sd):** mean 48.6 (10.4) y **Race**: 100% Egyptian **Co-morbidities:** NR **Previous ED treatment**: Papaverine hydrochloride in 8 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NA **Duration of ED, mean (sd):** 2.98 (1.19) y, range 0.7 - 6 y **Underlying disease:** (> 5 yr): Hypertension 8; Diabetes 7 ; diabetes + hypertension 3 ; Transverse Myelitis:2 **SCI: 2** Radical cystectomy:1 Hyperprolactemia:5 **Psychogenic ED**: 10 (19%) **Physiologic ED:** Vasculogenic 24 (46%) Neurogenic ED 5 (10%) Endocrinological 5 (10%) **Mixed ED**: NR; Undetermined cause 8 (15%)	**IG1:** PgE_1 IC with hand pressure around base and massage of shaft. **IG2:** Papaverine hydrochloride IC as above **IG1:** Dose: 20 µg/ml Duration: NA Frequency: Single **IG2:** Dose: 30 or 60 (if failed with low dose) mg/ml Duration: NA Frequency: Single Compliance all grps 100% **Run In period:** NR **Wash out period:** 3 d interval between injections **F/u duration:** 24-48 hrs post IC unless priapism then seen at 3hrs	**Primary outcome results:**IG1 vs. IG2, n (%) Positive response in: 42 (81%) vs. 33 (63%) Negative response: 10 (19%) vs. 19 (37%) Results also reported for subgroup based on dx (i.e. underlying dx) Erection duration, mean (sd): 2.5 (0.4) hrs vs. 2.52 (0.72) hrs Time to full erection, mean (sd): 15.4 (5.4) vs. 10 (3.7) min **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** NR (AE: Penile pain: Tolerable: 6 (11.5%) vs. 13 (25%) Intolerable: 0 vs. 4 (7.7%) **SAE:** Priapism: 0 **Ascertainment of outcomes assessed:** Clinician measures of erection duration/angle; also rating of erections (positive/good ≥ 2hrs at nearly 90 degrees; negative/poor: < 2hrs at ≤ 90 degrees; negative/absent: no tumescence; Priapism:> 3 hrs)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Mancini (2004) [179] **Study a, and b** **Funding source:** NR	**N screened =** 97 **N randomized =** 56 (36 vasculogenic (a) & 20 non-vasculogenic (b) pts randomized independently into 3 & 2 grps respectively) a: Vasculogenic **IG1a n=** 12 **IG2a: n =** 12 **CG, n=** 12 b: Non-vasculogenic **IG1b , n=** 10 **IG2b , n-=** 10 **ITT analysis used for primary outcome:** NR **Inclusion**: pts with atherosclerosis, and ED verified with IIEF Questionnaire; duration of ED no more than 3 mo in duration **Exclusion:** Organic cause of ED apart from vasculopathy	**Age, mean range:** 54.6-59.6 y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** < 3 mo **Underlying disease:** IG1a & IG2a & CG: vasculogenic IG1b, IG2b: not vasculogenic **Psychogenic ED**: NR **Physiologic ED:** 56 **Mixed ED**: NR	**IG1:** PgE1 (alprostadil) **IG2:** oral Sildenafil: **CG** Placebo: (oral) **IG1(a & b):** Dose: 5-20 ug (dose assessment based on 1-3 injection to verify the dose inducing a full erction lasing 10 min) Duration: 1 mo Frequency: 1 /wk Compliance: 100% **IG2 (a & b):** Dose: 25 mg Duration: 1 mo Frequency: every night Compliance: 100% **CG:** Dose: placebo Duration: 1 mo Frequency: every night Compliance: 100% **Run In period:** 1 wk (dose assessment phase IG1 a & b) **Wash out period:** 1 wk **F/u duration:** 7d post last tx	**Primary outcome results:**Peak Systolic Velocity, mean (sd): IG1a: non sign. from baseline IG1b: pre 21(4) post 26(7). IG2a & b: non sign. from baseline CG: pre 20(5) post 28(9) Erectile rigidity (IIEF), mean (sd), pre vs. post treatment: IG1a: 15 (5) vs. 22 (3) IG1b: 13 (7) vs. 21 (9) IG2a: 13 (4) vs. 18 (3) IG2b: 11 (8) vs. 12 (11) CG: 15 (5) vs. 20 (6) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** n=1 in IG1a, excluded in dose assessment phase (no response to PgE1 injection) **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Duplex Sonography examination, IIEF-15 questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Martinez-Piñeiro (1995) [180] **Funding source:** NR	**N screened =** NR **N randomized =** 105 (crossover design, intervention 1 and 2) **IG1**, **n =** 10 **IG2**, **n =** 60 **IG3, n =** 35 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: ED **Exclusion:** NR	**Age, mean, (range):** 53.6 (27-79) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1-3:** PgE_1 IC [as first intervention (n=58); as second intervention, (n=57)] + one of 3 concentrations of sodium nitroprusside (SN) **IG1:** Dose: 20 µg cross over to 100 µg SN diluted in 5% dextrose Duration: NA Frequency: 1 dose of each Compliance: 100% **IG2:** Dose: 20 µg cross over to 300 µg SN diluted in 5% dextrose Duration: NA Frequency: as IG1 Compliance: 100% **IG3:** Dose: 20 µg cross over to 400 µg SN Duration: NA Frequency: as IG1 Compliance, all: 100% **Run In period:** NR **Wash out period:** 1-7 d **F/u duration:** NR	**Primary outcome results:**sodium nitroprusside 100 µg was not effective in producing erections Erectile response, % of pts, [no erection/ partial rigidity/ full rigidity]: IG2 (PgE1 vs. 300 µg): [25/ 55/ **20**] vs. [33/ 52/ **15**] IG3 (PgE1 vs. 400 µg): [29/ 51/ **20**] vs. [40 / 46/ **14**] Duration of erection: (PgE1 vs. 300 µg vs. 400 µg), mean (range): 88.5 (5-220) vs. 51(5-129) vs. 42 (5-129) min **Other outcomes assessed:** Time required to initiate tumescence; patient satisfaction **Withdrawals/drop-outs/loss to f/u:** n=0 **WDAE:** 0 **TAE:** NR AE, n (%): IG1 vs. IG2 vs. IG3PgE1 vs. SN 100 µg vs. SN 300 µg vs. SN 400 µg: Pain during injection: 7 (7) vs. 0 vs. 0 vs. 0; Dizziness: 4 (4) vs. 1 (10) vs. 5 (8) vs. 1 (3); haematoma: 1 (0.9) vs. 0 vs. 1 (2) vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** clinical & pts assessment

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Montorsi (1997) [181] **Funding source:** NR	**N screened =** NR **N randomized =** 30 **IG, n =** 15 **CG, n =** 15 **ITT analysis used for primary outcome:** NR **Inclusion**: men with clinically localized prostate cancer stage B1 or B2, Gleason sum 7 or greater, prostatic specific antigen cell less than 20 ng **Exclusion:** NR	**Age, mean (range):** 62 (49-68) yr **Co-morbidities:** NR **Previous ED treatment**: NA **Smoking status**: NR **Body weight:** NR **Other:** clinical stage: B1 n=18, B2 n=12; Mean Gleason sum at biopsy = 4.2 (3-6); mean preoperative PSA = 9.2 (2.1-18.2) ng/ml	**Concomitant medications:** NR **Duration of ED:** NA **Underlying disease:** Prostate cancer **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other**: CG: no post-operative ED n=2 (13%)	**IG:** PgE1 (alprostadil), self injection **CG:** No treatment **IG:** Dose: 2.5-14 µg (mean dose used 8 µg) Duration: 12 wks Frequency: 3 times/wk, total 36 injections Compliance: 80% **CG:** Dose: NA Duration: as IG Frequency: NA Compliance: all **Run In period:** 1 mo **Wash out period:** NA **F/u duration:** 12 wks	**Primary outcome results:** IG1 vs. CG Recovery of spontaneous injections at 3 mo, n (%): Full: 8 (67) respond (needed injections once/4 time) vs. 3 (20) (p<0.01); Partial respond: 3 (33) (needed to inject more than 50% of times) vs. 10 failures (67) Color Doppler test (normal hemodynamics in n=10 (83%) (all responders, 2 partial responders) vs. n=2 (all responders); cavernous veno-occlusive dysfunction n=2 (all partial responders) vs. n=8 (failures) CG: cavernous artery insufficiency n=2 (17%) **Other outcomes assessed:** Nocturnal erections (during a 3-night period); hemodynamic results **Withdrawals/drop-outs/loss to f/u, n:** 3 vs. 0 **WDAE: I**G: n=3 (20%), reduced sexual interest (n=2), penile nodule (n=1) **TAE:** IG1: n=3 with at least one AE: one event of cavernous haematoma in n=2 (13%); one event of prolonged erection in n=1 (6%); CG: no AE **SAE:** NR **Ascertainment of outcomes assessed:** Sexual hx, physical examination; hemodynamics post µg alprostadil + genital & audiovisual sexual stimulation; RigiScan

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Montorsi (1998) [182] **Funding source:** NR	**N screened =** NR **N randomized =** 20 (crossover design to interventions a & b) **IG n=** 20 **CG n=** NA **ITT analysis used for primary outcome:** NR **Inclusion**: pts who failed to produce an erection with 1 dose of PgE1 at initial session post randomization **Exclusion:** NR	**Age, mean (range):** 54 (42-66) y **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: 10 (50%) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 0.9, (0.6-3.2) y **Underlying disease, n (%):** diabetes 5 (25%), hypertension 4 (20%), coronary artery occlusive disease 4 (20%), hyperlipidemia 4 (20%) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**Intervention:** **a)** PgE1 (alprostadil) **b)** PgE1& genital + audiovisual sexual stimulation **IG a:** Dose: 10 µg Duration: NA Frequency: 2 doses 10 min apart Compliance: 100% **IG b:** Dose: 10 µg Duration: NA Frequency: 1 dose followed by stimulation 10 min later Compliance: 100% **Run In period:** NR **Wash out period:** 1 wk between sessions **F/u duration:** NA	**Primary outcome results:**5-min period of max response (penile rigidity & tumescence–circumferential expansion), expressed as area under the curve, mean (sd) IGa vs. IGb Tumescence base 60 (3) vs. 70 (2) Tumescence tip 28.0 (2) vs. 35 (1) Rigidity base 53 (2) vs. 66 (2) Rigidity tip 33 (2) vs. 40 (1) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 5 **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Moriel (1993) [183] **Funding source:** NR	**N screened =** NR **N randomized =** 38 (cross over) **IG1/IG2, n =** 19 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: ED **Exclusion:** NR	**Age, mean (range):** 55 (23-77) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** NA	**IG1:** Trimix + sodium bicarbonate **IG2:** Trimix **CG:** NA **IG1:** Dose: 6 mg papaverine, 100 µg phentolamine + 10 µg PgE_1 (trimix), 7.5% sodium bicarbonate (0.03 mEq) Duration: NA Frequency: 1 dose Compliance: 100% **IG2:** Dose: trimix as IG1 Duration: NA Frequency: 1 dose Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:**Erectile response, n (%) with positive response: IG1 15 (79%) vs. IG213 (68%) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE**: 0 **TAE:** Patients' experience of discomfort or pain: IG1: 1 (5%); IG2: 11 (58%) **SAE:** 0 **Ascertainment of outcomes assessed:** NR **Other**: Authors don't state how erectile response was evaluated.

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Ogrinc (1995) [184] **Study a** **Funding source:** Upjohn Company	**N screened =** NR **N randomized =** 153 (4-way cross over) **IG, n=** 153 (4 various doses) **CG, n =**NR **ITT analysis used for primary outcome:** NR **Inclusion**: ED ≥ 4 mo **Exclusion:** anatomical deformation of penis; penile fibrosis; hx of priapism; recent onset of major disease; uncontrolled diabetes or hypertension; major psychiatric disorder; excessive cigarette use; use of other investigational agents. Previous use of IC vasoactive agents permitted.	**Age, range:** 23-69 y **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** PgE1 (alprostadil) in four doses **CG:** placebo **IG:** Dose: 2.5, 5, 7.5 & 10 µg Duration: NR Frequency: single injection / dose in a randomized order Compliance: 100% **CG:** Dose: placebo IC Duration: NR Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:**Erection response (full, partial or none), IG vs. CG: NR Positive response (% of total injections): by clinical/ evaluation: 17% By RigiScan 15% **Other outcomes assessed:** Agreement vs. disagreement between clinical & RigiScan monitoring: --Using 70% axial rigidity as criteria: agreement: 418/521 injections (80%)/ Disagreements: 17% present by clinical evaluation only; 3% erection present by RigiScan only --Using 60% axial rigidity as criteria: 422/521 injections (80%)/ 11% Sensitivity, RigiScan = 47.6% (80/168 with clinical response) Specifity, RigiScan: 95.8% (338/353 injections) **Withdrawals/drop-outs/loss to f/u:** n=25 **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan™ & clinical (palpation) evaluation

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Ogrinc (1995) [184] **Study b** **Funding source:** Upjohn Company	**N screened =** NR **N randomized =** 296 (parallel design) **IG, n =** 237 **CG, n=** 59 **ITT analysis used for primary outcome:** NR **Inclusion**: ED ≥ 4 mo **Exclusion:** anatomical deformation of penis; penile fibrosis; hx of priapism; recent onset of major disease; uncontrolled diabetes or hypertension; major psychiatric disorder; excessive cigarette use; use of other investigational agents. Previous use of IC vasoactive agents permitted.	**Age, range:** 21-74 y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/grp):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** IC PgE1 (alprostadil) in four various doses **CG:** IC placebo **IG:** Dose: 2.5, 5, 7.5 or 10 µg Duration: NR Frequency: single injection Compliance: NR **CG:** Dose: placebo Duration: NR Frequency: 1 dose Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 2 hr	**Primary outcome results:** Erection response (full, partial or none), 59 non response in CG (excluded from study) Positive response (% of total injections): by clinical/ evaluation: 11% By RigiScan: 23% **Other outcomes assessed:** Agreement vs. disagreement between clinical & RigiScan monitoring: --using 70% axial rigidity as criteria: agreement: 184/231injections (49.6%) disagreements: .11.3% erection present for clinical evaluation only; 9% erection noted by RigiScan criteria only --using 60% axial rigidity as criteria: agreement: 182/231 injections (79%) disagreements: 5.6% erection noted by clinical not RigiScan; 16% erection noted by RigiScan only Sensitivity, RigiScan = 67% (53/79 with clinical response) Specifity, RigiScan: 82% (131/152 injections) **Withdrawals/drop-outs/loss to f/u:** 6 (all IG) **WDAE** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System, & clinical (palpation) evaluation

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Porst (1993) [185] **Funding source:** NR	**N screened =** NR **N randomized** = 40 crossover design, a & b **IG1, n=** 40 **IG2, n=** non-randomized grp, nonresponders of IGa+ IGb: 5 **ITT analysis used for primary outcome?** No **Inclusion**: men with ED, age 23-78 y (eligibility criteria not described in detail) **Exclusion:** NR This study a diagnostic evaluation of corpus cavernosal function	**Age, mean (range):** 55.9 (23-78) **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease, n (%):** Diabetes 6 (15) Coronary heart disease 5 (12.5); hypertension: 9 (22.5); occlusive artery disease of lower limbs: 3 (7.5); cerebral infarction: 2 (5); post transurethral prostatectomy: 5 (12.5); radical prostatectomy: 2 (5 Rectum amputation: 1 (2.5) **Psychogenic ED:** 60% **Physiologic ED:** 40% **Mixed ED**: NR	**IG1:** PgE_1 **IG2:** nitric oxide donor linsidomine **IG1:** Dose: 20 µg Duration: NA Frequency: once Compliance (%): 100 **IG2:** Dose: 1 mg Duration: NA Frequency: once Compliance (%): 100 **Run In period:** NR **Wash out period:** ≥ 48 hrs between dose **F/u duration:** NR	**Primary outcome:** ▲ peak flow: averaged 1/3 less in IG1 vs. IG2 With < 30 cm/sec, in right / left arteries: Pathological values (%): IG1= 17.9% / 17.9 % IG2 a= 64.1% / 56.4% IG2 b: no erection observed in 5 (100%) Patient reported effectiveness of intervention, n (%) IG2 > effective IG1: 0 (0%) IG1= IG2: 4 (10%) IG1 slightly superior IG2: 6 (15%) IG1 Moderately superior IG2: 8 (20%) IG1 much superior IG2: 22 (55%) Researcher rated erection: IG1 vs. IG2: No erection: 0 vs. 3 (7%) Tumescence: 7 (17.5%) vs. 23 (57.5%) Semirigid: 7 (17.5%) vs. 9 (22.5%) Full: 26 (65%) vs. 5 (12.5%) **Other outcomes assessed:** peak systolic velocity **Withdrawals/drop-outs/loss to f/u:** 1 (2.5%) not included in analysis **WDAE:** NR **TAE:** Unpleasant tenseness or pain in penis: 17.5% Vs. NR Moderate/severe headache: NR vs. 7.5% **SAE:** NR **Ascertainment of outcomes assessed:** clinician and pts reported erection outcomes

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Roy (1990) [186] **Funding source:** NR	**N screened =** NR **N randomized =** 24 (3 x 3 factorial design, crossover study with assigned order of tx) **IG1 & 2, n =** 24 **CG, n=** 24 (same grp as IG) **ITT analysis used for primary outcome:** NR **Inclusion**: Non vasculogenic ED; Seeking treatment in urology clinic (nocturnal penile test was **Exclusion:** Penile BP index < 0.85 Outcomes reported for IG 1 vs. IG2 vs. CG	**Age, range:** 50-70 y **Co-morbidities:** NR **Previous ED treatment**: 4 previously papaverine 30 to 60 mg **Smoking status**: NR **Body weight**: NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED**: Some psychogenic (no data) **Physiologic ED:** Diabetes (no data) Neurogenic (no data) **Mixed ED**: NR	**IG1:** Vasoactive Intestinal peptide (VIP) IC, low dose + compressed penile base (CPB) for 1 min **IG2:** VIP, high dose + CPB **CG:** Placebo +CPB **IG1:** Dose: 200 pmol in 1 ml volume Duration: 1 wk Frequency: once/ wk **IG2:** Dose: 400 pmol in 1 ml volume Duration: 1 wk Frequency: once/ wk **CG:** Dose: 1 ml saline Duration: 1 wk Frequency: once/ wk Compliance all grps: 100% **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** 3 wks	**Primary outcome results:**Penile length increase by tx, mean %: 14.5 vs. 20.8 vs. 11(CG < IG1< IG2, p= 0.01) Diameter increase, mean %: 8.5 v. 13.7 vs. 3.9 (CG < IG1< IG2 p= 0.001) Penile rigidity score, mean: 1.3 vs. 1.4 vs. 1.3 (CG vs. IG1vs. IG2 p=0.056) Above parameters also reported by time (i.e. wk1, wk2, wk3) Repeat exposure to CG, IG1, IG2 ▼ diameter over time p=0.001 Repeat exposure to CG, IG1, IG2 ▼ rigidity over time p=0.008 Rigidity obtained: 0 vs. 0 **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Observer measurements; Rigidity: 15 min post treatment with scale 1-1 (no rigidity to full rigidity):

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sandhu (1999) [187] **Companion:** [164] **Funding source:** Senetek plc	**N screened =** 304 (dose assessment phase) * **N randomized =** 240 [cross over, intervention (a and b); and placebo] **IG, n=** 240 (133 phase II, maintenance phase) **ITT analysis used for primary outcome:** yes **Inclusion**: pts with ED ≥ 1 y in duration, ≥ 18y, currently in stable heterosexual relationship **Exclusion:** overt psychogenic aetiology, ability, any known systemic disease which produces overall weakness (other exclusion criteria is listed in the report) ***Note:** non responders to the non randomized dose assessment phase (details not reported in this table) entered into phase I, the result of which reported in this table	**Age, mean (range):** 58.5 (27-79) y **Co-morbidities:** NR **Previous ED treatment**: IC Alprostadil: 106 IC Papaverine/ phentolamine: 45 Other (Yohimbine, vacuum devices): 32 **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** atherogenic (n=58), DM (n=53), neurogenic (n=3), mixed **Psychogenic ED**: 0 **Physiologic ED:** 135 **Mixed ED**: 152	**IG:** vasoactive intestinal polypeptide (VIP) + Phentolamine **CG:** placebo **IG a & b:** Dose: 25 µg VIP + a=1 mg, or b=2 mg (35 ml volume) Duration: 6 mo Frequency: max 3 times/ wk Compliance: 88.2%; 68.2% (133/195) completed phase I; 94.7% (105/126) **CG:** Dose: placebo (35ml volume) Duration: as IG Frequency: as IG Compliance: as IG **Run In period:** NR **Wash out period:** 36 hrs between injections **F/u duration:** NR	**Primary outcome results:** Duration of erection, median, IGa vs. IGb vs. CG: Phase I (n=132): 50 vs. 30 vs. 15 min Phase II (n=126): 60 vs. 40 vs.27.5 min Grade III erection, IG (a or b) vs. CG (a or b) (%): Phase I, a=72.2 vs. 13.1; b= 65.3 vs. 15.9; overall IG vs. CG=73.7 vs. 12.9 Phase II, a=75 vs. 12.6; b= 75 vs. 10.6; overall IG vs. CG= 69.1 vs. 13.7 **Other outcomes assessed:** OS: Satisfied or very satisfied: 80% of pts; quality of life improvement: 81% of pts and 76% or partners **Withdrawals/drop-outs/loss to f/u:** 107 (44.5%): n=45 (18.8%) no injection, n=62 post 1st injection (AE, non compliance, other) **WDAE:** n=2 (death & priapism) **TAE (n):** a vs. b vs. placebo: % of injections with one or more AE: 47.5 vs. 45.4 vs. 68; bruising+ bleeding, 8 vs. 6 vs. 7; priapism (n=1) 0.05 vs. 0 vs. 0 Overall incidence of urethral bleeding 0.9% for both phases **SAE:** death n=1 (also n=1 MI) **Ascertainment of outcomes assessed:** Home filled diaries, f/u questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Schramek (1994)[188] **Funding source:** NR	**N screened =** NR **N randomized =** 24 (2 crossover design studies) Study I **IG1, n=** 7 (cross over a and b) Study II **IG2, n=** 17 (interventions a & b in random order) **CG randomized =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: ED with hx of PgE_1-induced penile pain **Exclusion:** NR Results reported for all pts (n=24) or by interventions (IG1 + IG2 (a), vs. IG1 + IG2 (b)	**Age, median (range):** 48, (28-62) y **Co-morbidities:** NR **Previous ED treatment**: PgE_1 in all cases **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: 3 **Physiologic ED:** 21 (arteriogenic, neurogenic, caverno-venogenic) **Mixed ED**: 0	**IG1 & 2:** **a** PgE_1 **b** PgE_1 + procaine IC **IG1/IG2 (a)** Dose: 20 µg Duration: NR Frequency: 1 dose **IG1/IG2 (b):** Dose: 20 µg PgE_1 + 10 mg (IG1b), or 20 mg (IG2b) procaine Duration: NR Frequency all grps: 1 dose of each a and b Compliance all grps: 100% **Run In period:** NR **Wash out period:** ≥ 2 days **F/u duration:** 2 in 2 d intervals **Other:** Authors combined results from 2 studies	**Primary outcome results:**Full erection (grade 5), proportion of pts: IGa: 16/24 vs. IG1b 5/7 vs. IG2b 11/17 ▼ by 1 grade in n=7 (all improved to grade 5 after cross over tx): IG1: 2/7; IG2: 5/17 ▲ in grade: IG1 0/7 vs. IG1/17 Duration of erection IGa vs. IG1b vs. IG2b, median (range): 142 (20-360) vs. 122 (20-180) vs. 111 (15-360) min Time from injection to erection: NR **Other outcomes assessed:** BP, pulse rate, penile sensitivity **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE** 0 **TAE, n (%)of pts/grp:** 37; IG1a vs. IG1b vs. IG2b: no pain 4 vs. 2 vs. 7; moderate pain 9 vs. 5 vs. 6; severe 2 vs. 0 vs. 4 Priapism: 2 events in n=1 after a and b **SAE:** 0 **Ascertainment of outcomes assessed:** Clinical evaluation of degree of erection on 5-point scale (1= no erection &5 = full erection)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Seyam (2005) [189] **Funding source:** NR	**N screened =** NR **N randomized =** 180 (crossover) **IG1-9 n=** 20 (in each grp) **CG, n=** 180 **ITT analysis used for primary outcome:** No **Inclusion**: ED ≥ 6 mo in duration **Exclusion:** Hx of priapism, sickle cell anemia, previous surgical intervention for ED	**Age, mean (sd):** 50.5 (11.7) yrs **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** IIEF-5 for 158 pts (Mean degree of ED = 7.6, sd = 5.8) Complete ED in 36; weak erection in 137; difficulty to maintain erection 6; recreational drug users = 12 (6.7%)	**Concomitant medications:** NR **Duration of ED, mean:** 40.2 mo **Underlying disease, n (%):** Organic disease 137 (76.5) 20 (11.2) arterial disease 6 (3.4) pure venous leakage **Psychogenic ED, n (%)**: 16 (8.9) **Physiologic ED, n (%):** 163 **Mixed ED**: 67 (37.4) **Other:** NR	**IG**: PgE1, papaverine, phentolamine [trimix] **CG:** PgE1 **IG1-3:** Dose: 2.5 µg PgE1 + 5, 10 (IG2), 20 (IG3), mg Papaverine + 1 mg Phentolamine **IG4-6:** Dose: 5 µgs PgE1 + 5, or 10 (IG5), or 20 (IG6) mg Papaverine + 1 mg Phentolamine **IG7-9:** Dose: 10 µg PgE1 + 5, or 10 (IG8), or 20 (IG9) mg Papaverine + 1 mg Phentolamine **CG:** Dose: 20 µgs PgE1 Duration, all grps: approx 6hrs Frequency all grps: once Compliance all grps: 100% **Run In period:** NR **Wash out period:** 1 wk **F/u duration** NR	**Primary outcome results:**(IG vs. CG) Grade 4 + 5 erections, n (%): 122 (68) vs. 120 (67) Grade 5 erections, n (%): 61 (34) vs. 66 (37): Overall Cavernous artery diameter mean (sd), mm: IG: Right: 0.9(.21); Left: 0.9 (.2) vs. CG Right: 0.9 (0.2); Left: 0.9 (0.2), NS Peak systolic velocity, cm/s: IG Right: 29 (12); Left: 29 (12) vs. CG-Right: 30 (12); Left: 27 (12), NS Duration of erection, min: 120 (91) vs. 93 (67), NS Satisfaction, %: 63 (28) vs. 64 (26), NS **Other outcomes assessed:** Cost assessment, patient preference **Withdrawals/drop-outs/loss to f/u: n=**0 **WDAE:** n=1 (IG9) **TAE:** NR [AE: Priapism n=10 (none in IG2, IG4, and IG8); pain IG 32 (18%) vs. CG 26 (15%)] **SAE:** 0 **Ascertainment of outcomes assessed:** IEEF-5, Ultrasound imaging

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Soderdahl (1997)[190] **Funding source:** NR	**N screened =** NR **N randomized =** 50 (cross over design) **IG1, n=** 27 (pts were cross over to other arm post wash-out) **IG2 n=** 23 (pts were cross over to other arm post wash-out) **CG, n=** NA **ITT analysis used for primary outcome:** NR **Inclusion**: men with untreated organic impotence, & a stable sexual partnership **Exclusion:** pts with hormonal therapy (low testosterone treatment); psychogenic impotence; stated preference for either of the treatments, pts not achieving erection after either of the treatment regiments were excluded from analysis	**Age, mean (range):** 62.3 (38-84) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight**: NR	**Concomitant medications:** NR **Duration of ED (yr):** 40 (6-120) mo **Underlying disease:** Vascular n=15; surgical n=13; diabetic n=9; unknown n=7 **Psychogenic ED**: 0% **Physiologic ED:** All organic pts **Mixed ED**: NA	**IG1:** Trimix **IG2:** vacuum device **CG:** NA **IG1:** Dose: 0.25 –0.6 mL [30 mg/mL papaverine HCl, 5 mg/ mL phentolamine, 0.5 mg/ mL PGE) for at least 15 doses Duration: 18-20 mo Frequency: mean 5.8 uses /mo Compliance: 71% **IG2:** Dose: NA Duration: 18-20 mo Frequency: at least15 times; mean 5.4 use / mo Compliance: 80% **Run In period:** NR **Wash out period:** NR **F/u duration:** 18-20 mo	**Primary outcome results:** Satisfaction scores rated 0-10, IG1 vs. IG2, mean: Erection quality 5 vs. 4 (mean pre-treatment/ pre-impotence score = 1.6/ 6.6 for all) Penile sensation: 5 vs. 5 (pre impotence mean score = 6.5) **Other outcomes assessed:** partner reported quality & satisfaction **Withdrawals/drop outs/loss to f/u:** n=6 (12%) **WDAE:** NR **TAE:** NR [AE: n=11 bruising, injury or skin changes causing to stop treatment or drop out, IG1 n=4 (9%), vs. IG2 n=7 (16%)] **SAE:** required an extra visit to doctor IG1 n=5 (11%), IG2 n=2 (4.5%) **Ascertainment of outcomes assessed:** Pt filled questionnaire at end of 1st period; clinician filled questionnaire at end of study

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sogari (1997) [191] **Funding source:** NR	**N screened =** NR **N randomized =** 230 **IG1 n =** 115 **IG2 n =** 115 **CG n =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: ED **Exclusion:** NR Data reported as IG1 vs. IG2	**Age:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: 50 (43.9%) vs. 38 (33.3%) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (sd):** IG1: 32.2 (40.2) vs. 33.5 (54.8) mo **Underlying disease (diagnosis):** Hypertension; alcoholism; diabetes; Peyronie's disease; acute MI, or angina, all non sign. between grps	**IG1:** Trimix + atropine sulfate in combination (IC) **IG2:** Trimix alone **IG1:** Dose: 50 mg papaverine, 10 µg PgE_1, 0.2 mg phentolamine (trimix), 0.075 atropine Duration: NA Frequency: 1 dose Compliance: NR **IG2:** Dose: Trimix as IG1 Duration: NA Frequency: 1 dose Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:**erectile response assessed subjectively by examiner, IG1 vs. IG2: Tumescence 40 (35%) vs. 45 (40%) Poor erection 22 (19%) vs. 17 (15%) Full erection 52 (46%) vs. 52 (46%) **Other outcomes assessed:** intracorporeal pressure **Withdrawals/drop-outs/loss to f/u:** n=2; one from each grp **WDAE:** 0 **TAE:** (NR) **AE:** Painful sensation: 57 (50%), vs. 63 (53.8%)NR **SEA:** 0 **Ascertainment of outcomes assessed:** NA

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Titta (2006) [192] **Funding source:** NR	**N screened =** NR **N randomized =** 57 **IG1, n =** 29 **IG2, n =** 28 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion:** men with non-nerve sparing (NNS) radical pelvic surgery screened one d prior to surgery; in a stable heterosexual relationship for at least 6 mo **Exclusion:** NR	**Age, mean (range):** 63.5 (55-72) y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NA **Underlying disease, n (%):** clinically localized prostate cancer 50 (87.7); invasive bladder cancer 7 (12.3) **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 57 (100) **Mixed ED, n (%):** NR	**IG1:** PgE1-IC + sexual counseling **IG2:** PgE1 alone **IG1:** Dose: 10µg (lowest efficious dose= 18.1µg, mean 9.1 µg) Duration: 18 mo Frequency: twice/wk Compliance: 72.4% **IG2:** Dose: as IG1(lowest efficious dose= 19.5µg, mean 13.8 µg) Duration: as IG1 Frequency: as IG1 Compliance: 28.5% **Run In period:** NA **Wash out period:** NR **F/u duration:** 18 mo (3, 6, 9, 12, and 18 mo) **Note:** open label sildenafil 100 mg (1 hr prior to sexual intercourse, min 4 doses/3 mo); all responders switched to sildenafil twice/wk at the end of trial	**Primary outcome results:** IIEF, mean score at 18 mo (IG1 vs. IG2): 26.5 vs. 24.3, p<0.05 IIIEF, mean pre vs. post surgery: 26.3 vs. 8.4 18 mo, IG1 vs. IG2: 26.5 vs. 24.3 Sexual satisfaction: pre vs. post surgery: 10.2 vs. 3 18 mo, IG1 vs. IG2: 9.7 vs. 6.8 IIEF-OF": Pre vs. post surgery: 9.8 vs. 3.3 18 mo, IG1 vs. IG2: 9.2 vs. 7.8 IIEF-SD: Pre vs. post surgery: 8.6 vs. 8.5 18 mo, IG1 vs. IG2: 9 vs. 6.2 IIEF-SD: Pre vs. post surgery: 9.1 vs. 6.8 18 mo, IG1 vs. IG2: 9.0 vs. 7.3 Sildenafil responder rate, n (%): 8 (27.5) vs. 5 (17.8) **Other outcomes assessed:** **Withdrawals/drop-outs/loss to f/u, n (%):** 0 vs. 8 (28.5), p<0.05 **WDAE, n (%):** prolonged post injection pain 0 vs. 3 (10.7) **TAE, n (%):** NR **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF, and IC training test

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Van der Windt, F (2002) [193] **Funding source:** Byk BV	**N screened =** NR **N randomized =** 70 (parallel) **IG1, n =** 35 **IG2, n =** 35 CG: NA **ITT analysis used for primary outcome:** No **Inclusion**: age range 20-70 yrs, medically & psychologically fit to use IC injection, in a stable & monogamous sexual relationship **Exclusion**: major organic cause for ED	**Age, mean (range)** 56 (23-75) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** premature ejaculation 20 patients (35%)	**Concomitant medications:** NR **Duration of ED:** mean= 3.4 y **Underlying disease:** NR **Psychogenic ED (n)**: 12 vs. 13 **Physiologic ED:** 5 vs. 3 **Mixed ED:** 11 vs. 13	**IG1:** papaverine-phentolamine (Androskat) + sexula counseling **IG2:** papaverine + phentolamine **IG1:** Dose: mean 0.34 ml (titrated from 0.25 ml) Duration: NR Frequency: NR Compliance: 10 (29%) **IG2:** Dose: mean dose = .27ml Duration: NR Frequency: Compliance: 7 (20%) **Run In period:** NR **Wash out period:** NR **F/u duration, mean (range):** 11.3 (2-19) mo **Other:** Screening determined dosage with use of hx, visual sexual stimulation and vibro-tactile stimulation	**Primary outcome results:** IG1 vs. IG2: Increase in penile circumference: mean (millimetres): 27 vs. 30 Duration of erection: mean: 47 vs. 56 min % (self reported) erection score: mean %: 84% vs.79% **Other outcomes assessed:** Acceptance of IC injection (mo used before stopping): 4.7 vs. 1.7 **Withdrawals/drop-outs/loss to f/u:** N= 13 **WDAE:** 12% discontinued due to prolonged erection **TAE:** NR AE in 14% of patients; 3 (5%) priapism, 4 (7%) haematoma, and 1 (2%) curvature of the penis **SAE:** 0 A**scertainment of outcomes assessed:** Physical exam, telephone interview

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Vanderschueren (1995) [194] **Funding source:** NR	**N screened =** NR **N randomized =** 210 (cross over) **IG1-3 & CG, n =** 210 (NR for dose allocations) ITT analysis used for primary outcome: **NR** **Inclusion**: men with ED, at least 4 mo in duration, with stable responders to PG-E1 (ED defined as inability to achieve rigidity sufficient for vaginal penetration) **Exclusion:** cavernous fibrosis, anatomical deformation of the penis, Peyronie's disease r a hx of priapism, major disease, drugs that could substantially affect the evaluation of EF	**Age, mean (range):** 53 (29-70) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 4.8 (0.5- 41) y **Underlying disease:** diabetes in 7%; other NR **Psychogenic ED**: 36% **Physiologic ED:** 28%; (vasculogenic 21%, diabetes I 7%) **Mixed ED**: 15%	**IG1:** PgE1 new sterile solution IG2: PgE1 sterile powder IG3: PgE1 pediatri sterile solution Each administered in 4 doses) **CG:** placebo **IG1-3:** Dose: a= 2.5, or b=5, or c=10, or d=20 µg Duration: NR Frequency: one injection of each formulation at the randomized dose Compliance: NR **CG:** Dose: 0 µg PgE1 Duration: NR Frequency: as IG Compliance: NR **Run In period: NR** **Wash out period: at least 3 d** **F/u duration:** NR	**Primary outcome results:**Duration of erection, mean (sd): [IG1 vs. IG2 vs. IG3], min: 2.5 µg: 30 (9) vs. 27 (8) vs. 33 (8) 5 µg: 52 (10) vs. 68 (12) vs. 64 (12) 10 µg c: 29 (8) vs. 35 (9) vs. 35 (9) 20 µg: 52 (11) vs. 50 (10) vs. 51 (11) CG: 0 (0) vs. 0.5 (0.5) vs. 1.6 (1.4) % of pts with positive response ,RigiScan (>/=70% for >/= 10 min), and clinical assessment, data extracted from bar graph and it is approximate: 2.5 µg: RigiScan: 33 s. 27 vs. 40; clinical assessment: 40 vs. 33 vs. 44 5 µg: RigiScan 50 vs. 48 vs. 52; clinical assessment: 65 vs. 75 vs. 70 10 µg: RigiScan 38 vs. 48 vs. 39, clinical assessment 50 vs. 52 vs. 63 20 µg: RigiScan 43 vs. 45 vs. 42; clinical assessment 55 vs. 58 vs. 55 CG: RigiScan 0 vs. 2 vs. 5; clinical assessment 0 vs. 0 vs. 5 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 3 (1.5%) **WDAE:** n=3; severe penile pain 1 (0.5%); systemic medical events 2 (1%) **TAE:** NR; AE: penile pain, IG1 9% vs. IG2 14% vs. IG3 17% vs. CG 11% **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan; clinical assessment

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Viswaroop (2005)[195] **Funding source:** NR	**N screened =** **N randomized =** 50 **IG1, n =** 25 **IG2, n =** 25 **CG, n =** NA **ITT analysis used for primary outcome:** NR **Inclusion:** men 21-65 y wit ED (irrespective of aetiology, marital status and duration of ED) **Exclusion:** contraindication to use of sildenafil or papaverine	**Age, mean (sd):** 30 (10.2) **Race:** NR **Co-morbidities, n (%):** DM 6 (12); hypertension 3 (6); abused alcoholic 2 (4); depressive illness 4 (8) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** 30 (60) **Physiologic ED, n (%):** 20 (40) **Mixed ED, n (%)**: NR	**IG1:** papaverine IC then oral sildenafil **IG2:** oral sildenafil then papaverine IC injection **IG1:** Dose: papaverine 30 mg; sildenafil 50 mg Duration: NA Frequency: sinlgle dose Compliance: NR **IG2:** Dose: as IG1 Duration: as IG1 Frequency: as IG1 Compliance: NR **Run In period:** **Wash out period:** 2 d between tx for each arm **F/u duration:** 5 min post injection of papaverine; 30 min post ingestion of sildenafil	**Primary outcome results:** Penile length (cm), mean (sd): baseline 7.71 (1.26) papaverine: 11.98 (2.4) sildenafil 11.66 (2.20) Penile circumference (cm), mean (sd): Baseline: 7.50 (1.07) Papaverine: 10.2 (1.5) Sildenafil: 9.67 (1.39) **Other outcomes assessed:** angle of erection; Pts tx preference **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE:** NR; AE reported, priapism n=5 (10) with injection; headache 2(4), blurring vision 1 (2) and dyspepsia 1 (2) **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** Penile measurement; interview

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
von Heyden (1993) [196] **Funding source:** Deutsche Forschungsge-meinschaft	**N screened =** NR **N randomized =** 16 **IG/ CG, n =** 16 (crossover design) **ITT analysis used for primary outcome:** NR **Inclusion**: undergoing home auto-injection with PgE_1 **Exclusion:** ED due to severe venous incompetence, sickle cell anemia, or endocrinological, neurological or psychiatric dx; Peyronie's dx; hx of priapism, coagulopathy, recent MI, unstable angina or stroke; use of medication known to interfere with EF within 1 mo of study entry	**Age, mean (sd):** 56, range 46-70 y **Co-morbidities:** DM 2, heart attack 2, coronary bypass 2, hypertension 1, transurethral prostatic resection 1 **Previous ED treatment**: PgE_1 for mean of 1.3 yr (range 0.3-6); mean dosage 6.21 µg (95% confidence interval 4.33-8.10) **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** arterial insufficiency 9, moderate venous insufficiency 1, mixed vascular disease 6 **Psychogenic ED**: 0 **Physiologic ED:** 16 **Mixed ED**: 0 **Other:** 1 patient had borderline hypergonadotropic hypogonadism	**IG:** PgE_1 **CG:** placebo **IG:** Dose: mean effective dose 21.4 (2.5 –40) µg Duration: NR Frequency: varied (injections were repeated until erection lasted longer than 2 hr, or drug intolerance developed with minimum of 2 d between injections) Compliance: **CG:** Dose: placebo (saline) Duration: NR Frequency: Placebo was given at random during the escalating dose schedule Compliance: **Run In period:** NR **Wash out period:** 2 or more d **F/u duration:** 2 hrs post injection	**Primary outcomes:** Approximate % of patients with highest value at or below dosage IG [2.5-40 µg (range)] vs. CG Maximal rigidity base: 19-98% vs. 0% Maximal rigidity tip: 19-98% vs. 7% Maximal sustained rigidity base: 19-98% vs. 0% Maximal sustained rigidity tip: 12-98% vs. 0% Total duration of ≥ 60% rigidity base 22-100% vs. 0% Total duration of ≥ 60% rigidity tip 41- 100% vs. 8% **Other outcomes assessed:** Rigidity assessed with penis buckling test; cavernous artery peak flow velocity; systolic & diastolic BP **Withdrawals/drop-outs/loss to f/u:** 4 **WDAE:** 4 (pain on last dose (15 µg in 2; 20 µg, and 25 µg in 2) **TAE:** 22/135 injections (16.3%); all: Burning sensation or mild to moderate penile pain 18/135 IG (13.3%) Haematoma 2/135 IG (1.5%) **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Wegner (1994) [197] **Funding source:**	**N screened =** 60 **N randomized** = 20 (crossover trial) **IG1/ IG2 (a,b), n =20** **ITT analysis used for primary outcome:** NR **Inclusion**: Men with ED who presented to ED clinic for evaluation. Who undergo evaluation of the cause of their dysfunction, including sexual hx, physical exam. **Exclusion:** NR	**Age, mean (range):** 54.2 (29-87) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status, n (%):** (30) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** n (%); DM 4 (20) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** n (%); Alcohol abuse 2 (10) Primary neurologic causes 1 (5)	**IG1:** PgE1 **IG2 (a,b):** SIN-1 **IG1:** Dose: 20 µg Duration: NR Frequency: once min 3 days inbetween Compliance (%): 100% **IG2a:** Dose: 1 mg Duration: NR Frequency: once Compliance: 100% **IG2b:** Dose: 2 mg Duration: Frequency: once Compliance: 100% **Run In period:** NR **Wash out period**: 3 d between injections **F/u duration** (on and off treatment)**:** NR	**Primary outcome results:** IG1vs. IG2 a vs. IG2 b Erectile Response, n (%): Full rigidity (5): 2 (10) vs. 0, vs.0 Full medium rigidity (4): 4 (20) vs. 2 (10) vs. 2 (10) Minimal to Full without rigidity (1-3): 14(70) vs. 18 (90), vs. 18 (90) No response: 0 in all grps **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** No dropouts **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Clinician assessed quality of erection using a 6 point scale, (0-5, with 0 being no response, 4 Full medium rigidity. and 5 Full rigidity)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Wegner (1995) [198] **Funding source:** NR	**N screened =** 60 **N randomized =** 40 (cross over) **IG1-3, n=** 40 **ITT analysis used for primary outcome?** NR **Inclusion**: Pts with ED => 6 mo duration Exclusion: NR	**Age, mean (range):** 53 (34-71) yr **Co-morbidities:** NR (see 'Other') **Previous ED treatment**: NR **Smoking status**: n=12 **Body weight**: NR **Other:** alcohol abuse (n=3), DM (n=8)	**Concomitant medications:** NR **Duration of ED:** 3.2 y (6 mo – 7 y) **Underlying disease:** pelvic surgery (n=3), neurological causes (n=2) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** Diagnosis of ED included testing with PGE1, cause of ED, sexual hx, physical examination	**IG1:** Pg-E1 **IG2:** linsidomine chlorhydrate (SIN-1) **IG3:** SIN-1 + urapidil **IG1:** Pg-E1 Dose: 20 μg Duration: NR Frequency: once **IG2:** SIN-1 Dose: 1 mg Duration: NR Frequency: once **IG3:** SIN-1 + urapidil Dose: 1 mg (SIN-1), 10 mg (urapidil) Duration: NR Frequency: once Compliance all: NR **Run In period:** NR **Wash out period:** 3 d **F/u duration:** 3 d (assessed 5, 10, 20, 30 min after injection)	**Primary outcome results:** N pts with full response (grade 6) (rigidity)/ rigid erection (grade 5), n (%) IG1: 8 (20)/ 8 (20) IG2: 0 (0)/ 3 (8) IG3: 2 (5)/ 8 (20) IG1 vs. IG2, p = 0.0001 IG2 vs. IG3, p = 0.0004 **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR AE, n of events: 5 severe hypotension in IG3; pain upon injection IG1=3; IG2=1; IG3=3 **SAE:** NR **Ascertainment of outcomes assessed:** inspection and palpation (0= no response; 5= full tumescence; 6= full tumescence with rigidity)

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C6-Subcutaneous Treatment Trials

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rosen, RC (2004) [199] **Funding source**: NR	**N screened** = NR **N randomized** = 25 **IG1/IG2/CG, n** = 25 (3 way cross over) **ITT analysis for primary outcomes:** NR **Inclusion**: age 21-55 y; within 40% of ideal weight, ED diagnosis of 6 mo or longer; IIEF EF score 16 or less; inadequate response to 100 mg Viagra defined by ability to attain erection sufficient for intercourse equal or less than 50% of times within last 12 mo **Exclusion**: Current use of Viagra (last 4 wks prior to enrolment); ED due to untreated endocrine disease, penile anatomic deformities, prostate cancer or radical prostatectomy; clinically S hepatic, renal, cardiovascular, psychiatric or CNS disease, (i.e. stroke or SCI)	**Age, mean (sd):** 48 (5), range 37-54 y **Race, n (%):** White 19 (76), Black 5 (20), Hispanic 1 (4), other 0 **Co-morbidities, n (%)**: DM 2 (8); hypertension 7 (29); hyperlipidemia 3 (12) **Previous ED treatment:** Viagra (100 mg) **Smoking status:** 11 (42%) **Body weight, mean (sd):** 97 (18) kg, range 64-129 kg	**Concomitant medications**: NR **Duration of ED, mean (sd):** 8 (5) y, range 2-22 y **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED:** NR	**IG1:** subcutaneous PT-141 low dose (+ visual sexual stimulation) **IG2:** subcutaneous PT-141 high dose (+ visual sexual stimulation) **CG:** placebo **IG1/IG2:** Dose: 0.4 mg (IG1), 0.6 mg (IG2) injected in the lower right quadrant of abdomen (3 way crossover design always starting with lower dose) Duration: NA Frequency: once/ dose, three visits Compliance: 100% **CG:** Dose: NA Duration: NA Frequency: as IG Compliance: 100 **Run In period:** NA **Wash out period:** 3-14 d **F/u duration:** last outcome measure taken up to 145 min post injection (pts were monitored for 12 & 24 hr post injection)	**Primary outcomes (EF):** IG1 (n=24) vs. IG2 (n=21) vs. CG (n=23), mean (SE): Duration of rigidity, min: >/= 60%, base: 28 (6), vs. 41 (8), vs. 6. (2)/; tip: 19 (5) vs. 24 (6), vs. 4 (2) >/= 80% base: 14 (4), vs. 17 (5), vs. 2 (0.6)/; tip: 5 (2), vs. 8.(3), vs. 0.4 (0.2) RAU: Base: 29 (5), vs. 41 (6), vs. 9 (2) Tip: 23 (4), vs. 33 (5), vs. 7 (2) **Other outcomes assessed:** Tumescence activity untis (TAU) **Withdrawals/drop-outs/loss to f/u:** n=1 (this pts was replaced) **WDAE:** n=0 **TAE:** 24 vs. 24 vs. 0; including nausea, headache, vomiting, back pain, diaphoresis, flushing, fatigue, muscle cramps **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan TM; Rigidity Assessment System (Pharmacokinetic data, 3) **Other:** pts with severe ED (IIEF- EF score 6-10) (n=10): 6 mg PT-141 resulted in mean duration of >/= 60 and >/=80% base rigidity of 36 and 15 min ($p<0.01$) respectively compared to 8 and 2 min after placebo

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Segraves (1991) [200] **Funding source:** NR	**N screened =** NR **N randomized =** 12 **IG/ CG, n =** 12 **ITT analysis used for primary outcome:** NR **Inclusion**: coital erectile failure for at least 6 mo, and any 1 or more of hx of adequate erections upon awakening at least 2/wk for preceding mo, hx of adequate erections lasting ≥ 5 min during foreplay and/or hx of adequate EF during masturbation **Exclusion:** current use of hypotensive or psychoactive medication; prior use of neuroleptic medications; penile blood pressure index ≤ 0.70; serum testosterone ≤ 450 ng/mL; serum PRL ≥ 30 ng/mL; erectile problem judged to be related to current marital discord; presence of dx known to be frequently associated with ED	**Age:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: 12 **Physiologic ED:** 0 **Mixed ED**: 0	**IG:** apomorphine hydrochloride subcutaneously (brachial) **CG:** placebo subcutaneously (brachial) **IG1:** Dose: (titrated wkly until full rigidity or AE) 0.25, and 0.50 0.75 and 1.0 mg n=12 received only first 2 doses; n=9 first 3 doses, and n=5 all doses Duration: NR Frequency: once/wk Compliance: NR **CG:** Dose: placebo Duration: NR Frequency: once /wk Compliance: NR **Run In period:** NR **Wash out period:** 50 min between injections in each session; 1 wk between sessions **F/u duration:** NR	**Primary outcome results:**penile tumescence (▲ in circumference): n=11 exceeded 1 cm after apomorphine injection Average max erection = 2 cm, range 0.3–3.0 cm **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** NR; AE, n (%): 8 (67); yawning, drowsiness, nausea, and extreme **SAE:** NR **Ascertainment of outcomes assessed:** Barlow strain gauges; Max erection, made by visual inspection without palpation, rated independently by subject and investigator on scale of 0–100%; Max level of SD rated on scale of 0–100% by subject **Other:** 3 pts (25%) did not proceed to the next dose level due to AE; sign. relationship between nicotine use an absence of AE (chi-square 6.9, p<0.01)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Wessells (2000) [201] **Companion study (part II)** [202] **Study I (psychogenic study)** **Funding source:**	**N screened =** NR **N randomized =** 10 (cross over) **IG/ CG=** 10 **ITT analysis used for primary outcome:** NR **Inclusion**: age 18-75 y, part I: psychogenic ED pts with normal organic etiology & normal nocturnal penile tumescence (> 10 in of tip rigidity > 70%); part II, men with organic ED (mean organic risk factor of 2.2) (ED defined as the persistent inability to obtain and maintain erection sufficient for sexual satisfaction) **Exclusion:** Concurrent use of erectogenic medications, radical prostatectomy, cancer-chemotherapy, Peyronie's disease, or other genital anomalies	**Age, mean (range):** Reported for study I + Study II: 51.6 (22-67) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment, n**: IC injection; sildenafil 5; IU Pg E- IU 1 **Smoking status**: smokers n=2 **Body weight:** NR **Other:** mean serum testosterone level: 362 mg/ml; mean IIEF score (items 3 and 4) 0.77 (0-2)	**Concomitant medications:** testosterone replacement therapy (n=3) **Duration of ED:** NR **Underlying disease, n:** reported for total pts, hypoganodism 3; hypercholesterolemia 5; obesity 4; hypertension 3; peripheral neuropathic injury 2; DM 2; heart dx 2; venoocclusive dysfunction 1; pudendal arterial insufficiency 1 **Psychogenic ED:** 100% **Physiologic ED:** 0 **Mixed ED:** 0 **Other:** NPT (mean baseline): 3 erectile events /night, 30 min of base rigidity > 60%, 9 min tip rigidity > 80%	**IG:** subcutaneous injection Melanotan II **CG:** placebo **IG1:** Dose: 0.025-0.157 mg/kg (total injections, part I & II = 39) Duration: NR Frequency: 2 injections Compliance: 100% **CG:** Dose: placebo (total injections study I & II Duration: NR Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** 48 hrs **F/u duration:** 6 hrs post injection **Other:** one subject (no allocation to study grps) received three placebo and one active injections erroneously	**Primary outcome results:** Erectile activity/injection: NR (combined results of Study I & study II 27/39 (69%) vs. 1/41 (2.4%) RigiScan (mean), n=16 injections: Erections with response (%): 75 vs.0 Erectile events (n): 3.45 vs. 2.35 Total erectile duration (min): 163 vs. 55 Tip rigidity 80-100% (min): 38 vs. 3 Tip rigidity 60-79% (min): 40 vs. 5 Average tip rigidity (%): NR Erectile latency (min): 127 vs. ND Tip RAU: 78 vs. 10 Tip TAU: 50 vs. 14 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** 0 **TAE:** combined results for Study I & II; n of events/total injections, (%) Nausea: 15/39 (38) vs. 4/41 (10) Stretch/yawn: 22/39 (56) vs. 5/41 (12) **SAE:** 0 **Ascertainment of outcomes assessed:** Penile rigidity by RigiScan and visual analog scale; SD and side effects by questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Wessells, (2000) [201] **Companion study (part II)** [202] **Study II (organic study)** **Funding source:**	**N screened =** NR **N randomized =** 10 (cross over) **IG/ CG=** 10 **Inclusion**: age 18-75 y, men with organic ED (mean organic risk factor of 2.2) (ED defined as the persistent inability to obtain and maintain erection sufficient for sexual satisfaction) **Exclusion:** Concurrent use of erectogenic medications, radical prostatectomy, cancer-chemotherapy, Peyronie's disease, or other genital anomalies	**Age, mean (range):** Part II 56.2 (37-67) y **Co-morbidities:** NR **Previous ED treatment, n**: intracavernous injection; sildenafil 5; IU Pg E- IU 1 **Smoking status**: smokers n=2 **Body weight:** NR **Other:** mean serum testosterone level: 362 mg/ml; mean IIEF score (items 3 and 4) 0.77 (0-2)	**Concomitant medications:** testosterone replacement therapy (n=3) **Duration of ED:** NR **Underlying disease, n:** as study I **Psychogenic ED**:0 **Physiologic ED:** 100% **Mixed ED:** 0 **Other:** see study I	**IG:** subcutaneous injection Melanotan II **CG:** placebo **IG1:** Dose: 0.025-0.157 mg/kg Duration: NR Frequency: two injections; total injections = 19 Compliance: 100% **CG:** Dose: placebo Duration: NR Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** 48 hrs **F/u duration:** 6 hrs post injection **Other: *** n=1 received three placebo and only one Melanotan II injections erroneously	**Primary outcome results:** Erectile activity/injection: NR (combined results of Study I & study II 27/39 (69%) vs. 1/41 (2.4%) RigiScan (mean): Erections with response (%): 63 vs. 5 Erectile events (n): 3 vs. 0.7 Total erectile duration (min): 98 vs. 25 Tip rigidity 80-100% (min): 45 vs. 2 Tip rigidity 60-79% (min): 10 vs. 1 Average tip rigidity (%): 47 vs. 6 Erectile latency (min): 8 vs. ND Tip RAU: 59 vs. 5 Tip TAU: 29 vs. 6 IIEF- Q12 (sd), [IG (19 injections) vs. CG (21 injections)] very low or none 6 vs. 1 Low 3 vs. 3, Moderate 5 vs. 1, High 5 vs. 0, Very high 0 vs. 0 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** 0 **TAE:** combined results for Study I & II; n of events/total injections, (%) Nausea: 15/39 (38) vs. 4/41 (10) Stretch/yawn: 22/39 (56) vs. 5/41 (12) **SAE:** 0 **Ascertainment of outcomes assessed:** Penile rigidity by RigiScan and visual analog scale; SD and side effects by questionnaire

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C7- Intra-urethral Suppositories

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Ekman, P (2000) [203] **Funding source:** Astra Lakemedel AB	**N screened =** NR **N randomized =** 166 **IG1, n =** 83 **IG2, n =** 83 **CG, n =** NA **Intention to Treat (ITT) analysis:** yes **Inclusion**: men 18 y or older, with ED **Exclusion:** hypersensitivity to alprostadil (MUSE), abnormal penile anatomy, acute or chronic urethritis or indwelling catheter, penile implant, untreated hypogonadism, testosterone substitution for < 3 mo, known risk of priapism, concomitant tx with appetite suppressants or anticoagulants, partner planning to become or already pregnant. Also concomitant dx (poorly controlled diabetes, hypertension, unstable angina, heart failure, severe vascular dx, severe neurological or psychiatric dx)	**Age, mean (sd):** 60 (10) y **Race**: 100% Caucasian **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (sd):** 86 (12) kg	**Concomitant medications:** NR **Duration of ED:** 41 (31) mo **Underlying disease, (%):** > 1 cause: Vascular 47 vs. 43 neurogenic 18 vs. 17 Diabetes 21 vs. 21 hormonal 0 vs. 4 Psychogenic 12 vs. 7 Unknown 27 vs. 27 Other 22 vs. 17 **Psychogenic ED:** NA **Physiologic ED:** NA **Mixed ED:** NA **Other:** capable of partial erection mean (%)= 78 (76 vs. 81)	**IG1:** PgE1 alprostadil (MUSE) (optional pubic band) **IG2:** PgE1 alprostadil (MUSE), (optional pubic band) **IG1:** Dose: starting dose of 250 µg (clinic), titrated up to 250,500,1000 µg or down to 125 µg after 4 wks at 4 wk intervals (home application) Duration: 12 wks Frequency: at least 4 applications/ 4 wk Compliance: NR **IG2:** Dose: as IG1, starting dose of 500 µg (titration regiment as IG1) Duration: 12 wks Frequency: as IG1 **Run In period**: NR **Wash out period:** NR **F/u duration:** NR	**Primary outcomes (EF)**: Quality of erection reported for both IG1 & IG2 combined: Grade 4/5 at least once, n (%): 122 (73); these pts all reported coitus Grade below 4, n (%): 44 (27) IIEF (Q1-5 & 15), mean change in score (%): Q1= 1.8 (100); Q2= Q3=1.7 (100); Q4=1.9 (146); Q5=1.9 (136); Q15=1.2 (136) all sign. p <0.001 Final dose (% of total n=142): 125 µg - 1%; 250 µg – 6%; 500 µg – 18%; 1000 µg – 75% Sexual intercourse at least once: 113 (68%) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 24 (included 1 due to depression, and 3 unknown **WDAE:** 9 (5%) penile pain, hypotension**)** **TAE:** NR AE, n (%): Pain 50 (30%) with 4 (2%) rated severe; Hypotension, dizziness: (no detail reported) **SAE:** 0 **Ascertainment of outcomes assessed:** Pts filled personal diary; IIEF; Erection Assessment Scale (EAS)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Lazzeri (1994) [204] **Funding source:** NR	**N screened =** NR **N randomized =** 20 (parallel design) **IG1, n =** 5 **IG2, n =** 5 **IG3, n =** 5 **CG, n =** 5 **ITT analysis used for primary outcome:** NR **Inclusion**: ED **Exclusion:** NR	**Age, mean (SE):** 55.4 (5) y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: 20 **Physiologic ED:** 0 **Mixed ED**: 0	**IG1:** capsaicin IU **IG2:** papaverine IC **IG3:** papaverine IC + capsaicin IU **CG:** placebo IU **IG1:** Dose: capsaicin 10^{-5} M Duration: NR (injection length= 2 min) Frequency: 1 dose **IG2:** Dose: 8 mg Duration: as IG1 Frequency: 1 dose **IG3:** Dose: 8 mg + capsaicin 10^{-5} M Duration: as IG1 Frequency: 1 dose **CG:** Dose: saline Duration: as IG1 Frequency: 1 dose Compliance all grps: NR **Run In period:** NR **Wash out period:** NA **F/u duration:** NR	**Primary outcome results:** No response was reported for all variables with placebo, results for IG1 vs. IG2 vs. IG3: Penile diameter, Mean (sd) maximal ▲: 2.9 (0.93) vs. 3.7 (1.1) vs. 3.8 (0.96) Rigidity, mean maximal (%): 43 (12) vs. 63 (10) vs. 74 (16) Mean latency (seconds) 219 (44) vs. 198 (10) vs. 107 (29) Mean duration (seconds) 322 (58) vs. 248 (39) vs. 390 (48) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan (1997) [205] **Companions**[206-208] **Funding source:** Vivus Inc.	**N screened =** NR **N randomized, phase I-clinic test =** 1511 (at clinic test with alprostadil) **N randomized – Phase II-home tx=** 996 (responders to alprostadil test) **IG, n =** 485 **CG, n =** 511 **ITT analysis used for primary outcome:** no **Inclusion**: men with chronic ED without spontaneous erection sufficient for intercourse within past 3 mo; response = 4 or 5 to initial dose response test (125 – 1000 µg alprostadil) **Exclusion:** hx of urethral stricture or obstruction, indwelling urethral catheter, penile implant or prior penile surgery, sickle cell dx, paraplegia or quadriplegia, congestive heart failure, unstable angina, or recent acute MI; poorly controlled DM (complete list could be found in original study)	**Age, mean (range):** 62 (38-84) vs. 61 (30-83) y **Co-morbidities:** NR **Previous ED treatment**: 52% vs. 57% **Smoking status**: NR **Body weight**: NR	**Concomitant medications:** NR **Duration of ED:** 51 (3-528) mo **Underlying disease:** Vascular disease: 29% v. 28% Diabetes: 19 vs. 19 Surgery or trauma: 32% vs. 31% Other: 21% vs. 21% **Psychogenic ED**: NA **Physiologic ED:** 100% primary organic ED **Mixed ED**: NA **Other:** capable of partial erection (% of men): 63.3% vs. 60.9%	**IG:** alprostadil home tx **CG:** placebo home tx **IG1:** Dose: 125 µg (n=116, 12%), 250 µg (n=171, 17%), 500 µg (n=302, 30%), 1000 µg (n=407, 41%) Duration: 3 mo Frequency: NR Compliance: NR **CG:** Dose: same as IG Duration: 3 mo Frequency: NR Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 3 mo **Other**: 88% of IG rated the transurethral application of alprostadil as neutral	**Primary outcome results:** IG (n=411) vs. CG (n=500), % of successful tx Intercourse: 50 vs. 10 Intercourse/orgasm: 56 vs. 15 Intercourse/orgasm/10-min erection sufficient for intercourse: 57 vs. 15 **Other outcomes assessed:** 88% of IG rated the transurethral MUSE neutral, comfortable or very comfortable **Withdrawals/drop-outs/loss to f/u:** n=123 (12) **WDAE, n (%):** 15 (2) **TAE, n (%):** Penile pain: 159 (33) vs. 17 (3); also in 11% of administrations of alprostadil Minor urethral trauma: 25 (5) vs. 5 (1) Urinary tract infection: 1 (0.2) vs. 3 (0.6) Priapism-prolonged erection: 0 vs. 0 Penile fibrosis: 0 vs. 0 Dizziness: 9 (2) vs. 1 (0.2) Hypotension (dose response observed):0 v. 1 (0.2) **SAE:** NR **Ascertainment of outcomes assessed:** EAS (1= no response to 5= full rigidity); comfort by self assessment

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Peterson (1998) [209] **Funding source:** VIVUS Inc.	**N screened =** NR **N randomized =** 234 (CCT-crossover design) **IG1/IG2/IG3/ CG, n =** 234 **ITT analysis used for primary outcome:** NR **Inclusion**: men with ED 3 mo before enrolment, in stable relationship, who tolerated, and had a measurable response to 500 µg alprostadil in clinic **Exclusion:** Waking or early-morning erections sufficient for vaginal penetration within past 3 mo; hx of urethral stricture or obstruction; penile implant; indwelling urethral catheter or penile surgery; sickle cell dx; paraplegia or quadriplegia; uncontrolled congestive heart failure; unstable angina or acute MI within in 3 mo; poorly controlled DM; use of investigational tx other than IC injections within 2 mo of study entry; hx of epilepsy; active vasculitis; life expectancy < 6 mo; morbid obesity	**Age, mean SD):** 60 (10), range 26.8-81.5 y **Co-morbidities:** NR **Previous ED treatment, n (%):** None 94 (40), counselling 22 (10), hormonal tx 44 (18.8), IC 78 (33), band therapy 10 (4), vacuum pump 43 (18), other 6 (3) **Smoking status** NR **Body weight:** NR **Other:** Acute onset 67 (29), gradual onset 167 (71)	**Concomitant medications:** Testosterone replacement therapy and concomitant medications for unrelated conditions continued at stable dose throughout study **Duration of ED:** 4, range 0.25-30 **Underlying disease:** Vascular 92 (39), diabetes 42 (18), surgery/trauma 58 (25), other 42 (18) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** MUSE **IG2:** prazosin hydrochloride **IG3:** MUSE+prazosin (ratios 1:1, 1:2 and 1:4) **CG:** placebo **IG1:** Dose: 125, 250, 500 or 1000 µg Duration: 2-4 wks Frequency: 2 doses **IG2:** Dose: 250, 500, 1000 or 2000 µg Duration: 2-4 wks Frequency: 2 doses **IG3:** Dose: 1 of 9 combinations Duration: 2-4 wks Frequency: 2 doses **CG:** Dose: placebo Duration: 2-4 wks Frequency: 1 dose Compliance all: NR **Run In period:** NA **Wash out period:** at least 2 wks **F/u duration:** 7, -60 min after dosing	**Primary outcome (EF):** Grade 3 or higher, (%): 52 vs. 13 vs. 59 vs. 3 Grade 4 or 5, (%): 31 vs. 3 vs. 36 vs. 0.4 Median visual analogue scale (1-100), range: 37-50 vs. 8-22 vs. 42-60 vs. 4 **Other outcomes assessed:** pts comfort with **Withdrawals/drop-outs/loss to f/u:** 17 **WDAE:** 2 **TAE:** NR AEs, % (range) of total doses: penile pain or discomfort: 17–24 vs.1-6 vs. 17–32 vs. 2 testicular pain: 2-4 vs. 0-1 vs. 2-7 vs. 0.4 urethral pain: 1-9 vs. 0-2 vs. 2-14 vs. 2 dizziness 0–6 vs.0-1 vs. 0–12 vs. 0; hypotension: 1–4 (dose response for MUSE)vs. 0-2 vs. 0–14% vs. 0 prolonged erections, 4-6 hr, n (%): 2 (1) minor urethral bleeding, n (%): 12 (5) **SAE:** 0 **Ascertainment of outcomes assessed:** erection grading system (0-5)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Shabsigh (2000) [210] **Funding source:** Schwarz Pharmaceuticals AL	**N screened =** NR **N randomized =** 111 (two phase cross over study, Phase I: office dose titration; phase II: at home treatment) **IG1/IG2, n =** 111 **CG, n=** NA **ITT analysis used for primary outcome:** yes (Phase I, n= 95; Phase II, n= 68) **Inclusion**: ED at least 6 mo, stable heterosexual relationship **Exclusion**: pts with past IC or IU tx, chemotherapy, other meds that might produce bleeding or bruising after drug administration, monoamine oxidase inhibitors up to 2 wk before enrolment, \concomitant medication for ED or oral alpha-adrenergic receptor blocking agents, had ED due to urologic abnormality, penile fibrosis or untreated endocrine disorder (hypogonadism) or systolic BP < 100 mm Hg	**Age, mean (sd):** 59.2 (10.6) y, range 30-79 y **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** Blood pressure, mean (sd): Systolic: 139(15) mm Hg Diastolic: 83 (8) mm Hg Heart rate: 73 (10) beats per minute	**Concomitant medications:** NR **Duration of ED, mean (sd):** 5 (4) y \ **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** IC injection of alprostadil (EDEX) **IG2:** IU injection of alprostadil (MUSE) with option of ACTIS **IG1:** Dose: mean optimal dose = 27.3 µg (up to 40 µg, also most frequently used dose) Duration: phase I=1-14 d; phase II=21 d Frequency: phase II=max of 9 IU/ 21 d administrations in 21 d Compliance: NR **IG2:** Dose: optimal dose = 921 µg (up to 1000 µg, 33% of all administrations) Duration: as IG1 Frequency: as IG1 Compliance: NR **Run In period:** 1 to 14 d **Wash out period:** NR **F/u duration:** 3 wk off treatment	**Primary outcome results:** IG1 vs. IG2 Grade $\geq$ 3, n (%): By physician: 59 (62) vs. 19 (20) Patient assessment: 63 (66) vs. 25 (26) Positive buckling tests (1 kg), n (%): 58 (61) vs. 20 (21) Erection sufficient for intercourse, (%): 82 vs. 47 Satisfaction rating mean: 6 vs. 3 IIEF score, baseline all vs. IG1 vs. IG2, mean (sd): EF Q1-5, 15: 9 (6) vs. 25 (7) vs. 17 (9) Intercourse satisfaction Q6-8: 5 (4) vs. 11 (3) vs. 8 (4) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n:** 43 (phase I, 16; phase II, 27) **WDAE:** NR **TAE:** pts with at least 1 AE [phase I]; [phase II], (%): [31 vs. 56], [53 vs. 58] Application site reaction: [4 vs. 16], [2 vs. 10] Other penile pain: [20 vs. 30], [34 vs. 25] Prolonged erection: [2 vs. 0], [3 vs. 0] **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF (Q1-5, 15; and Q9, 10; and Q6-8; and Q13, 14), Buckling test; grading system 0-3

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Shokeir (1999) [211] **Funding source:** NR	**N screened =** NR **N randomized =** 60 (parallel design) **IG1, n =** 30 **IG2, n =** 30 **CG =** NA **ITT analysis used for primary outcome:** NR **Inclusion**: men 18 y or older, with ED of primarily organic aetiology, inability to achieve erection sufficient for intercourse at least 1 time during 3 mo before study period **Exclusion:** previous use of IC injections Data reported as IG1 vs. IG	**Age, mean (sd):** 55 (18) vs. 56 (17) y **Co-morbidities:** NR **Previous ED treatment, n (%)**: 16 (53) vs. 17 (57); vacuum pumps, band therapy, hormones **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (sd):** 36 (8) vs. 38 (10) **Underlying disease, n (%):** Vascular disease: 9 (30) vs. 6 (20); diabetes: 15 (50) vs. 18 (60); surgery/ trauma: 3 (10) vs. 3 (10); other causes 3 (10) vs. 3 (10) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** IC PgE1(injection) **IG2:** IU MUSE **IG1:** Dose: 20 µg Duration: 3 mo Frequency: at least 1/wk Compliance: 33% **IG2:** Dose: 1 mg Duration: 3 mo Frequency: at least 1/wk Compliance: 83% **Run In period:** NR **Wash out period:** NR **F/u duration:** 3 mo	**Primary outcome results:** IG1 vs. IG2 Erection score of 4 and 5 in clinic, n (%): 27 (90) vs. 18 (60) Sexual intercourse (at least once) at home: 26 (87) vs. 16 (53) **Other outcomes assessed:** Ease of treatment **Withdrawals/drop-outs/loss to f/u:** n = 25, IG1 n=20 vs. IG2 n=5 **WDAE, n:** 9 (due to pain) vs. 0 IG1: IG2: 0 **TAE, n (%):** All AE, Urogenital pain 14 (47) vs. 2 (7); dizziness 0 vs. 2; urethral bleeding 0 vs. 1 **SAE:** 0 **Ascertainment of outcomes assessed:** Personal diaries, Erection Assessment Scale 0-5

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Williams (1998) [212] **Funding source:** Grant from VIVUS Inc. Manufacturer of MUSE (Alprostadil (PGE_1) in transurethral route)	**N screened =** 249 **N randomized =** 159 (64% of screened pts who achieved erection adequate for intercourse on test dose) **IG, n =** 78 **CG, n =** 81 **ITT analysis used for primary outcome:** ITT efficacy 44% **Inclusion**: men 18 y or older with primary organic ED 3 mo or longer in duration, inability to achieve erection for intercourse on all attempts for 3 mo before study, stable, heterosexual, monogamous relationship, willing to have intercourse 4/mo + use contraception **Exclusion:** NR Data reported for IG vs. CG	**Age, mean (range):** 57.3 (25-78) y vs. 57.3 (26-77) y **Co-morbidities:** NR **Previous ED treatment, (%)**: 51 vs. 54 (constrictive bands, IC, vacuum, counseling) **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 59.6 (3-644) vs. 63.3 (4-417) mo **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** Vascular disease: 33% vs. 41% Diabetes 18% vs. 15% Surgery/trauma: 24% vs. 21% Other organic (includes; alcohol or tobacco use; neurological diseases; medication adverse reaction): 24% vs. 24% **Mixed ED**: NR	**IG1:** Alprostadil (PgE1) transuretrhal pellet as per protocol **CG:** Placebo **IG1:** Dose: Escalating dose of 125, 250, 500 or 1000 µg Duration: 3 mo Frequency: at least 1/mo Compliance: 53 (68%) **CG:** Dose: Placebo Duration: 3 mo Frequency: as IG 1/mo Compliance: 64 (79%) **Run In period:** 3 mo **Wash out period:** NA **F/u duration:** 3 mo **Other:** Final patient selected dose distribution (µg), n (%): 1000 µg =103 (65%) 500 µg= 27 (17%) 250 µg =21 (13%) 125 µg =5 (5%)	**Primary outcome results:** EAS, score ≥ 4: in all pts, 159 (64%) Intercourse ≥ once during 3 mo, n (%): 46(69) vs. 8/73 (11%), p<0.001 Intercourse/ total injections: 390/ 763 (51) vs. 46/611 (7.5) CG **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 42 (26%) [n=25 vs. n=17] **WDAE:** 4 **TAE:** self reported AEs, n (%): Urogenital pain/ burning: 5 (6) vs. 0 Penile pain: 4 (5) vs. 1 (1) Testicular pain: 2 (3) vs. 0 Urethral bleeding/spotting: 1 (1) vs. 1 (1) Urinary tract infection: 0 vs. 0 Prolonged erection < 5 hr: 1 (1) two events vs. 0 Priapism (≥ 6 hr)= firbrosis= hypotension: 0 vs. 0 Dizziness: 2 (3) vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** Erectile Assessment Scale (1=no response to 5=rigid erection) Comfort with therapy, intercourse rate, and AE by diary/self report

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C8-Topical Treatments of ED

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Cavallini (1991) [213] **Funding source:** NR	**N screened =** 51 **N randomized =** 33 **(crossover design)** **IG1/IG2/CG =** 33 (random order in each session) **ITT analysis used for primary outcome:** NR **Inclusion**: chief complaint of impotence **Exclusion:** psychogenic impotence; uncontrolled diabetes; thyroid, renal or hepatic disease; recent myocardial infarction; hypotension; use of organic nitrates or nitrites or of minoxidil within previous 4 mo	**Age, mean (range):** 58, 42–68) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** DM 12 (36.4); arteriosclerosis 9 (27.3); hypertension 4 (12.1; pelvic fracture or surgery 6 (18.2); SCI 1 (3), multiple sclerosis 1 (1) **Psychogenic ED**: 0 **Physiologic ED:** 33 **Mixed ED**: 0 **Other:** NA	**IG1:** 10% topical Nitroglycerin paste **IG2:** 2% minoxidil topically to glans penis **CG:** placebo (lubricating gel) topically to glans penis **IG1:** Dose: 2.5 g Duration: NR Frequency: once/wk; applied to shaft Compliance (%): 100% **IG2:** Dose: 1 mL Duration: NR Frequency: one/wk applied to glans Compliance (%): 100% **CG:** Dose: 2.5 g Duration: NR Frequency: as IG2 Compliance (%): 100% **Run In period:** NR **Wash out period:** 1 wk **F/u duration:** outcomes were measured one hr post dosing each; trail duration 3 wks	**Primary outcome results:**Change in circumference of base of penis and in rigidity over baseline values, assessed a few minutes after drug application Circumference (mm), mean (sd): IG1: 9.5 (5.3) IG2: 17.2 (7.5) CG: 4.3 (4.0) Rigidity, mean % (sd); range: IG1: 28.2 (11.1), range 0–80% IG2: 40.0 (13.3), range 0–85% CG: 13.6 (10.7), range 0–18% **Other outcomes assessed:** Examination of cavernous penile artery flow with Doppler sonography **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE, n:** pts with AE 17 (51.5); nitroglycerine 15 (45.5) vs. minoxidil 2 (6.1) vs. 0 Burning pain at application site, headache, hypotension **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Cavallini (1994) [214] **Funding source:**	**N screened =** NR **N randomized =** 132 cross over trial (data reported for n=116 completers) **IG1, n =** 39 **IG2, n =** 39 **IG3, n =** 38 **CG, n =** NA **ITT analysis used for primary outcome:** No **Inclusion**: pts with ED **Exclusion**: psycogenic, endocrine or pharmacological impotence, recent MI, hypotension, uncontrolled diabetes, liver or kidney disease, use of organic nitrates, nitrates or minoxidil in the previous 4 mo	**Age, mean (range):** 58 (42-71) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED:** at least 6 mo **Underlying disease, n (%):** diabetic neuropathy 11 (9.5); SCI 3 (2.6); pelvic fracture 6 (5.2), pelvic surgery 12 (10.3); diabetic angiopathy 18 (15.5); atherosclerosis 27 (23.3); hypertension 16 (13.8); DM 10 (8.6) **Psychogenic ED**: None **Physiologic ED:** Neurogenic (n=34), arterial (n=61) **Mixed ED** n=12	**IG1:** minoxidil – nitroglycerine - placebo **IG2:** nitroglycerine – placebo - minoxidi **IG3:** placebo – minoxidil - nitroglycerine **IG1:** minoxidil (2%) Dose: 1 ml Duration: 2 mo Frequency: twice/ d Compliance (%): NR **IG2:** nitroglycerine (10%) Dose: 2.5 g Duration: 2 mo Frequency: twice/ d Compliance (%): NR **CG:** placebo Dose: 2.5 g Duration: 2 mo Frequency: twice/ d Compliance (%): NR **Run In period:** **Wash out period:** **F/u duration:** 6 mo	**Primary outcome results:** N (%) pts with positive response (prompt erection, absence of penis flexure during intercourse, maintaining full erection until ejaculation): 51 (44) vs. 24 (20.7) vs. 2 (1.7%), p < 0.01 (IG1 vs. IG2 and IG2 vs. CG) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u, n (%):** 16 (13.8) **WDAE** NR **TAE, n (%):** pts (IG1 vs. IG2 and IG2 vs. CG) = 7 (6.0) vs. 52 (44.8) vs. 0, p < 0.01 (IG1 vs. IG2 and IG2 vs. CG), p < 0.05 (IG1 vs. CG) **SAE:** NR **Ascertainment of outcomes assessed:** Questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Claes (1992) [215] **Funding source:** NR	**N screened =** NR **N randomized =** 50 (cross over) **IG/ CG, n =** 50 (random order of active tx or placebo) **ITT analysis used for primary outcome:** No **Inclusion:** men with ED (defined as having erections insufficient in rigidity/ or duration for penetration during intercourse) **Exclusion:** hx of MI; hypotension, use of organic nitrates within previous 6 mo	**Age, mean (range):** 56 (**Race:** NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: NR **Body weight:** NR	**Concomitant Medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Physiologic ED:** NR **Psychogenic ED:** NR **Mixed ED**: NR	**IG:** Nitroglycerine (Deponit (TM)) delivered by transdermal therapeutic system **CG**: placebo **IG:** Dose: 10 mg Duration: 24 hr/ dose: 3 night Frequency: 3/dose (active or placebo) Compliance (%): **CG:** Dose: NA Duration: as IG Frequency:as IG Compliance (%): **Run In period:** NR **Wash out period:** NR **F/u duration (both on and off treatment):** NR	**Primary outcome results:** Excluded from analysis Rigidity >70% (normal): n=4 (9.8%) No erection, <70% rigidity: n=7 (17.1%); Change in rigidity from baseline, n (%); mean% (sd), range, IG: Base ▲ in n= 21 (51.2); 14 (3), 1-21% ▼ in n= 6 (14.6); 6 (2), 1-11 No change in n = 3 (7.3) Tip ▲: n=23 (56.1); 17 (4), 1-27% ▼: n=5 (12.2); 8 (3), 1-14% No change n = 2 (4.9) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u, n (%):** 9 (51.2) **WDAE:** 4 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan ambulatory unit in laboratory (pts were evaluated at baseline with IC injection of papaverine 40-80 mg)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Diamond (2004) [216] **Funding source:** NR	**N screened =** NR **N randomized =** 24 **IG/ CG, n=** 24 (3 way cross over, two active tx of high or low dose, and placebo) **ITT analysis used for primary outcome:** yes **Inclusion:** men 18 or older, diagnosis of ED, treated successfully with Viagra within 6mo, current users of Viagra **Exclusion:** ED caused by untreated endocrine disease, penile anatomic deformations, prostatic disorders, evidence of clinically sign. hepatic, renal, cardiovascular, psychiatric or CNS disease (stroke or SCI)	**Age, mean (se):** 50.9 (8.1); range 38-64 **Race, n (%):** White 16 (66.7) Black 6 (25.0) Hispanic 1 (4.2) Other 1 (4.2) **Co-morbidities, n (%):** DM 2 (8); hypertension 4 (17); hyperlipidemia 3 (13) **Previous ED treatment**: NR **Smoking status**: N 14 (59) **Body weight, mean (se):** 89.1 (15.2) Range 61.3-120.8	**Concomitant medications:** viagra (all pts) **Duration of ED, mean:** 6.2 y **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1/2:** cyclic heptapeptide melanocortin analog PT-141) delivered intranasally in 2 doses or placebo **CG:** placebo **IG1/2:** Dose: 7 (IG1) or 20 mg (IG2) Duration: 12 hrs Frequency: 3 times Compliance (%): 100 **CG:** Dose: NA Duration: 12 hrs Frequency: 1x Compliance (%): 100 **Run In period:** NA **Wash out period:** NA **F/u duration (both on and off treatment):** NR	**Primary outcome results:** Duration of erection (min) with rigidity $\geq$ 60%: Base, mean (se): 26.0 (5.52) vs. 53.8 (8.54) vs. 18.5 (3.72) Tip, mean: 6.3 vs. 23.8 vs. 7.2 **List (narrative) other outcomes assessed:** plasma concentrations of study drug (ng/ml), mean: IG1=38.8; IG2 = 122.1 **Withdrawals/drop-outs/loss to f/u [N and or %]:** 0 **WDAE (N and/or %): 0** **TAE, n (%):** AE in 5% or more of pts, 7 mg vs. 20 mg vs. placebo: 9 (37.5) vs. 8 (33.3) vs. 3 (12.5); including: Nausea = 1 (4.2) vs. 4 (16.7) vs. 0 Headache = 1 (4.2) vs. 0 vs. 0 Feeling hot = 2 (8.3) vs. 0 vs. 1 (4.2) Somnolence = 1 (4.2) vs. 0 vs. 1 (4.2) Flushing = 4 (16.7) vs. 4 (16.7) vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan, blood tests, physical exam

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Foldvari (1998) [217] **Funding source:** NR	**N screened =** NR **N randomized =** 5 in crossover design **IG1/IG2/IG3/CG, n=** 5 **ITT analysis used for primary outcome:** NR **Inclusion:** ED caused by vascular impairment; and previous response to 10 or 20 µg PgE_1 IC; with no venous leak **Exclusion:** NR **Note:** this study compared the in vitro transdermal absorption of PgE1 to in vivo efficacy of the medication in ED pts	**Age, range:** 54-70 y **Race (%):** NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment:** all pts PgE_1 IC, 10-20 µg **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/grp):** NR **Psychogenic ED**: 0 **Physiologic ED:** Vascular 5 (100%) **Mixed ED**: NR	**IG1:** topical PgE_1 + placebo **IG2:** PgE_1 + calcium thioglycolate+ placebo **IG3:** PgE_1 + methyl-salicylate+ placebo **CG:** placebo **IG1-3:** Dose: PgE1=1.5 g (all grps); Calcium thioglycolate= 1% (IG2); Methyl-salicylate=2% (IG3) Duration: NR Frequency: single dose/ intervention Compliance (%): 100% **CG:** Dose:1.5 g soy phosphatidylcholine 15% Duration: NA Frequency: as IG Compliance (%): 100% **Run In period:** NR **Wash out period:** at least 1 wk **F/u duration:** 45 min post dosing	**Primary outcome results:** Quality of erection: no dose reached threshold for erection. PSV (cm/s) at 0 min vs. 45 min, mean (sd): IG1 = 0 vs.12.3 (1.1) IG2 = 5.5 (2.6) vs. 1.3 (0.8) IG3 = 0 vs. 14.2 (4.4) CG = 2.0 (1.9) vs. 7.7 (6.8) Max peak flow Velocity: IG3 =32 cm/s **Other outcomes assessed:** Steady State Flux (mg/cm^2/ hr) of PgE_1: IG3 (0.191) > b (0.083) > IG2 (0.010) > CG Permeability coefficient (cm/hr x 10^{-4}) (i.e. rate + extent of penetration): IG3 (3.82) > IG1 (1.66) > CG (0.84) > IG2 (0.10); Total amount of PgE_1 absorbed: IG3 = 3.5 µg (microgram)/cm^2 **Withdrawals/drop-outs/loss to f/u:** IG1 1 vs. IG2 2 vs. IG3 0 vs. CG 2 **WDAE:** NR **TAE**: 0 **SAE:** NR **Ascertainment of outcomes assessed:** Peak Systolic Flow Velocity (arterial) by Duplex color Doppler: every 15 min for1 hr at 60 degree angle Normal at > 25 cm/s

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Goldstein (2001) [218] **Funding source:** MacroChem Co. sponsor for study drug. Some authors supported by MacroChem Co., Pfizer, Bayer,TAP, Zonagen and Schering Plough	**N screened =** 62 **N randomized =** 60 **IG, n =** 30 **CG, n =** 32 **ITT analysis used for primary outcome:** yes (n=60) **Inclusion:** male 21 or older; with ED of 6 mo or longer (decrease or absent of morning erection **Exclusion:** Previously enrolled in a Topiglan study; untreated endocrine or Peyronie's disease; radical prostatectomy; CAD; hypertension (Screening exclusion criteria: Placebo+ Erotic movie at 30 min from onset + vibrator at 45 min and then discontinued at 60 min. If erectile response ≥ 70 degree angle or grade 3 as rated by pts were withdrawn)	**Age, range:** 24-78 yr **Race (%):** NR **Co-morbidities:** NR **Previous ED treatment:** all Oral (Sildenafil); PgE1 in IC or IU route or PgE1 + papaverine + phentolamine IC or papaverine + phentolamine IC tx **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED, %:** Vascular: 97% **Mixed ED**: NR	**IG1:** Topiglan 1% (PgE1 formula)+ VS. + vibration **CG:** Placebo +VS + vibration **IG:** Dose: 0.25 ml Duration: Single Frequency: once Compliance: 100% **CG:** Dose: 0.25 ml (formulation similar to Topiglan without PgE1) Duration: Single Frequency: 2 Compliance: 100% **Run In period:** 7 d **Wash out period:** NA **F/u duration:** 2 wks (VS and vibration stopped at 60 min post dosing, outcome measured at 90 min post dosing)	**Primary outcome results:** Erection rigidity measured by angle of erection: IG1 vs. CG 44.5º (3.8)º vs. 33.5º (3.4)º (p= 0.033) Mean change of angle from baseline: 24.2º vs. 13.5º (p= 0.039) Rigidity as per Investigator assessment: Overall IG1 vs. CG: p= 0.003 Erection sufficient for vaginal penetration, n (%): 12 (38) vs. 2 (6.9), p =0.005 No tumescence, n (%): 3 (9.7) vs. 8 (27.6) **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 2 (3.2) **WDAE:** 0 **TAE:** 3 vs. 0 Conjunctivitis: 2 vs. 0 Hypotension: 1 vs. 0 **SAE:** 0 **Ascertainment of outcomes assessed:** Penile angle: measured by placing a protractor next to penis in standing position. Measure of angle at vertical axis; erection rigidity scale investigator assessed at 15-90 min (1-5)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gomaa (1996)[219] **Funding source:** no additional funding; no conflict of interest	**N screened =** NR **N randomized =** 36 **ITT analysis used for primary outcome:** NR **IG, n=** 36 **CG, n=** 36 **Inclusion**: Pts whose chief complaint was ED aged 31-65 y **Exclusion:** Pts with hypotension or glaucoma	**Age, median (range):** 48 (31-65) y **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** mean arterial flow = IG1: 0.06 (0.02) vs. CG: 0.06 (0.02)	**Concomitant medications:** NR **Duration of ED, median (range):** 39 (5-72) mo **Underlying disease:** DM, hypertension, anxiety, depression, and surgery **Psychogenic ED, n (%)**: 9 (25) **Physiologic ED, n (%):** 8 (22.2) (neurogenic), 7 (19.4) (arterial insufficiency) **Mixed ED, n (%)**: 8 (22.2)	**IG:** Topical cream **CG:** Placebo cream **IG:** Topical cream (3% aminophylline, 0.25% isosorbide dinitrate, 0.05% co-dergocrine mesylate) Dose: 2 g/d Duration: 7 d Frequency: once Compliance (%): NR **CG:** Placebo (lubricating gel) Dose: 2 g/d Duration: 7 d Frequency: once Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration (both on and off treatment):** 7 d	**Primary outcome results:** IG vs. CG Mean arterial flow: 0.25 (0.1) vs. 0.08 (0.07), p (between-arm) = NR, p (within-arm for IG1) < 0.001 and p (within-arm for CG) > 0.05. Erection sufficient for successful intercourse, n: 21 vs. 3, p < 0.001 Partial erection, n: 2 vs. 0, p = NR No response, n: 11 vs. 33, p = NR (3/9 pts with Psychogenic impotence reported improvement with both creams) **Other outcomes assessed:** erection outcome reported for three etiology type **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** No prolonged erection, priapism, CVD, headache **SAE:** NR **Ascertainment of outcomes assessed:** penile tumescence and arterial flow in laboratory measures; other outcomes from pts diary **Other**: the active cream was most effective in pts with psychogenic and neurogenic ED

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gramkow (1999) [220] **Funding source:** The Bryde Nielson Foundation	**N screened =** NR **N randomized =** 19 (cross-over design with 2 part study A, B) **Laboratory study:** **IG/ ICG, n =** 19 **Home study:** **IG/ ICG, n =** 18 **ITT analysis used for primary outcome:** no **Inclusion**: unable to complete intercourse, some erectile response to IC injection of 30 mg papaverine, with penile-brachial index > 60% **Exclusion:** Arterial hypotension, arterial insufficiency < 60 %, former coronary occlusion, hypersensitivity to nitroglycerine, used any kind of drug containing nitroglycerine within last 2 mo.	**Age, median (range):** 56 (39-5-65) y **Race (%)**: NR **Co-morbidities (unrelated to disease):** cancer (rectum, bladder), peyroni plaque, slipped disc, multiple sclerosis, chronic prostatitis **Previous ED treatment:** IC injection of 30 mg papaverine **Smoking status, n (%)**: smokers 7 (39) **Initial body weight:** NR	**Concomitant medications:** various medication **Duration of ED (yr):** NR **Underlying disease:** no specific cause reported **Psychogenic ED**: 12 **Physiologic ED:** 5 **Mixed ED**: 1 **Other:** N/A	**IG:** nitroglycerine plasters, topical absorption +VS **CG:** placebo of nitroglycerine plasters, topical absorption+ VS **IG:** Dose: 10 mg Duration: lab period 2 hr/session; home period varied in each pts Frequency: lab study: twice (1/d); home study 6 times Compliance (%): lab 100%; home study 94.4% used all plasters **CG:** Dose: 10 mg Duration: as IG Frequency: as IG Compliance (%): lab 100%; home study: 66.7% used all plasters **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** *Laboratory period* Penile rigidity: (only figure provided within text but N of patients in each % range category clear) No effect: 11 vs. 12 Poor effect: 1 vs. 1 Moderate effect: 3 vs. 3 Good effect: 2 vs. 0 Excellent effect: 1 vs. 2 No sign tx effect found in IG vs. CG p=0.7656 *Home period* Median score (scale 1-3), median range: 1-2 vs. 1-2.5 **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u:** 1 (5.3) RigiScan data could not be collected during lab test **WDAE:** 1 vs. 0 (severe pain with plaster) **TAE:** IG: headache 35 cases; 23 cases of smarting pain at the application site **SAE:** NR **Ascertainment of outcomes assessed:** Laboratory study: RigiScan monitoring; home study: questionnaire (3 item point Scale; 1= no effect; 3= good effect)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Le Roux (1999) [221] **Funding source:** NR	**N screened =** NR **N randomized =** 14 **IG, /CG, n =** 14 **ITT analysis used for primary outcome:** NR **Inclusion**: pts with erectile failure who previously responded to IC injections **Exclusion:** NR	**Age, mean (range):** 44 (23-57) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** all had tx with IC injection 14 (100%) **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease, n:** pelvic fracture (n=1), spinal paraplegia from tuberculosis (n=1), spinal myelopathy of unknown aetiology (n=1), vasculogenic impotence (n=1) **Psychogenic ED, n (%):** 10 (71.4) **Physiologic ED, n (%):** 4 (28.6) **Mixed ED**: NR	**IG:** vasoactive cream (aminophylline, co-dergocrine mesylate, isosorbide dinitrate) **CG:** placebo (gel) **IG1:** Dose: 2 mL syringes (aminophylline 3%, co-dergocrine mesylate 0.05%, isosorbide dinitrate 0.25%); total applications =77 Duration: NR Frequency: 8 application with each cream used alternatively Compliance (%): NR **CG:** Dose: NA Duration: NR Frequency: as IG; total applications =76 Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 wks	**Primary outcome results:** Penile response 77 vs. 76 applications in n=8: Erection adequate for intercourse: 3 (3.9) vs. 4 (5.3) [all in one pt] Partial response: 13 (16.9) vs. 13 (17.1) No response: 61 (79.2) vs. 59 (77.6) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** 6 (43%) did not complete the trial **WDAE:** 0 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** Penile response by grading system (good, partial, no response) by pts diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan (2002) [222] Study a **Funding source:** NedMex Inc.	**N screened =** NR **N randomized =** 161 **IG1, n =** 42 **IG2, n =** 39 **IG3, n** = 40 **CG, n =** 40 **ITT analysis used for primary outcome:** No **Inclusion:** ED ≥ 3mo, monogamous & stable relationship with consenting female partner, mild-moderate ED classified by IIEF-EF domain (score 14-21) **Exclusion:** ED caused by untreated endocrine disease, clinically sign. renal or hepatic disease, use of prescribed or over the counter medication, supplements, or devices for ED	**Age, mean (sd):** 56.5 (7.1), range 21-65 y **Race, %: IG vs. CG** White 86 vs. 75; African-American 7.3 vs. 10; Asian 0 vs. 2.5; Hispanic 5.8 vs. 12.5; Other 2.6 vs. 0 **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (sd):** 93.4 (37.3) kg	**Concomitant medications:** NR **Duration of ED:** 95% of pts had ED for longer than 1 y; 5% under 1 y **Underlying disease, %:** CVD 54.3%; DM 15.7% **Psychogenic ED**: NR **Physiologic ED:** 100% **Mixed ED**: NR	**IG1-3:** Topical alprostadil cream **CG:** Placebo cream **IG1:** Dose: IG1= 0.05 mg, IG2= 0.1mg, IG3= 0.2 mg Duration: 6 wks Frequency: 3 application in 3 wks Compliance (%): 100 **CG:** Dose: NA Duration: 6 wks Frequency: as IG Compliance (%): 100 **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 wks	**Primary outcome results:** IIEF- EF, change from baseline, mean (sd): IG: 1.8 (1.1) vs. 0.7 (1.2) vs. 3.7 (1.2) CG: -0.8 (1.1) Total IIEF score, change from baseline, mean (sd): IG: 4.7 (2.3) vs. 1.4 (2.4) vs. 7.2 (2.5) CG: -1.7 (2.2) SEP-Q3/Q1 (penetration success rate), mean (sd): IG: 69.4 (34.2) vs. 69.1 (39.3) vs. 82.9 (24.6) CG: 55.3 (40.0) GAQ, % improved: IG: 80% vs. 70% vs. 93% CG: 54% **Other outcomes assessed:** Other IIEF domains **Withdrawals/drop-outs/loss to f/u:** IG 22 (18.2) vs. CG 0 **WDAE, n (%):** IG 6 (14.3) vs. 7 (17.9) vs. 9 (22.5), CG 0 (urogenital pain) **TAE, n (%):** IG 28 (66.7) vs. 26 (66.7) vs. 31 (77.5), CG 21 (52.5) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, GAQ, SEP

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan (2002) [222] Study b **Funding source:** NedMex Inc.	**N screened =** NR **N randomized =** 142 **IG1, n =** 37 **IG2, n =** 35 **IG3, n** = 35 **CG, n =** 35 **ITT analysis used for primary outcome:** No **Inclusion**: ED ≥ 3mo, monogomous & stable relationship with consenting female partner, severe ED classified by IIEF EF Domain score (score < 14) **Exclusion:** ED caused by untreated endocrine disease, clinically sign. renal or hepatic disease, use of prescribed or over the counter medication, supplements, or devices for ED	**Age, mean (sd):** 55.6 (8.0), range: 21-70 y **Race (% by respective grp)**: Caucasian 88.8%; African-American 4.3%; Asian 0.7% (only in IG2); Hispanic 4.8%; Other 2.1% **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (sd):** 92.6 (36.8) kg **Other:** IIEF-EF, mean (sd): IG 6.7 (3.6); CG 7.8 (3.5)	**Concomitant medications:** NR **Duration of ED** (% by respective grp**):** .25 –1 yr 7.25%; > 1 y 92.75% **Underlying disease, %:** CVD 58.25% (slightly lower in IG1); DM 50.75 (slightly higher in IG1) **Psychogenic ED**: NR **Physiologic ED:** 100% **Mixed ED**: NR	**IG1-3:** Topical alprostadil cream **CG:** Placebo cream **IG1:** Dose: IG1= 0.1 mg, IG2= 0.2mg, IG3= 0.3 mg Duration: 6 wks Frequency: 3 application /3 wk Compliance (%): 100 **CG:** Dose: NA Duration: 6 wks Frequency: as IG Compliance (%): 100 **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 wks	**Primary outcome results:** Data reported for IG n=34, 29, 29; CG n=35 IIEF, change from baseline, mean (sd) EF domain IG: 6.29 (1.38) vs. 6.49 (1.48) CG: 2.67 (1.34) Total IIEF score: IG: 11.47 (2.74) vs. 12.96 (2.96) vs. 17.65 (2.92); CG: 6.24 (2.67) SEP-Q3/Q1 (penetration success rate), mean (sd): IG: 32.3 (18.0) vs. 36.2 (29.3) vs. 38.6 (22.8); CG: 15.6 (17.2) GAQ, % improved: IG: 59% vs. 76% vs. 83%; CG 26% **Other outcomes assessed:** Other IIEF domain scores **Withdrawals/drop-outs/loss to f/u, n (%):** IG 15 (14) vs. CG 0 **WDAE, n (%):** IG 1 (3) vs. 7 (20) vs. 8 (23); CG 0 **TAE, n (%):** IG 11 (30) vs. 21 (60) vs. 18 (51); CG 4 (11) **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF, SEP, GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan (2006) [223] **Funding source:** NexMed (study drug supply); co-author a paid consultant of NexMed	**N screened =** **N randomized =** 1732 **IG1, n =** 434 **IG2, n =** 430 **IG3, n =** 434 **CG, n =** 434 **ITT analysis used for primary outcome:** yes (pts with at least one study medication) **Inclusion:** men at least 21 y, in a stable relationship, and hx of ED of at least 3 mo in duration **Exclusion:** ED due to untreated endocrine disease or sing penile pathology (i.e. penile fibrosis, Peyronie disease)	**Age, mean (se):** 61 (0.47) y **Race:** White 86%; Black 8.3%; Hispanic 3.9%; other 1.8% **Co-morbidities, n (%):** DM 305 (17.6); cardiac 503 (29); prostatectomy 220 (12.7) slightly higher in IG1; hypertension 783 (45.2) **Previous ED treatment:** sildenafil [failures 352 (18.8)] **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG1-3:** Alprostadil topical cream **CG:** Placebo cream **IG1-3:** Dose: IG1=100 µg, IG2 = 200 µg, IG3=300 µg Duration: 12 wks Frequency: up to 24 applications (2/wk) Compliance: NR **CG:** Dose: Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wks drug free **Wash out period:** **F/u duration:** 16 wks	**Primary outcome results:** IIEF-EF, LS mean change from baseline (se): IG: 1.6 (0.34) vs. 2.5 (0.34) vs. 2.4 (0.34), CG –0.7 (0.34) SEP, LS mean % change form baseline (se): SEP-2: IG 2.9 (1.63) vs. 5.1 (1.65) vs. 7.2 (1.65), CG –4.5 (1.65) SEP-3: IG 7.0 (1.61) vs. 13.8 (1.63) vs. 9.1 (1.63), CG 0.4 (1.64) GAQ, % improved: IG 40% vs. 47% vs. 52%, CG 20% **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** **WDAE, n (%):** 46 (2.7) **TAE, n (%):** 198 (45.6) vs. 267 (62.1) vs. 292 (67.3) vs. CG 54 (12.4) Body as whole: IG 5 (1.2) vs. 1 (0.2) vs. 0 CG 1 (0.2); nervous system IG 5 (1.2) vs. 7 (1.6) vs. 11 (1.2), CG 1 (0.2) Skin rash: IG 2 (0.5) vs. 5 (1.2) vs. 2 (0.5) CG 1 (0.2); urogenital system: IG 186 (42.9) vs. 254 (59.1) vs. 279 (64.9) CG 51 (10.6) **SAE, n (%):** IG 0, CG 1 (0.2) died due to cardiac arrest **Ascertainment of outcomes assessed:** IIEF-EF; SEP; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Steidle (2002) [224] **Funding source:** NexMed manufacturer of Alprostadil topical	**N screened =** 303 **N randomized =** 265 from 2 Phase II RCT, 12 settings **IG1, n =** 36 **IG2, n =** 66 **IG3, n =** 61 **IG4, n =** 29 **CC, n =** 73 **ITT analysis used for primary outcome:** NR **Inclusion**: men 21-75 y, with diagnosed ED of at least 3 mo in duration, and IIEF score of 21 or less **Exclusion:** NR	**Age, mean (sd):** 82.1 (7.4) y **Race (%):** White: 84.7; African American: 6.5; Asian 0.6; Native American 1.9; Hispanic 6.6; Other 1.2 **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight, mean (sd):** 92.5 (38) kg	**Concomitant medications:** NR **Duration of ED (yr):** 0.25 -1 yr: 7 % >1yr: 93 % **Underlying disease, %:** CVA 56.8; DM 37% **Psychogenic ED, n (%):** IG 48 (25) vs. CG 18 (25) **Physiologic ED, n (%):** IG 72 (37.5) vs. CG 28 (38) **Mixed ED, n (%):** IG 72 (37.5) vs. CG 27 (37) **Other: Mean** IIEF-EF domain, mean (sd): 12 (4.8)	**IG1-4:** Alprostadil (PgE_1) topical **CG:** Placebo **IG1-4:** Dose: 0.1ml IG1=50 µg IG2=100 µg IG3=200 µg IG4=300 µg Duration: 6 wks Frequency: 10 doses Compliance (%): NR **CG:** Dose: 0.1 ml placebo Duration: 6 wks Frequency: as IG Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration (both on and off treatment):** 6 wks	**Primary outcome results:** IIEF-EF change from baseline, mean (sd): 3.36 (1.3), 3.40 (0.88, 5.34 (0.92), 9.44 (1.43) vs. 0.98 (0.84) GAQ, % improved: IG1 p= 0.028, IG2 p= 0.007, IG3 p< 0.001 or IG4 p<0.001 vs. CG SEP-Q3, %: 59.4 (6.3), 53.4 (4.4), 62.6 (4.5), 66.8 (7.1) vs. 42.6 (4.2) **Other outcomes assessed:** self evaluation of erection; SEP Q3/Q4 **Withdrawals/drop-outs/loss to f/u, n (%):** IG 0, 2 (3), 2 (3), 6 (21) vs. CG 3 (4); all IG 10 (5.2) vs. CG 3 (4.1) **WDAE, n (%):** IG 6 (14), 8 (11), 16 (21), 7 (20) vs. CG 1 (1) **TAE, n (%):** reported only if ≥ 3% (n) 214 **SAE:** Near Syncopal episode for approximately 10 minutes: 1(1.3%) in IG3 **Ascertainment of outcomes assessed:** IIEF-EF; GAQ; SEP Patient self-evaluation of erection (PSAE), score 1-5

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Yonessi, M (2005) [225] **Funding source:** research council of Mazandaran University of Medical Sciences, Sari, Iran	**N screened =** 94 **N randomized =** 80 **IG1, n =** 40 **CG, n =** 40 **ITT analysis used for primary outcome:** NR **Inclusion**: ED **Exclusion:** anatomical defects of penis or other sexual disorders; spinal cord injury; major psychiatric disorder; poorly controlled diabetes; stroke; heart attack within 6 mo; treatment with organic nitrate; active peptic ulcer disease; migraine; vision disorders; allergic rhinitis	**Age, mean (range):** 47.2 (26-63) vs. 50.8 (37-65) y **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Previous ED treatment**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED, mean (range):** 1.4 (0.6-2.8) vs. 1.5 (0.6-3.0) **Underlying disease:** NR **Psychogenic ED:** 23 (57) vs. 24 (60) **Physiologic ED:** 17 (42) vs. 16 (40) **Mixed ED**: 0	**IG:** 1% sildenafil topically to glans penis + placebo tablet **CG:** placebo topically to glans penis + sildenafil tablet **IG1:** Dose: 0.5 g 1% sildenafil gel + placebo tablet Duration: NR Frequency: NR Compliance (%): 100% **CG:** Dose: 100 mg oral sildenafil and placebo gel Duration: NR Frequency: NR Compliance (%): 100% **Run In period:** NR **Wash out period:** NA **F/u duration:** up to 2 wk **Other:** tablets were taken 1 hr before sexual activity	**Primary outcome (EF)**: Erection (complete, moderate, none) and onset of erection, n (%): Full erection: 5 (12.5) vs. 28 (70.0) Moderate erection: 5 (12.5) vs. 6 (15.0) None: 6 (15) vs. 30 (75.0) Onset of erection (full E), mean (sd): IG1: 7.4 (3.6) vs. 37.8 (14.9) min **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE, n (%):** 0 **TAE, n (%):** pts with AE, 4 (10) vs. 4 (8) including headache in IG, headache, dyspepsia, visual disturbances in CG **SAE:** 0 **Ascertainment of outcomes assessed:** NR

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C9-Testosterone Treatment of ED

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Adel (2006) [226] **Funding source:** NR	**N screened =** NR **N randomized =** 89 **IG, n =** 45 **CG, n =** 44 **ITT analysis used for primary outcome:** NR **Inclusion:** men with 5 or more consecutive mo of ▼ libido and quality of sexual erections; 2 or more morning total T <300 ng/dl (plasma free T was not entry criterion); normal rectal examination; PSA <4 ng/ml; urine flow rate of 12 ml/s or greater **Exclusion:** generalized skin disease that could affect T absorption; body weight < 7% or above 140% of ideal weight; hx of alcohol or drug abuse; hypotension; primary hypogonadism	**Age, mean (sd):** 54 (12), range35-65 y **Race:** NR **Co-morbidities, n (%):** DM, hypertension, anxiety and depression (no numeric data provided) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** **Duration of ED:** NR **Underlying disease, n (%):** various aetiologies (no specific cause) **Psychogenic ED, n (%):** 30 (33.7) **Physiologic ED, n (%):** 34 (38.2); vascular 18 (20.2), neurogenic 16 (18), **Mixed ED, n (%):** 25 (28.1)	**IG:** Testosterone cream **CG:** Placebo cream **IG:** Dose: 2 g cream containing testosterone 0.8%, isosorbide dinitrate 0.5% and co-dergocrine mesylate 0.06% Duration: 2 mo Frequency: 2/d on right upper arm shuoulder Compliance: NR **CG:** Dose: 2 g lubricating gel Duration: as IG Frequency: as IG Compliance: NR **Run In period:** **Wash out period:** at least 4 wks in pts with oral or Injectable T tx **F/u duration:** 2 mo (fu every 15 d), last measure of RigiScan at 60 min post dosing	**Primary outcome results:** Result in bracket correspond to psychogenic, vasculogenic, neurogenic and mixed etiology sub-grps) RigiScan results, IG vs. CG: - Full erection: 18% vs. 0 [11, 1, 3, 3% vs. 0] - Partial erection: 53% vs. 6% [3, 5, 5, 4% vs. 2, 1, 2, 1%] - Tumescence: 3% vs. 2% [1, 0, 0, 2% vs. 1, 0, 1, 2%] - No response: 7% vs. 36% [1, 0, 0, 2% vs. 11, 8, 5, 12%] Pts diary results: - Full erection with successful intercourse: 40% vs. 0 - Partial erection insufficient for intercourse: 37% vs. 0 - Spontaneous erection: 38% vs. 0 **Other outcomes assessed:** serum T concentration, sign increase with active cream compare to baseline and vs. CG **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** NR; skin irritation 1 (1) vs. 0; headache 11% vs. 0; no priapism **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** RigiScan post dosing in laboratory (5, 10, 15, 30, 60 min); pts diary every 15 d

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Aversa (2003) [227] **Funding source:** Ministro dell'Universita e della Ricerca Scientifica e Tecnologica	**N screened =** 105 (reference sample) **N randomized =** 20 **IG, n =** 10 **CG, n=** 10 **ITT analysis used for primary outcome:** N **Inclusion**: arteriogenic ED (reduced PSV, but normal end systolic velocity) ED lasting 6 mo or longer. stable relationship, normal ECG, no hx of haematological or prostate dx, no antiandrogen drugs ingestion and response to Sildenafil scored as < 24 on the EF score of the IIEF; serum testosterone values between 10-13 nmol/l and serum free testosterone values between 200-300 pmol/l; no response to past T tx (100 mg) on 6 consecutive attempts **Exclusion:** pts with T levels in hypogonadal range (< 10 nmol/l)	**Age, mean (sd):** 54 (2) vs. 56 (4) **Race (%)**: NR **Co-morbidities, n:** Systemic hypertension 3 vs. 4; DM type 2: 3 vs. 2; Cardiovascular disease: 3 vs. 2; Dyslipidaemia: 5 vs. 3 **Previous ED treatment**: NR **BMI, mean (sd)**: 23 (2) vs. 24 (2) kg/m^2 **Smoking status, n:** 6 vs. 6 **Body weight:** NR	**Concomitant medications:** Pts using less than 2 medications, n 3 vs. 6; using more than 2 medications: 4 vs. 7 **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** 20 **Mixed ED**: NR Other: Measurement of flow parameters on cavernous arteries (Measured in morning after standardized pharmacostimulation using 10 µg PgE1 with option of additional re-dosing of 10 µg PgE1 + 1 mg phentolamine),	**IG1:** Testosterone (patch) + Viagra **CG:** placebo (patch) + Viagra **IG:** Dose: 5 mg testosterone + 100 mg Viagra Duration: 1 mo Frequency: patch (daily), Viagra as needed (max of 20 tablets) Compliance: 100% **CG:** Dose: placebo + 100 mg Viagra Duration: 1mo Frequency: placebo (daily), Viagra as needed (max of 20 tablets) Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** 1 mo	**Primary outcome results:**IG vs. CG, mean (sd) IIEF-EF (>24) baseline: 14 (1) vs. 13 (1); post tx: 22 (2) vs. 14 (0.7) IIEF-intercourse satisfaction: (0-15), baseline: 7 (1) vs. 8 (2); post tx: post tx: 12 (2) vs. 8 (1) GAQ, (% yes): 80 vs. 10 PSA, baseline: 1 (0.7) vs. 1 (0.8); post tx: 2 (1) vs. 1 (0.8) Free T (200-700 pmol/l, baseline: 251 (17) vs. 236 (22) vs. 473 (40) vs. 256 (19) **Other outcomes assessed:** Hormonal and biochemical outcomes; IIEF domains of SD, OF, OS; LH, total T **Withdrawals/drop-outs/loss to f/u:** 0 **WDAE:** 0 **TAE:** 0 **SAE**: 0 **Ascertainment of outcomes assessed:** IIEF; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Boyanov (2003)[228] **Funding source:** NR	**N screened =** NR **N randomized =** 48 (Open-label trial) **IG, n =** 24 **CG, n =** 24 **ITT analysis used for primary outcome:** NR **Inclusion**: Men aged 45-65 y, type 2 DM, and symptoms of mild androgen deficiency or ED; in a stable relationship; waist-hip ratio of 0.9 or greater; low testosterone levels (total testosterone < 15.1 nmol/l) **Exclusion:** concurrent dx other than DM, or surgical intervention likely to impair sexual function, amputation or chronic renal failure, ACE inhibitors' use, hx of alcoholism, prostate enlargement or abnormalities	**Age, mean (sd):** 58 (5) y **Race (%)**: NR **Co-morbidities, (%):** peripheral or autonomic neuropathy or retinopathy (50%), CHD (17%), nephropathy (33%) **Blood glucose, mean (sd):** 10 (2) HbA1C **Previous ED treatment**: NR **BMI, mean (sd)**: 31 (5) kg/m^2 **Smoking status**: NR **Body weight:** 94 (19) vs. 95 (20) kg	**Concomitant medications:** oral hypoglycaemic agents in 62.5% (metformin in 25%, metformin + sulphonylurea in 37.5%), insulin mono therapy 12.5%, hypoglycaemic agents + insulin 25% (metformin in 12.5%, sulphonylurea in 12.5%); ACE inhibitors in 35% **Duration of ED:** NR **Underlying disease:** diabetes, andropause **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** Mean duration DM = 6 (1-18) y	**IG:** Testosterone- oral **CG:** No treatment **IG:** Dose: 120 mg/d Duration: 3 mo Frequency: twice (80 and 40 mg)/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: NA Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 3 mo	**Primary outcome results:** IG vs. CG, mean (sd) IIEF (abridged 5-item version) score at Baseline: 2 (0.7) vs. 2.5 (0.8) 3 mo: 1.1 (0.9) vs. 2 (0.9), $p < 0.05$ SBP (mmHg), mean (sd): Baseline: 122 (8) vs. 120 (8); Post tx: 120 (10) vs. 122 (8) mmHg DBP (mmHg), mean (sd): Baseline: 80 (4) vs. 76 (6) Post tx: 82 (4) vs. 76 (6) mmHg Total serum T (nmol/l), mean (sd): Baseline: 9.6 (2.3) vs. 10.8 (3) Post tx (10 hr post last drug administration): 15.5 (3.4) vs. 11.2 (3.2) **Other outcomes assessed:** body weight, BMI reduction (evident in IG), fasting blood glucose level (sign drop in IG); serum triglyceride levels (drop in both grps); symptoms of androgen deficiency (nervousness, weakness, insomnia, libido) **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** 0 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF-5; SD by 4 point scale (0-3) questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Boyanov (2003) [228] **Funding source:** NR	**N screened =** NR **N randomized =** 48 (Open-label trial) **IG, n =** 24 **CG, n =** 24 **ITT analysis used for primary outcome:** NR **Inclusion**: Men aged 45-65 y with DM type 2 and symptoms of mild androgen deficiency or ED, married or living in a stable relationship with a female sexual partner for 6 mo or longer, waist-hip ratio of 0.9 or more, T levels below the normal range of adults or in the lower third of this range (total T < 15.1 nmol/l) **Exclusion:** concurrent dx other than DM or surgical intervention likely to impair sexual function, amputation or chronic renal failure, ACE inhibitors' use, hx of alcoholism, prostate enlargement or abnormalities	**Age, mean (sd):** 58 (5) y **Race (%)**: NR **Co-morbidities:** peripheral or autonomic neuropathy or retinopathy (50%), CHD (16.7%), nephropathy (33%) **Blood glucose, mean (sd):** 10 (2) HbA1C **Previous ED treatment**: NR **BMI, mean (sd)**: 31 (5) kg/m^2 **Smoking status**: NR **Body weight, mean (sd):** 94 (19) vs. 95 (20) kg	**Concomitant medications:** insulin therapy (12.5%), hypoglycaemic agents (25%), or ACE inhibitors only **Duration of ED:** NR **Underlying disease:** DM (mean duration = 6, range1-18 y), andropause **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Testosterone- oral **CG:** No treatment **IG:** Testosterone (oral) Dose: 120 mg/d Duration: 3 mo Frequency: twice (80 and 40 mg)/d Compliance: NR **CG:** No treatment Dose: NA Duration: as IG Frequency: NA Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 3 mo	**Primary outcome results:** IG vs. CG, mean (sd): IIEF (abridged 5-item version) score at baseline: 2 (0.7) vs. 2.5 (0.8) 3 mo: 1.1 (0.9) vs. 2 (0.9), p < 0.05 SBP (mmHg): Baseline: 122 (8) vs. 120 (8) 3 mo: 120 (10) vs. 122 (8) DBP (mmHg): Baseline: 80 (4) vs. 76 (6) 3 mo: 82 (4) vs. 76 (6) Total T (nmol/L): Baseline: 9.6 (2.3) vs. 10.8 (3) 3 mo: 15.5 (3.4) vs. 11 (3.2) **Other outcomes assessed:** insomnia, nervousness, weakness, libido, fasting blood glucose, total cholesterol, high-density lipoprotein (HDL)-cholesterol, low-density lipoprotein (LDL)-cholesterol, triglyceride **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** 0 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF questionnaires, anthropometrical measures**,** routine blood biochemistry

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Cavallini (2004) [229] **Funding source:** NR	**N screened =** 224 **N randomized =** 150 (n/ grp is not reported) **N (total) completed** = 130 **IG1, n =** 40 **IG2, n =** 45 **CG, n =** 45 **ITT analysis used for primary outcome:** No **Inclusion**: pts > 60 yrs with symptoms of androgen decline: ▼ libido and erectile quality, depressed mood, irritability, fatigue, and free testosterone < 6 pg/ml **Exclusion**: lower urinary tract obstructive symptoms, prostate volume > 20 cm 3, ▲ PSA level and/or prostate cancer, alcohol or cigarette consumption, < 6 mo after major surgery or MI, diabetes, untreated hypertension, CVD, neoplasm, ongoing psychological/pharmacological or antineoplastic therapy, ▲ PRL serum levels	**Age, mean (range):** 66 (60-74) y **Co-morbidities:** NR **Previous ED treatment**: NR **Body weight:** NR **Other:** testosterone (nmol/l) =10 (2) vs. 11 (2) vs. 11 (2)	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Testosterone undecanoate -oral **IG2:** Propionyl-L carnitine + acetyl -L-carnitine(carnitine)- IM **CG:** Placebo (starch)-oral **IG1:** Dose: 160 mg/d Duration: 6 mo Frequency: daily Compliance: NR **IG2:** Dose: 2 g/d Duration: 6 mo Frequency: daily Compliance: NR **CG:** Dose: 500 mg starch tablet Duration: 6 mo Frequency: daily Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** at 6 mo (immediately post tx), and 6 mo post end tx (12 mo)	**Primary outcome results:** IIEF-15 EF, median (range): Baseline= 8 (5-22); 6 mo= 16 (6-29) vs. 24 (8-29) vs. 9 (6-22), p < 0.01; 12 mo= 8 (5-22) Sexual intercourse satisfaction, median (range): baseline= 4 (2-7); 6 mo= 5 (3-10) vs. 6 (3-10) vs. 4 (3-5) PSA, mean (sd): 2 (1) vs. 2 (1) vs. 2 (1) ng/mL (not different from baseline) NPT (3-night full erection duration): baseline= 83 (19) min; 6 mo =120 (26) vs. 158 (28) vs. 88 (23) min; 12 mo 87 (21) vs. 85 (23) vs. 87 (19) Free T (pg/mL) mean (sd): baseline= </=5 (0.9); 6 mo= 23 (4) vs. 5 (1) vs. 4 (0.7); 12 mo= 10 (2) vs. 11 (2) vs. 10 (2), (IG1 vs. IG2, p=> 0.05) **Other outcomes assessed:** PSA, prostate volume, PSV, Total T, LH, EDV, resistive index (RI), IIEF domains of orgasm, SD, sexual well-being **Withdrawals/drop-outs/loss to f/u, n (%):** 20 (13) **WDAE:** 0 **TAE, n (%):** 3 (2); 2 mild epigastralgia, 1 mild headache **SAE:** NR **Ascertainment of outcomes assessed:** IIEF (Q15); nocturnal penile tumescence (NPT) by RigiScan

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Clopper (1993) [230] **Funding source:** USPHS grant, NIH General Clinical Research Centre Grant, and fund from the Children's Growth Foundation	**N screened =** 11 **N randomized =** 9 (Blind crossover design) **IG1, n =** 3 **IG2, n =** 3 **CG, n =** 3 **ITT analysis used for primary outcome:** NR **Inclusion**: Hypogonadal male subjects at least 15 y, and being treated for hypopituitarism. **Exclusion:** Non-hypogonadal men and younger than 15 yrs.	**Age, mean (range);** 18 (16.2-20.9) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment; n (%):** 7 (78), T enanthate tx (50 –400 mg/mo) **Smoking status**: NR **Body weight mean (range):** 66 (51-113) kg	**Concomitant medications:** None **Duration of ED:** NR **Underlying disease:** Previous pituitary tumours. **Psychogenic ED:** NR **Physiologic ED:** NR **Mixed ED:** NR	**IG1:** Testosterone IM **IG2:** Gonadotropin IM **CG:** Placebo IM **IG1:** Dose: 2000 units human chorionic gonadotropin (1cc IM) Duration: 6mo Frequency: 1/2 wks (5 injections of saline to maitain 3 times/ wk) Compliance: 100 % **IG2:** Dose: 1cc IM injection Duration: 6 mo Frequency: 3 times/wk Compliance: 100% **CG:** Dose: 1cc IM injection Duration: 2 mo Frequency: 3 x per wk Compliance (%): (100) **Run In period:** 4 wks **Wash out period:** min 4 wks (mean 6.7wks) **F/u duration** (on and off treatment)**:** NR **Other**: Min of 6mo on either treatment and then placebo for 2mo	**Primary outcome results:**Weekly frequency, mean (sd): Erection, wkly frequency: baseline =4 (3); Post tx: 8 (6) vs. 8 (7) vs. 5 (3) % of sleep with erection: Baseline = 0.3 (0.1); Post tx: 0.6 (0.2) vs. 0.6 (0.2) vs. 0.4 (0.2) % Time erection with max circumference: baseline= 0.6 (0.04); Post tx: 0.3 (0.1) vs. 0.2 (0.2) vs. 0.1 (0.05) # of erections per night: Baseline =7 (2); Post tx: 6 (2) vs. 6 (3) vs. 7 (3) Coitus, mean #/ wk (sd): Baseline =1.4 (1); Post tx: 0.9 (1) vs. 0.8 (1) Plasma T (ng/dl): baseline =23 (43); Post tx: 921 (383) vs. 1028 (773) vs. 34 (30) Urinary LH: 5265 (3294) vs. 8017 (10232) vs. 20047 (11864) vs. 8105 (6401) **Other outcomes assessed:** ejaculation, masturbation **Withdrawals/drop-outs/loss to f/u:** None **WDAE:** None **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Self reports of sexual behaviour (7-point Likert scale)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Gomaa (2001) [231] **Funding source:** NR	**N screened =** NR **N randomized =** 42 (crossover-two phases) **IG1/IG2 n =** 42 **ITT analysis used for primary outcome:** NR **Inclusion**: ▼in libido, Serum total testosterone near lower end of normal [defined as > 250 ng/dl] 200 – 350 ng/dl selected **Exclusion:** hx prostate dx, including: prostate cancer, recurrent prostatitis, benign hyperplasia or prostatic hypertrophy. Cavernous fibrosis, anatomical deformation of penis, glaucoma, hypotension or cardiac arrhythmia	**Age, mean (range):** 54 (41- 67) y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment:** NR **Smoking status**: all non-smoker **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED, n (%)**: 19 (90) **Physiologic ED, n:** Vasculogenic: 18 Neurogenic; 5 **Mixed ED**: 0	**IG1:** Co-dergocrine mesylate 0.06% + isosorbide dinitrate 0.5% + topical T 0.8% (polypharmacy cream) **IG2:** topical T 0.8% **IG1:** Dose: 2 g in 2 x15 divided doses Duration: 1 mo Frequency: once/d applied to shaft at bedtime or 15 min before sexual activity Compliance: 100% **IG2:** Dose: 2 g in 2 x 15 divided doses Duration: 1 mo Frequency: once/d Compliance: 100% **Run In period:** If on IC vasodilator or androgen preparation: 6 wks- 2 wks post Papaverine test **Wash out period:** 1 wk **F/u duration:** 2 mo	**Primary outcome results:** Full erection with intercourse, mean n (%): 6 (3) vs. 4 (2), (p<0.05) Erectile response (30 d), n of pts with at least 2 positive response/mo (%): Full: 28 (66) vs. 13 (31); Partial: 2 (5) vs. 2 (5); Tumescence: 3 (7) vs. 0 No response: 9 (21) vs. 27 (64) **Other outcomes assessed:** Serum T level ▲ in all compared to onset (p<0.05); penile arterial flow ▲ IG1 vs. IG2, p<0.001; SPV: IG1 vs. IG2, p <0.001;quality of life (QOL) in favour of T-gel **Withdrawals/drop-outs/loss to f/u:**0 **WDAE:** 0 **TAE, n (%):** 5 (12), all in IG1 with mild transient headache **SAE:** 0 **Ascertainment of outcomes assessed:** Questionnaire for SD (analogue), frequency of activity, erectile response (full, partial, tumescence, no response)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Haren (2005) [232] **Funding source:** Organon Pty Ltd	**N screened =** NR **N randomized =** 76 **IG, n =** 39 **CG, n =** 37 **ITT analysis used for primary outcome:** Y **Inclusion**: healthy men, at least 2 symptoms on the St-Louis University ADAM questionnaire, a free testosterone index (FTI) between 0.3 and 0.5 total T>8 nmol/l. **Exclusion:** prostate cancer or a PSA > 5 ng/ml, International Prostate Symptoms Score (IPSS) > 20, abnormal prostate on digital rectal examination, hx of testicular, liver, or renal dx, DM, cardiac failure, a score of greater than 15 on the Geriatric Depression Scale, sign. joint pain, prior use of androgen, bisphosphonates, oral, IV or intraarticular glucocorticoid within the preceding 6 mos. or an haematocrit greater than 50%.	**Age, mean (sd), range:** 68.5 (6), 60-86 y **Co-morbidities:** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Body weight**: NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Testosterone -oral **CG:** Placebo- oral **IG:** Dose: 80 mg TU (Andriol) Duration: 12 mo Frequency: twice/d Compliance: 69.7% took 90% or more of tablets; 27% took between 51-89% of the assigned tablets **CG:** Dose: placebo Duration: 12 mo. Frequency: twice/d Compliance: 80% took 90% or more of tablets; 20% took between 51-89% of the assigned tablets **Run In period:** NR **Wash out period:** NR **F/u duration:** 12 mo	**Primary outcome results:** Androgen deficiency (ADAM) questionnaire (% 'yes' response): Report of less strong erections: baseline: 95 vs. 95 12 mo: 86 vs. 93 (p>0.05) ADAM questionnaire when calculated bioavailable T (cBT) < 3.1 nmol/l): Report of less strong erections: Baseline: 100 vs. 95 12 mo: 89 vs.94 (p>0.05). **Other outcomes assessed:** improvement in libido, energy, strength, enjoyment of life, mood, ability to play sports, and work performance **Withdrawals/drop-outs/loss to f/u:** 6 vs. 12 **WDAE:** NR **TAE:** NR **SAE:** 0 **Ascertainment of outcomes assessed:** Androgen deficiency (ADAM) questionnaire: (ED: are your erections less strong?); cBT: calculated from TT

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kunelius (2002) [233] **Funding source:** Laboratories Besins Iscovesco supplied the study drug Funding: Sigrid Juselius Foundation and the Academy of Finland	**N screened =** 178 **N randomized =** 120 **IG, n =** 60 **CG, n =** 60 **ITT analysis for primary outcome:** NR **Inclusion**: Nocturnal penile tumescence ≤ 1 / wk; One of the following andropause symptoms: ▼libido, ED, urinary dx, asthenia or a depressive mood; total serum T ≤ 15 nmol/L and/or serum SHBG > 30 nmol/l **Exclusion:** abnormal liver parameters; PSA > 10 µg/l; prostate weight > 100 g; acute prostatitis, abnormal prostate in clinical or ultrasonographic exam; prostactectomy/transurethral resection of the prostate; sign cardiovascular dx; abnormal lipid profile; alcohol abuse; uncured cancer, neurological impotence, psychiatric dx; taking hormones or drugs affecting sexual function (other criteria could be found in the full report)	**Age, mean (sd):** 58.4 (5.3, range 50 70 y) y **Co-morbidities:** NR **Previous ED treatment, n**: 5 vs. 9 (not specified) **BMI, mean (sd)**: 26 (2) vs. 26 (3) kg/m^2, (p>0.05) **Smoking status**: NR **Body weight:** 79.5 (9) vs. 81 (9.7) kg **Other, n:** Testosterone ≤ 15 nmol/L: 51 Testosterone <9 nmol/L: 5 SHBG > 30 nmol/L: 111 SHBG >62 nmol/L: 22 Free Androgen Index: 35.5 ± 10.8	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Dihydrotestosterone (DHT) gel Transdermal **CG:** Placebo Transdermal gel **IG:** Dose: 125 mg/ d for 30 d, titrated up to 250 mg/day according to DHT levels Duration: 6 mo Frequency: Once/d Compliance: 100% **CG:** Dose: placebo (NA) Duration: 6 mo Frequency: Once daily Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** 6 mo	**Primary outcome results:** IG vs. CG, mean (sd): Ability to maintain erection during intercourse: 3.2 (1.4) vs. 3 (1.6), p< 0.04 Serum T (nmol/l): 6 (4) vs. 15 (5) p<0.001) **Other outcomes assessed:** SHBG: 39 (13) vs. 43 (17) nmol/l p=0.003 FSH: 4 (4) vs. 16 (5) IU/l, p<0.001 LH: 2 (2) vs. 5 (3) IU/l, p<0.001;DHT: 8 (5) vs. 2 (0.7) nmol/l, p<0.001 **Withdrawals/drop-outs/loss to f/u, n (%):** 6 (5), All in IG1 **WDAE:** 0 **TAE:** Mild headache: 3 vs. 2 Skin irritation:0 vs. 0 Hair growth on shoulder/arm: 1 vs. 0 Mild depression: 2 vs. 2 **SAE:** 0 **Ascertainment of outcomes assessed:** General well being questionnaire: A modified Psychological General Well-Being scale (13 items) and 12 items from IIEF

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
McNicholas (2002) [234] **Funding source:** Auxilium UK Ltd.	**N screened =** NR **N randomized =** 208 **IG1, n=** 68 **IG2, n =** 72 **IG3, n=** 68 **CG, n=** NA **ITT analysis used for primary outcome:** No **Inclusion**: ageing men with low serum T (≤ 10.4 nmol/l) and associated signs and symptoms of hypogonadism **Exclusion:** NR	**Age, mean (sd):** 58 (10) y; range: 31-80 y **Co-morbidities:** NR **Previous ED treatment**: NR **BMI, mean (sd):** 28 (4) kg/m^2 **Smoking status**: NR **Body weight mean (sd):** 86 (12) vs. 88 (12) vs. 89 (12) kg **Other:** Testosterone, (mean, SD): all pts 8 (2.3) nmol/l PSA, mean (sd): all pts 1.3 (1.3) ng/mL	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease, n:** Primary hypogonadism: 6 vs. 10 vs. 4; Secondary hypogonadism: 62 vs. 62 vs. 64 (aging (%): 60 vs. 56 vs. 59; Normogonadotrophic (%): 13 vs. 22 vs. 25) **Psychogenic ED**: 0 **Physiologic ED:** 100% **Mixed ED:** NR	**IG1:** Testim, testosterone gel **IG2:** Testim, testosterone gel **IG3:** Andropatch, patch (open label) **IG1:** Dose: 50 mg Duration:90 d Frequency: daily Compliance: 97% **IG2:** Dose: 100 mg Duration: 90 d Frequency: daily Compliance: 97% **IG3:** Dose: 2 x 2.5 mg Duration: 90 d Frequency: daily Compliance: 96% **Run In period:** NR **Wash out period:** NR **F/u duration:** NA	**Primary outcome results:** IG1 vs. IG2 vs. IG3, change from baseline, mean (sd): Sexual function: Spontaneous erections, mean /wk: 0.6 (1.4) vs. 0.5 (1.4) vs. 0.3 (1.2) Motivation, mean/wk: 0.4 (1.2) vs. 0.4 (1.3) vs. 0.5 (1.4) Desire mean/wk: 0.8 (1.0) vs. 0.7 (1.4) vs. 0.5 (1.2) Performance mean/wk: 0.3 (1) vs. 0.4 (0.9) vs. 0.3 (1) **Other outcomes assessed:** serum free T; C-average T; C-average dihydrotestosterone **Withdrawals/drop-outs/loss to f/u:** NR **WDAE, (%):** 4 vs. 0 vs. 13 most related to skin irritation **TAE:** incidence of 1 or more AE= 35% vs. 29% vs. 63%, erythema, irritation, and reactions at application site **SAE:** 0 **Ascertainment of outcomes assessed:** sexual function and mood questionnaires for hypogonadal men physical exam, scoring system for skin irritation

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Merza (2005) [235] **Funding source:** Ferring Pharmaceuticals Ltd.	**N screened =** NR **N randomized =** 39(the trial was followed by a 6 mo open label phase) **IG, n =** 20 **CG, n =** 19 **ITT analysis used for primary outcome:** NR (analysed for 20 vs.18) **Inclusion:** men 40 or older, with borderline hypogonadism defined as T level <10 nmol/L or a free androgen index <30%), presenting with sexual dysfunction **Exclusion:** prostate or breast cancer, prostatic hypertrophy, raised serum PSA (>2.5 µg); uncontrolled hypertension; DM; uncontrolled cardiac disease; renal failure; liver disease; polycythaemia; hx of aggressive behaviour, alcohol or drug abuse; anticoagulant tx or testosterone replacement tx	**Age, mean (sd):** 62 (9.7), range 40-77.4 y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG:** Testosterone patch **CG:** Placebo **IG:** Dose: 328 mg patch delivering 5 mg/d Duration: 6 mo Frequency: one/d (in the morning) Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NA **F/u duration:** 6 mo	**Primary outcome results:** Not measured MED QoL score, mean (sd): Baseline: 61.4 (17.5) vs. 54.2 (15.9) 6 mo: 61.8 (22.1) vs. 43.6 (4.21), p=0.017 GWBI score, mean (sd): Baseline: 75.8 (13.4) vs. 63.5(16) 6 mo: 75.8 (13) vs. 60.8 (11) **Other outcomes assessed:** Hormones; bone turnover markers, bone mineral density, fat mass, lean mass, laboratory safety measures **Withdrawals/drop-outs/loss to f/u, n (%):** 0 vs. 1 (5.3) **WDAE, n (%):**0 vs. 1 (5.3) due to angina **TAE, n (%):** NR **SAE, n (%):** NR **Ascertainment of outcomes assessed:** laboratory testing for body composition, markers of bone turnover, hormone measurements; QoL measured by questionnaires (the Male Erectile Dysfunction Quality of Life questionnaire, MEDQoL; and General Well-Being Index, GWBI) scored 0-100

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Padma-Nathan (2006) [223] **Funding source:** NexMed (study drug supply); co-author a paid consultant of NexMed	**N screened =** **N randomized =** 1732 **IG1, n =** 434 **IG2, n =** 430 **IG3, n =** 434 **CG, n =** 434 **ITT analysis used for primary outcome:** yes (pts with at least one study medication) **Inclusion:** men at least 21 y, in a stable relationship, and hx of ED of at least 3 mo in duration **Exclusion:** ED due to untreated endocrine disease or sing penile pathology (i.e. penile fibrosis, Peyronie disease)	**Age, mean (se):** 61 (0.47) y **Race:** White 86%; Black 8.3%; Hispanic 3.9%; other 1.8% **Co-morbidities, n (%):** DM 305 (17.6); cardiac 503 (29); prostatectomy 220 (12.7) slightly higher in IG1; hypertension 783 (45.2) **Previous ED treatment:** sildenafil [failures 352 (18.8)] **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR	**IG1-3:** Alprostadil topical cream **CG:** Placebo cream **IG1-3:** Dose: IG1=100 µg, IG2 = 200 µg, IG3=300 µg Duration: 12 wks Frequency: up to 24 applications (2/wk) Compliance: NR **CG:** Dose: Duration: 12 wks Frequency: as IG Compliance: NR **Run In period:** 4 wks drug free **Wash out period:** **F/u duration:** 16 wks	**Primary outcome results:** IIEF-EF, LS mean change from baseline (se): IG: 1.6 (0.34) vs. 2.5 (0.34) vs. 2.4 (0.34), CG –0.7 (0.34) SEP, LS mean % change form baseline (se): SEP-2: IG 2.9 (1.63) vs. 5.1 (1.65) vs. 7.2 (1.65), CG –4.5 (1.65) SEP-3: IG 7.0 (1.61) vs. 13.8 (1.63) vs. 9.1 (1.63), CG 0.4 (1.64) GAQ, % improved: IG 40% vs. 47% vs. 52%, CG 20% **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** **WDAE, n (%):** 46 (2.7) **TAE, n (%):** 198 (45.6) vs. 267 (62.1) vs. 292 (67.3) vs. CG 54 (12.4) Body as whole: IG 5 (1.2) vs. 1 (0.2) vs. 0 CG 1 (0.2); nervous system IG 5 (1.2) vs. 7 (1.6) vs. 11 (1.2), CG 1 (0.2) Skin rash: IG 2 (0.5) vs. 5 (1.2) vs. 2 (0.5) CG 1 (0.2); urogenital system: IG 186 (42.9) vs. 254 (59.1) vs. 279 (64.9) CG 51 (10.6) **SAE, n (%):** IG 0, CG 1 (0.2) died due to cardiac arrest **Ascertainment of outcomes assessed:** IIEF-EF; SEP; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rabkin (2000) [236] **Funding source:** NR	**N screened =** 104 **N randomized =** 74 **IG, n =** 39 **CG, n =** 35 **ITT analysis used for primary outcome:** N **Inclusion:** men 18 yrs, HIV seropositive (CD4 cell counts less than 0.4 X 10^9/L), clinically deficient or low-normal serum T < 17.4 nmol/L (except acquired immunodeficiency syndrome with severe fatigue, upper limit 22.6 nmol/L), sexual dysfunction, at least one associated hypogonadal mood symptom, receiving medical care for HIV illness **Exclusion:** substance use in past 6 mo, psychotic symptoms, sign suicidal risk, sign cognitive impairment, unstable medical condition including new onset of an opportunistic infection in the past mo, symptomatic benign prostate hyperplasia, current or anticipated use of a new antiretroviral medication within 4 wks, or use of anabolic steroids in past mo	**Age, mean (sd):** 38 (7.3) vs. 40 (9) y **Race, n (%)**: non-white 18 (47) vs. 18 (56) **Co-morbidities:** NR **Previous ED treatment**: NR **Smoking status**: NR **Body weight:** NR **Other:** T level (nmol/L), mean (sd): 13 (5) vs. 3 (4); n=14 (20) baseline T levels below 10.4 nmol/l (hypogonadal)	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** HIV-positive with hypogonadal symptoms and sexual dysfunction 74 (100%) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** testosterone cypionate,- IM **CG**: placebo- IM **IG:** Dose: initial 200 mg, ▲ to 400 mg Duration: 6 wks Frequency: bi-weekly Compliance: NR **CG:** Dose: initial 200 mg, ▲ to 400 mg Duration: 6 wks Frequency: bi-weekly Compliance: NR **Run In period:** NA **Wash out period:** NR **F/u duration:** 6 wks + 12 wks (maintenance for responders) = 18 wks	**Primary outcome results:** CGI, sexual interest, EF& mood, mean (%): 28(74) vs. 6 (19) = P < 0.001 CGI, improved/much improved among completers, n (%): 20 (63) vs. 4 (20); not different between hypogonadal men and men with normal T levels Reynolds sexual function scale, mean (SE): morning erections 5.4 (0.4) vs. 4 (0.4), P=0.008 Total serum T (nmol/L), mean change from baseline: IG responders=non responders 35 (15) vs. CG responders = 11.4 (7.4), non responders= 2 (6.4), p=0.005 **Other outcomes assessed:** mood, depression, anxiety, quality of life, laboratory measures **Withdrawals/drop-outs/loss to f/u:** 4 (vs.3) **WDAE:** NR **TAE, n (%):** Pts with 1 or more AE: 16 (41) vs. 7 (20), p=0.05; AE include ▼ ejaculation; testicular atrophy; irritability; acne (21% of pts vs. 0); tension; bossiness; hair loss **SAE:** 2 (IG) hospitalized due to HIV **Ascertainment of outcomes assessed:** Clinical global impressions scale ratings (CGI): 7-point scale Reynolds sexual function scale (self report10-point); Structured assessment of tx emergent AEs

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Raul (1997) [237] **Funding source:** National Institute on Aging	**N screened =** 40 **N randomized =** 18 (cross over design) **IG/ CG, n =** 18 **ITT analysis used for primary outcome:** NR **Inclusion**: men 45-74 yr, with primary diagnosis of ED or hypo active SD, (ED: inability to achieve and maintain vaginal penetration until orgasm on at least 50% of the attempts during the preceding 6 mo; Hypoactive SD: SD for any sexual activity of less than twice per mo during the preceding 6 mo) **Exclusion:** evidence of medical disorder, intake of drug especially neurological, vascular or endocrine action drugs; alcohol or other substances of abuse; presence of major psychopathology; obesity (> 20% above ideal body weight)	**Age, median (range):** Median 60 (46-67) y **Race (%)**: Caucasian 97; NR 3 **Co-morbidities:** NR **Previous ED treatment** NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, median (range):** 4 y (6 mo- 12 yr) **Underlying disease:** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG:** Testosterone IM (enanthate) **CG:** placebo (sesame oil vehlicle) **IG1:** Dose: 200 mg Duration: 6 wks Frequency: twice/ wk Compliance: NR **CG:** Dose: NR (0) Duration: 6 wks Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** 4 wks **F/u duration:** 16 wks	**Primary outcome results:** Frequency (times/ wk), median (range): SD 6 (0-7) vs. 4 (0-7) Masturbation 1 (0-2) vs. 0.16 (0-2); Sex with partner 1 (0-2) vs. 0.54 (0-2.7) Morning erections 1.25 (0-7) vs. 0.67 (0-7 Degree of erection (score 1-6): Masturbation: 6 (3-6) vs. 6 (1-6) Sex with partner: 6 (4-6) vs. 6 (1-6) T (ng/ml), mean (sd): Baseline: 412 (48) vs. 481 (205) Period 1: 318 (66) vs. 455 (143) Period 2: 420 (87) vs. 397 (73) **Other outcomes assessed:** Sexual behaviour and mood Plasma T, LH (sign. compare to baseline in IG), dihydrostestosterone **Withdrawals/drop-outs/loss to f/u:** n=6 (n=1 excluded from analysis due to diagnosis of primary hypoactive SD) **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Psychological assessment: 1) ED by brief sexual function questionnaire (19 items), 2) mood assessment by POMS (65 items), 3) distress by SCI-90-R (90 items each on a 5-point scale

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Rochira (2006) [238] **Funding source:** Ministero dell'Università e della Ricera Scientifica	**N screened =** NR **N randomized =** 24 (Italy) **Grp 1** Hypogonadal not treated **IG1/CG1, n = 12** **Grp 2** Hypogonadal treated **IG2/CG2, n = 12** **ITT analysis used for primary outcome:** NR **Inclusion:** hypogonadal men (serum T level of 20 ng/dL used as cut-off); pts included 14 pts who had been withdrawn from T replacement tx for at least 3 mo and 10 hypogonadal pts at 1st diagnosis **Exclusion:** NR **Note:** n=24 healthy subjects were recruited as control grp; data not shown in this table	**Age, mean (sd):** 34.54 (11.5) y **Race:** NR **Co-morbidities, n (%):** hypogonadal 24(100) including Klinefelter syndrome 7 (29) **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** hypogonadalism **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** 100% **Mixed ED, n (%):** NR	**IG1/2:** Sildenafil **CG:** Placebo **IG1/2:** Dose: 50 mg Duration: 3 nights Frequency: 1 hr before bedtime; on 2nd (IG1) or 3rd (IG2) night post nocturnal monitoring Compliance: 100% **CG1-2:** Dose: NA Duration: as IG Frequency: as IG Compliance: 100% **Run In period:** 1 night (adaptation) **Wash out period:** NR **F/u duration:** **Note:** T tx started for grp1 no longer than 20 d post enrolment (250 IM/ 21d); T tx period was a non-randomized open label 6 mo study for all hypogonadal men; NR in this evidence table	**Primary outcome results:** IG vs. CG, mean (sd): N of valid erections: Grp 1: 2.71 (0.18) vs. 0.76 (0.22) Grp 2: 4.29 (0.24) vs. 2.79 (0.27) Duration of rigidity >70% (min): Grp 1: 43.59 (5.14) vs. 10.57 (3.83) Grp 2: 105 (13.02) vs. 52.02 (8.75) Max rigidity, %: Grp 1: 79.21 (3.44) vs. 60.83 (3.83) Grp 2: 91.75 (1.54) vs. 84 (2.10) Max ▲ of circumference (mm): Grp 1: 33.46 (0.89) vs. 25.79 (1.45) Grp 2: 43.58 (1.31) vs. 40 (1.70) **Other outcomes assessed:** duration of ▲ of circumference of at least 30 mm (sign more in IG vs. CG) **Withdrawals/drop-outs/loss to f/u, n (%):** 0 **WDAE, n (%):** 0 **TAE, n (%):** 0 **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** RigiScan monitoring for nocturnal penile tumescence measures

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Seftel (2004) [239] **Companion study** [240] **Funding source:** Auxilium Pharmaceuticals Inc.	**N screened =** NR **N randomized =** 406 **IG1, n =** 99 (double blind) **IG2, n =** 106 (double blind) **IG3, n =** 102 (open label) **CG, n =** 99 **ITT analysis used for primary outcome:** Yes **Inclusion:** hypogonadal men 20-80 (secondary to aging and also normogonadotrophic) with morning T level up to 300 ng/dL (10.4 nmol/L), with one or more symptoms of low testosterone (fatigue, reduced libido, reduced sexual functioning, ▼ muscle mass) **Exclusion:** NR Note: pts with T levels of > 300 were also randomized as protocol deviations (n=15) *n of pts evaluated for frequency of intercourse differs from those evaluated for SD & night time erections because requirement for steady sexual partner was not a requirement for study entry*	Age, mean: 58 y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **BMI, mean:** all pts 30 kg/m^2 **Smoking status**: NR **Body weight, mean range:** 95-99 kg **Other:** Testosterone (nmol/L) all pts: 10.4-34.7; Mean (sd): 234 (57) vs. 232 (62) vs. 239 (69) vs. 229 (80) ng/dL Sexual function (likert scale), mean (sd) Baseline: 2 (1) vs. 3 (1) vs. 2 (1) vs. 2 (1)	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** primary 6%, or secondary 94% (58-71% due to aging 19-32% due to normo-gonadotrophic) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Testosterone gel **IG2:** Testosterone gel **IG3:** Testosterone patch **CG:** placebo gel **IG1:** Dose: 50 mg (n= 43 titrate ▲ at 60 d) Duration: 90 d Frequency: daily Compliance: 100% **IG2:** Dose: 100 mg (n=4 titrated ▼at 60 d) Duration: 90 d Frequency: daily Compliance: 100% **IG3:** Dose: 2 x 12.2 mg patches Duration: 90 d Frequency: daily Compliance: 100% **CG:** Dose: NA Duration: 90 d Frequency: daily Compliance: 100% **Run In period:** 7 d **Wash out period:** NR **F/u duration:** 30 and 90 d	**Primary outcome results:** IG1 vs. IG2 vs. IG3 vs. CG (at 90 d) ▲ SD from baseline (likert scale, mean daily score): 0.5 vs. 1 vs. 0.6 vs. 0.5 Pts with ▲ # of night time erections/ wk (%): 30 vs. 51 vs. 40 vs. 26 (at 30 d; no sign. difference at 90 d) Pts with ▲ in intercourse from baseline (%): 6 vs. 36 vs. 13 vs. 28 % of full erection: no data (not sign) C-average Serum T, mean (sd): 218 (74) vs. 315 (112) vs. 373 (145) vs. 487 (213) **Other outcomes assessed: change in** # of d/wk with nighttime or d time erections, former correlated with serum T levels at 30, and 90 d; mood; PSA levels **Withdrawals/drop-outs/loss to f/u, n (%):** 21 (5) due to AE **WDAE, n (%):** all 21 (5%); 1 vs. 5 vs. 15 vs. 0 **TAE:** NR (AE included: in IG2 vertigo; CA; depression with suicidal intent; UTI/pneumonia; hypertension; 15 in IG3 due to local dermal site reactions) **SAE:** NR **Ascertainment of outcomes assessed:** Self report daily diary, SD by Likert scale (0-7)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Seidman (2006) [241] **Funding source:** NIH (partnership for Gender-Specific Medicine)	**N screened =** NR **N randomized =** 30 **IG, n =** NR **CG, n =** NR **ITT analysis used for primary outcome:** NR **Inclusion:** men 35 or older with MDD, and low serum T (350 ng/dl or less) **Exclusion:** bipolar illness, schizophrenia, substance abuse or dependence (current or within last yr); active suicidal ideation; or acute severe or unstable medical illness; men age over 50 with PSA level of 4.0 or higher or an abnormal digital rectal exam were excluded	**Age, mean (sd):** 52 (8) y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** T level, mean (sd) ng/dl HAMD score 21 (8)	**Concomitant medications, n (%):** **Duration of ED:** NR **Underlying disease, n (%):** MDD in all **Psychogenic ED, n (%):** 100% **Physiologic ED, n (%):** NR **Mixed ED, n (%):** NR **Other:** duration of current MDD , median 26 mo, range 4-120 mo	**IG:** T enanthate IM injection **CG:** placebo injection (sesame oil) **IG:** Dose: 200 mg Duration: 6 wks Frequency: once/wk Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NA **F/u duration:** 6 wks	**Primary outcome results:** DSPS-M section II, mean (sd): -Full erection on awakening: Baseline: 1.15 (1.82) vs. 1.47 (1.66) Post tx: 2.08 (2.29) vs. 2.18 (2.0) -Full erection on fantasy/ daydream: baseline 1.15 (1.72) vs. 1.88 (1.86) Post tx 1.78 (2.16) vs. 1.71 (1.83) -Full erection on masturbation: Baseline 1.08 (1.66) vs. 1.59 (1.91) Post tx 1.69 (2.25) vs. 1.71 (1.90) -Full erection during sexual activity: Baseline 1.54 (1.94) vs. 1.18 (1.78) Post tx 1.77 (2.17) vs. 1.53 (1.62) -A satisfying orgasm: Baseline 1.92 (1.44) vs. 1.82 (1.81) Post tx 2.31 (2.06) vs. 2.06(1.44) -Serum T level, mean: Baseline 262.5 (8) Post tx 981.3 vs. 297.7 ng/dl **Other outcomes assessed:** no association for changes in T level and depressive symptoms **Withdrawals/drop-outs/loss to f/u, n (%):** 1 (3.3) **WDAE, n (%):** 1 (3.3) **TAE, n (%): NR** **SAE:** 1 MI in CG **Ascertainment of outcomes assessed:** self reported sexual function; HAMD; DSPS-M section II (scale 0-8, 0=none; 8=4 or more per d)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Shabsigh (2004) [242] **Funding source:** Solvay Pharmaceuticals Inc.	**N screened =** 354 **N randomized =** 75 **IG, n =** 39 (ITT, n=37) **CG, n =** 36 (ITT, n=33) **ITT analysis used for primary outcome:** yes **Inclusion**: men 18-80 y, with ED of 3 mo or longer, in a stable sexual relationship with a female ≥ 6mo, morning serum total T of 400ng/dl or less at screening visits, nonresponders to Sildenafil monotherapy (determined by IIEF) **Exclusion:** hx of prostate or breast cancer, clinically sign or uncontrolled medical or psychiatric conditions (including DM), neurological dx that cause ED, generalized skin dx that would affect gel absorption, hyperprolactinemia, drug or alcohol abuse, prostate dx with concomitant urine flow rate of less than 12 ml/s	**Age, mean (sd):** 57 (10), range = 26-73 vs. 59 (9), range = 40-79 y **Race, n (%):** White 53 (71); Black 7 (9); Asian 2 (3); Hispanic 8 (11) **Co-morbidities:** NR **Previous ED treatment:** NR **BMI, mean (sd):** 32 (5) vs. 31 (6) kg/m^2 **Smoking status, n (%):** 4 (11) vs. 6 (18) **Body weight:** NR	**Concomitant medications:** NR **Duration of ED, n (%):** 6-12 mo: 2 (5) vs. 4 (12); > 12 mo: 35 (95), vs. 29 (88) **Underlying disease, n (%):** DM 7 (19) vs. 4 (12) Hypertension 12 (32) vs. 13 (39); Hpyperlipidemia 10 (27) vs. 4 (12); Prostate dx 5 (14) vs. 1 (3) **Psychogenic ED, n (%):** 1 (3) vs. 2 (6) **Physiologic ED n, (%):** 20 (54) vs. 14 (42) **Mixed ED, n (%):** 16 (43) vs. 17 (52)	**IG:** Testosterone gel + Sildenafil- oral **CG:** Placebo gel + Sildenafil -oral **IG:** Dose: 1% T gel + 100 mg Sildenafil Duration: 12 wks Frequency: gel 1x/day + Sildenafil as indicated Compliance: 100% **CG:** Dose: 5 g placebo gel + 100 mg Sildenafil Duration: 12 wks Frequency: gel: 1/day + Sildenafil as indicated Compliance: 100 % **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** longer than 12 wks (end point not specified)	**Primary outcome results:** IIEF- EF domain, mean change from baseline: 4.4 vs. 2.1, p =0.029 IIEF-Q5: IG better than CG, (12 wk, p=0.008, end point p=0.004) Pts who improved at least 1 category from baseline for IIEF-Q3 or 4, n (%): 26 (79) vs. 22 (71) IIEF-Q3-4, n (%) with positive response: 12 wks: 19 (58) vs. 13 (42) Endpoint: 19 (51) vs. 13 (39) Serum T levels ▲ from baseline at 12 wks: IG, p</=0.004; IG vs. CG, p</=0.001 **Other outcomes assessed:** no correlation between serum T levels and IIEF at endpoint; QoL **Withdrawals/drop-outs/loss to f/u, n (%)**: 7 (19) vs. 5 (14) **WEAE, n:** 1(3) vs. 0 **TAE:** 1 vs. 0; detail not reported **SAE:** 0 **Ascertainment of outcomes assessed:** IIEF; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Shamloul (2005) [243] **Funding source:** NR	**N screened =** 40 **N randomized =** 40 **IG1** (non responders to sildenafil)**, n =** 10 **CG1, n =** 10 (1) **IG2** (partially responders to sildenafil)**, n =** 10 **CG2, n =** 10 (2) **ITT analysis used for primary outcome:** NR **Inclusion**: Men with ED associated with PADAM (partial androgen deficiency in aging men) symptoms. Suffering from ED for at least 6 mo. All patients were married and engaged in regular sexual activity (2 x wk); pts recruited after a sildenafil trial. **Exclusion:** Patients with prostate hypertrophy, prostate carcinoma and mammary carcinoma. No patients were diabetic or hypertensive	**Age, mean (sd);** 56 (2.4) y **Race:** NR **Co-morbidities:** NR **Previous ED treatment**: Sildenafil for 2wks **BMI, mean (sd):** 29 (3.2) kg/m^2 **Smoking status**: NR **Body weight, mean (sd):** 81 (1.4) kg	**Concomitant medications:** NR **Duration of ED:** at least 6 mo **Underlying disease:** None **Psychogenic ED**: None **Physiologic ED:** None **Mixed ED**: None	**IG1:** Sildenafil + TRT (Testosterone underacanoate- oral) **CG1:** TRT **IG2:** Sildenafil + TRT **CG2:** TRT **IG1/IG2:** Dose: 50 or 100 mg + 120 mg Duration: 2 mo Frequency: 3 capsules/ d Compliance: all **CG1/CG2:** Dose: 120 mg Duration: 2 mo Frequency: as IG Compliance: all **Run In period:** 2 wks **Wash out period:** None **F/u duration:** 2 mo	**Primary outcome results:** IIEF-5, mean (sd): IG1 vs. CG1: Baseline: 10 (1.3) vs. 10 (1.4) Post-tx: 15 (1.4) vs. 11 (1.5) IG2 vs. CG2: Baseline: 15 (1.6) vs. 15 (1.2) Post-tx: 17.5 (2) vs. 16 (1) Serum total T (nmol/L) level, IG+CG, baseline vs. post tx, mean (sd): 7.3 (1.4) vs. 11 (1.3) **Other outcomes assessed:** PADAM score mean (sd): baseline 28.4 (2) vs. post tx 22.4 (1.3); serum FSH, LH, PRL levels **Withdrawals/drop-outs/loss to f/u:** None **WDAE:** None **TAE, n:** 3, headache (sildenafil 100 mg) **SAE:** None **Ascertainment of outcomes assessed:** partial androgen deficiency in aging men (PADAM) rating score and IIEF-5 questionnaires

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Wang (2000) [244] **Funding source:** Unimed Pharnaceuticals Inc Grant from NIH GrantM0-00543	**N screened =** NR **N randomized =** 227 (16 centres) **IG1, n =** 73 **IG2, n =** 78 **IG3, n =** 76 **CG, n =** NA **ITT analysis used for primary outcome:** **Inclusion:** men with morning T ≤ 10.4 nmol/L (300 ng/dL); clinically healthy, if on lipid lowering agents or tranquilizers: dose stabilized for at least 3 mo prior to screening. **Exclusion:** hx of chronic medical illness or alcohol and drug use; presence of a generalized skin dx, hx of skin irritability with T patches; Ideal body weight < 80% or > 140 %	**Age, mean:** 58 y **Race (%)**: NR **Co-morbidities:** NR **Previous ED treatment**: NR **BMI, mean:** all pts 30 kg/m^2 **Smoking status**: NR **Body weight, mean range:** 95-99 kg **Other:** Testosterone (nmol/L) all pts: 10.4-34.7; Mean (sd): 234 (57) vs. 232 (62) vs. 239 (69) vs. 229 (80) ng/dL Sexual function (likert scale), mean (sd) Baseline: 2 (1) vs. 3 (1) vs. 2 (1) vs. 2 (1)	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease:** primary 6%, or secondary hypogonadal 94% (58-71% due to aging 19-32% due to normo-gonadotrophic) **Psychogenic ED**: NR **Physiologic ED:** all 100% **Mixed ED**: NR	**IG1/ IG2:** Testosterone transdermal gel **IG3:** Testosterone patch **IG1:** Dose: 50 mg/d (↑ to75 mg/d at 90 d in n=20 with T <10.4nmol/l at 60) Duration: 180 d Frequency: daily Compliance: 93% **IG2:** Dose: 100 mg/d (↓ to 75 mg/d at 90 d ifT >34.7 nmol/l at 60 d) Duration: as IG Frequency: daily Compliance: 96% **IG3:** Dose: 2 patch, 5 mg/d Duration: 180 d Frequency: daily Compliance: 65% (1^{st} 90 d); 74% (2^{nd} 90 d) **Run In period:** 7 d **Wash out period:** NR **F/u duration:** 180 d (f/u at 0 and every 30 d)	**Primary outcome results:** Self assessment: Satisfaction of erection: ▲ from baseline in both grps, p=0.0001 % of full erection: ▲ from baseline in both grps, p=0.0001 (slightly better in 100 mg/d T gel) **Other outcomes assessed:** sexual function (desire, enjoyment, motivation, performance) and mood; lean mass, muscle strength, ▼ fat mass all improved with T gel and T patch with less skin irritation using T gel **Withdrawals/drop-outs/loss to f/u, n (%):** 17 (22.4) vs. 8 (5.3) **WDAE, n (%):** 17 (22.4) vs. 8 (5.3) **TAE, n (%):** skin irritation 5.5% with T gel, vs. 66% in T patch**;** other PSA elevation; depression memory loss, high blood pressure, Hct and Hgb rise (in T patch); gynecomastia; transient abnormal laboratory tests, headache, asthma, hypertension, dizziness anxiety and nervousness **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** pts questionnaire, laboratory and clinical examination

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Yassin (2006) [245] **Funding source:** NR	**N screened =** **N randomized =** 69 (open label randomized) **IG1, n =** 35 **IG2, n =** 34 **ITT analysis used for primary outcome:** NR **Inclusion:** hypogonadal (serum T 3.4 $ngml^{-1}$ or less) age 34-78 y, with at least 6 mo hx of ED of any severity; hx of no response to 6-8 attempts with 20 mg tadalafil (poor EF score, persistent dissatisfaction) **Exclusion:** clinically sign disease known to contradict with T or tadalafil; severe DM, IPSS > 18; prostatitis, hyperprolactinaemia (>20 $ngml^{-1}$); CV attacks in last 6 mo	**Age, mean (sd):** 58.3 (9.7) vs. 59.9 (9.1) y **Race:** NR **Co-morbidities, n (%):** DM type I 2 (5.9) vs.0; DM type II 6 (17.6) vs. 5 (14.3); hypertension 11 (32.4) vs. 13 (37.1); dyslipidaemia 7 (20.6) vs. 6 (17.1); BPH/LUTS 16 (47.1) vs. 11 (31.4) **Previous ED treatment:** all pts had tadalafil monotherapy **Smoking status:** 13 (38.2) vs. 15 (42.9) **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** hypogonadalism **Psychogenic ED, n (%):** 0 **Physiologic ED, n (%):** 100% **Mixed ED, n (%):** 0 **Other:** ED severity, n (%): midland moderate 23 (67.7) vs. 26 (74.3); severe 12 (35.3) vs. 8 (22.9) Mean IPSS: 15 (both grps)	**IG:** sildenafil + T gel (Testogel®) **CG:** T gel alone **IG1:** Dose: 20 m sildenafil + 5 g containing 50 mg T Duration: 10 wks Frequency: sildenafil twice/wk; T gel NR Compliance: 100% **IG2:** Dose: 5 g containing 5 mg T Duration: 10 wks Frequency: NR Compliance: **Run In period:** 4 wks T gel tx **Wash out period:** 2 wks (post tadalafil Monotherapy) **F/u duration:** 10 wks Other: IG CG were assigned to add tadalafil to T tx at the end of 10 wk trial	**Primary outcome results:** Mean (sd), IG1 vs. IG2 IIEF-EF domain: Baseline 11.3 (3.0) vs. 11.3 (2.8) 10 wks: 18.3 (0.2) vs. 18.2 (0.4) (% improved in IIEF-EF with T-gel monotherapy in IG1 wk 4 = 43% vs. IG2 at wk 10 65%) IIEF-OF: Baseline 5.4 (2.6) 10 wks: 7.1 (1.4) vs. 7.1 (0.3) IIEF SD: Baseline 6.1 (2.8) 10 wks: 8.7 (0.8) vs. 7.8 (0.9) IIEF-IS: Baseline 8.9 (1.6) 10 wks: 13.1 (1.4) vs. 12.8 (1.2) IIEF-OS: Baseline 5.0 (1.5) 10 wks 8.2 (0.4) vs. 8.6 (0.3) **Other outcomes assessed:** partner satisfaction **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE:** 0 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** Serum hormone analysis; IIEF; pts and partner questionnaire on efficacy of erectile quality/rigidity

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

C10-Off Label Treatments

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Aydin (1996) [246] **Funding source:** NR	**N screened =** NR **N randomized =** 79 **IG1, n =** 20 **IG2, n =** 21 **IG3, n** = 20 **CG, n =** Placebo **ITT analysis used for primary outcome:** **Inclusion:** men of various ages with hx of ED confirmed with clinical examination **Exclusion:** NR	**Age, mean (sd):** 38 (11.3) y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%)**: NR	**IG1:** Testosterone **IG2:** Tradazone **IG3:** Hypnosis **CG:** Placebo **IG1:** Dose: 120 mg/d Duration: 16 wks Frequency: daily Compliance: NR **IG2:** Dose: 100-150 mg/d Duration: as IG1 Frequency: as IG1 Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 16 wks	**Primary outcome results:** Improved in sexual function (full erection or ability to have intercourse with occasional failure), n (%): IG1: 12 (60) IG2: 14 (66.7) IG3: 16 (80) CG: 7 (38.9) Overall improvement achieved by 60, 67, and 80% of IG1, IG2, and IG3 respectively **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** 0 vs. 5 (23.8) vs. 0 vs. 0; pts in trazadone grp experienced sedation **SAE, n (%):** NR **Ascertainment of outcomes assessed:** pts diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Becker (1998) [247] **Funding source:** Zonagen USA	**N screened =** 40 **N randomized =** 40 **IG1, n =** 10 **IG2, n =** 10 **IG3, n =** 10 **CG, n =** 10 **ITT analysis used for primary outcome:** NR **Inclusion:** hx of ED for less than3 y; ED likely to be organic who not responded positively to placebo test **Exclusion:** CVA; DM, neurological disease, tolerance to the study medication	**Age, mean (range):** 48 (26-70) y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** likely 100% **Mixed ED, n (%)**: NR	**IG:** Phentolamine **CG:** Placebo **IG1-3:** Dose: 20 mg (IG1), 40 mg (IG2), 60 mg (IG3) Duration: NR Frequency: NR Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: NR Compliance: NR **Run In period:** NR **Wash out period:** NA **F/u duration:** NR	**Primary outcome results:** Full erection (sufficient for vaginal penetration), n (%): IG1: 3 (30) IG2: 5 (50) IG3: 4 (40) CG: 2 (20) **Other outcomes assessed:** NA **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** 0 **TAE, n (%):** 1 events (stuffy nose) only with 60 mg **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** pts diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Costabile, R. (1999) [248] **Funding source:** NR	**N screened =** NR **N randomized =** 51 cross over **IG screened =** NR **IG randomized =** 51 cross over **CG screened =** NR **CG randomized =** 51 cross over **Inclusion**: At least 3 mos. of ED **Exclusion:** Pts with sign. cardiac disease	**Age, mean (range):** 65 yrs (range 31-80) **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR **Other:** NA	**Concomitant medications:** NR **Duration of ED (mos./ yr)(mean [range]):** 36 mos. (range 4 mos.- 30 yrs) **Underlying disease (diagnosis) (N or % of diseased/grp):** NR **Psychogenic ED (N [%]:** psychogenic 4(2) **Physiologic ED (N [%]:** arterial insufficiency 39(20), hypertension 18(9), diabetes 12(6), veno-occlusive dysfunction 10(5), surgical 6(3), neurogenic 4(2) **Unknown ED (N [%]:** unknown 7(4) **Other:** NA	**IG:** trazodone, oral **CG:** placebo, oral **IG:** Dose: 50 mg Duration: 3 mos. Frequency: 1/d, bedtime Compliance: 94% 1 **CG:** Dose: 50 mg Duration: 3 mos. Frequency: 1/d, bedtime Compliance: 94% 1 **Run In period:** 3 nights **Wash out period:** 3 wks **F/u duration (both on and off treatment):** NA **Other:** NA	**Primary outcome results:** **Index of sexual satisfaction (mean):** IG 27.5, CG 30.8 = no sign. difference **Patient diary evaluations (%):** first treatment interval, erection improvement IG 19, CG 24; sex drive improvement IG 35, CG 40 = no sign. difference when both treatment intervals combined **List (narrative) other outcomes assessed:** physical examination, laboratory evaluations, pre screening penile Doppler ultrasound **ITT analysis used for primary outcome?** N **Withdrawals/drop-outs/loss to f/u [N and/or %]:** N=3 **WDAE (N and/or %):** NR **TAE (N [%]):** dry mouth IG 12(25), CG 8(16.7); drowsiness IG 9(18.8), CG 6(12.5); fatigue IG 7(14.6), CG 4(8.3) **SAE:** NR **Ascertainment of outcomes assessed:** Index of sexual satisfaction: details not provided. Patient diary evaluations**:** self reported, administered monthly, documented sexual activity, libido and AE, extracted 2 questions-did this medicine improve your erection? did you notice a change in your sex drive while taking this medicine?

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Enzlin, P (2000) [249] **Funding source:** Searle Continental Pharma Inc.	**N screened =** 39 **N randomized =** 34 **IG1 randomized =** 16 **IG2 randomized =** NA **CG randomized =** 17 **Inclusion**: age 18-65; in stable heterosexual relationship for ≥6 mo; ED ≥4 mo **Exclusion:** ED caused by sickle cell anemia and trait, thyroid or endocrine disorders (except diabetes), spinal cord lesion, or pelvic surgery or trauma; hx of myocardial infarction, coronary angioplasty or coronary bypass graft surgery in past 3 mo (except antihypertensive drugs since 2 mo before onset of ED); ejaculation disorder; medication known to possibly cause ED	**Age, mean (sd):** IG1 49 (11) CG 46 (8) **Race (%)**: NR **Co-morbidities (unrelated to disease):** Diabetes 1 **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** Antihypertensives 1 **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/ grp):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** trazodone orally **IG2:** NA **CG:** placebo orally **IG1:** Dose: 200 mg Duration: 4 wk Frequency: 1 dose/day Compliance (%): 1 wk: 71.4% good 4 wk: 57.1% good **IG2:** NA Dose: Duration: Frequency: Compliance (%): **CG:** Dose: placebo Duration: 4 wk Frequency: 1 dose/day Compliance (%): NR **Run In period:** 2 wk, including 2 or 3 nights of adaptation with RigiScan Plus® **Wash out period:** NA **F/u duration (both on and off treatment):** 4 wk and 2 or 3 days	**Primary outcome results:** Mean difference in total duration of nocturnal erection, minutes Base IG1 ▲ 8, CG ▲ 3 Tip IG1 ▲ 7, CG ▼ 4 **List (narrative) other outcomes assessed:** Rigidity and tumescence; SD (Derogatis Sexual Functioning Inventory); quality of partner relationship (Dyadic Adjustment scale); depressive symptoms (Hamilton Depression Rating scale) **ITT analysis used for primary outcome?** N **Withdrawals/drop-outs/loss to f/u [N and/or %]:** 1 (CG) **WDAE (N and/or %):** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** RigiScan Plus® Rigidity Assessment System **Other**: Not a very well reported study

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Georgitis, W. (1995) [250] **Funding source:** U.S. Army Health Services Command	**N screened =** NR **N randomized = NR** **IG1, n =** 34 **CG, n =** 26 **ITT analysis used for primary outcome:** NR **Inclusion**: Non insulin-dependent DM men Patients with fasting serum glucose > 200mg/dl or HbA_{1c}>10% included only if impotence persisted after improved glycemic control **Exclusion**: Patients receiving anticoagulants, with past Hx of peptic ulcer disease or whose impotence was not cause by diabetes. Patients on beta-blockers, aldomet or clonidine excluded	**Age:** Mean IG1: 59.1 ± 6.4 Mean CG: 64.6 ± 7.6 **Race: (n)** Black: 20; Hispanic: 5; White: 35 **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C):** Initial: IG1 vs. CG: 8.1 ± 1.8 vs. 7.4± 1.5. End: 8.0 ± 1.7 vs. 7.2 ± 1.3 **Previous ED treatment**: NR **BMI (kg/m^2)**: Mean IG1 vs. CG: 28.0 ± 4.2 vs. 28.5 ± 3.0 **Smoking status**: IG1 vs. C: Active 3 vs. 8; Quit: 15 vs. 19; Nonsmokers: 8 vs. 7 Pack yrs: 39 ± 5 vs. 37 ±9 **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** IG1 vs CG: 5.2 ± 3.8 vs 6.0 ± 5.0 **Underlying disease (diagnosis):** Diabetes Duration (yrs): IG1:13.6 ± 8.7 CG: 14.2 ± 10.9 **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** Treatment for diabetes, IG1 vs CG: Diet:3 vs 0. Oral:18 vs 12. Insulin:13 vs 9. Combination: 0 vs 2 Onset of ED, gradual/abrupt IG1 vs CG: 31/3 vs 24/2 Duration of hypertension, IG1 vs CG:16.6 ± 12.6 vs 10.9 ± 8.6 yrs Ankle brachial SBP ratios abnormal in 6% of IG1 vs 0% CG Penile brachial blood pressure rations abnormal in 38& of IG1 vs 27% CG Autonomic dysfunction in IG1 vs CG: 82% vs 100%.	**IG1:** Oral Pentoxifylline (Trental™) **CG:** Placebo **IG1:** Pentoxifylline Dose: 400 mg Duration: 3 mo Frequency: 3/day Compliance (%): NR **CG:** Placebo Dose: N/A Duration: 3 mo Frequency: 3/day Compliance (%): NR **Run In period:** NR **Wash out period:** NR **F/u duration** (on and off treatment)**:** 3 mo **Other:** NR	**Primary outcome results:** Self reported EF: IG1 vs CG: No difference Frequency of nocturnal penile tumescence IG1 vs CG: No difference Frequency of attempted intercourse or desired intercourse IG1 vs CG: No difference **Other outcomes assessed:** Rigidity, change in tumescence, erectile events /night, all abnormal in both IG1 and CG at baseline: No improvement observed in both IG1 and CG after 3 mo **Withdrawals/drop-outs/loss to f/u:** NR **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Self assessed EF using questionnaire and Likert scale at 3 time points Nocturnal penile tumescence: Monitored at 3 time points before and after intervention using RigiScan™ monitor. Peripheral vascular measurements done by Doppler ultrasound using Model 1059 Mini-lab III and a PVR IV Pulse Volume recorder

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Hatzichristou (2001) [251] **Funding source:** Schering-Plough Corporation	**N screened =** NR **N randomized =** NR **IG1 randomized =** 5 **CG randomized =** 5 **Inclusion**: hx of ED ≥ 3mons, mild to moderate ED defined from IIEF **Exclusion:** impotence caused by untreated endocrine disease, penile curvature, clinical hx of sign. liver or renal disease, symptomatic uncontrolled heart disease, concomitant nitrate therapy for underlying condition; sitting or supine SBP > 160 mmHg or diastolic > 95mmHg, symptomatic postural hypotension < 6 mons, psychoses, uncontrolled bipolar disorder or depression, prior or current use of therapy for ED	**Age, mean (SE):** 34.8 (8.13) **Race (%)**: NR **Co-morbidities (unrelated to disease):** 1 person had pulmonary disease, 1 had prostatitis-like syndrome **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: None **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED (mons) mean (SE):** 31.8 (23.56) **Underlying disease (diagnosis) (N or % of diseased/ grp):** Mild arteriogenic ED: n = 1 Mild veno-occlusive dysfunction: n= 2 **Psychogenic ED**: 0 **Physiologic ED:** 5 **Mixed ED**: 0	**IG1:** oral phentolamine (Vasomax) tablets **CG:** oral placebo tablets **IG1:** Dose: 40 milligrams Duration: 3 nights Frequency: 1x/ night Compliance (%): 100% **CG:** Dose: NA Duration: 3 nights Frequency: 1x/night Compliance (%): 100% **Run In period:** NR **Wash out period:** ≥ 6 days, ≤ 30 days **F/u duration (both on and off treatment):** NR	**Primary outcome results:** Penile tumescence (non sig.) Penile rigidity at tip: IG1: 5.24 ± 1.6, at base, 5.77 ± 1.62 IG1: ▲mean erectile events/sleep hr: 0.24 ± .08 CG: 0.13 ± .05 IG1: ▲mean duration of events: 5.53 ± 2.57 CG: 2.6 ± 1.04 **List (narrative) other outcomes assessed:** None **ITT analysis used for primary outcome?** No **Withdrawals/drop-outs/loss to f/u [N and or %]:** 0 **WDAE (N and/or %):** 0 **TAE:** 0 **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan device, medical an sexual hx, IIEF score

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Korenman (1993) [252] **Funding source:**	**N screened =** 24 **N randomized =** 18 **IG1, n =** 8 **CG, n =** 10 **ITT analysis used for primary outcome:** NR **Inclusion**: Borderline to definite penile arterial insufficiency as determined by PBPI, interest to re-establish EF by both partners and willingness to participate. **Exclusion:** Actively progressive illness, severe physical disability, major mental or emotional disease, hepatic or renal insufficient, hx of major cardiac arrhythmia, abuse of alcohol and other substances, and those lacking sexual partner. **Other:** Open label study was done after initial 12 wks finished. All 18 pts went on drug.	**Age, mean (range):** 65 $\pm$ 1.4 (54-76) **Race:** NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** NR **Duration of ED:** 6.2 $\pm$ 1.1 y **Underlying disease (diagnosis):** n(%) Hypertension 13 (72.2); Diabetes 6 (33.3); ASCVD 10 (55.6); Hypogonadism 4 (22.2); Compensated hypergonadotropic hypogonadism 1 (5.6) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** Pentoxifylline **CG:** Placebo **IG1:** Dose: 400mg Duration: 12 wks Frequency: NR Compliance (%): 100% **CG:** Dose: NR Duration: 12 wks Frequency: NR Compliance (%) 100%: **Run In period:** NR **Wash out period:** NR **F/u duration** (on and off treatment)**:** NR	**Primary outcome results:** IG1 vs. CG n/N (%) No improvement (one episode of coitus**)** 4/8 (50) vs. 10/10 (100) Pentoxifylline improved the PBPI in 18 males (0.76 $\pm$ 0.01, p = <0.0001) **Other outcomes assessed:** Patients initially receiving placebo placed on pentoxifylline: 5/10 (50) experienced successful intercourse. Pentoxifylline improved the PBPI in 18 males 0.76 (0.01), mean (sd) 9 (50) improved into normal range **Withdrawals/drop-outs/loss to f/u:** None **WDAE:** None **TAE:** None **SAE:** None **Ascertainment of outcomes assessed:** Report of patient verified by partner; penile-brachial pressure index determination (PBPI), daily log of improvement in EF.

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Kurt, U. (1994) [253] **Funding source:** NR	**N screened =** **N randomized = 100** **IG1, n =** 25 **IG2, n =** 25 **IG3, n =** 25 **CG, n**= 25 **ITT analysis used for primary outcome:** NR **Inclusion**: ED ≥ 6 mo. < I coitus within several 30 day periods. Absence of normal sexual performance periods in last 6 mo. Sufficient libido, no ejaculation problems. Absence of specific diseases: Eg. DM, neurological disorders, atherosclerotic vascular disease. No Hx of chronic or recent psychological problem. No Hx of recent trauma interfering with neurorvascular structures related to erections. Positive papaverine test (30 -60 mg IC) producing a rigid > 30 min erection. **Exclusion:** NR	**Age**: Mean 47.0 (range 23-68) yrs **Race:** NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Body weight:** NR **Other:** NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease (diagnosis):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other** NR	**IG1:** Oral Trazodone **IG2:** Oral Ketanserin **IG3:** Oral Mianserin **CG:** Placebo **IG1:** Trazodone Dose: 50 mg Duration: 30 days Frequency: 3/day Compliance (%): NR **IG2:** Ketanserin Dose: 20 mg Duration: 30 days Frequency: 2/ day Compliance (%): NR **IG3:** Mianserin Dose: 10 mg Duration: 30 days Frequency: 3/ day Compliance (%): NR **CG:** Dose: placebo Duration: 30 days Frequency: NR Compliance (%): NR **Run In period:** **Wash out period:** NR **F/u duration** (on and off treatment)**: 30 days** **Other:** NR	**Primary outcome results:** Positive response rate: IG1> IG3> IG2> CG (p=0.0004 in IG1 vs. CG) (p= 0.002 in IG1 vs. IG2) (p= 0.03 in IG1 vs. IG3) IG2 and IG3 Not sign. vs. CG **Other outcomes assessed:** NR **Withdrawals/drop-outs/loss to f/u:** Total N = 15 5 = loss to f/u 3= preferred IC treatment 2= preferred vacuum device 2= Hx concomitant drug use 2= social reasons 1= penile implant inserted Final analysis value: IG1: 23, IG2: 21, IG3: 19, CG: 22 **WDAE:** **TAE**: IG1: N=5: Sedation (n=2), Xerostomia (n=2), blurred vision (n=1) IG2: N=2: Vertigo (n=1), Fatigue (n=1) IG3: N=2: Severe sedation (n=2) CG: N= 2: Nausea (n=2) **SAE:** IG1: priapism in 1 patient 7 days after onset of intervention. IG1: severe sedation in 1 patient requiring cessation **Ascertainment of outcomes assessed:** Positive response= 3+ successful intercourse events without manipulation (in patient with previously inadequate rigidity without manipulation)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Mann, K (2001) [254] **Funding source:** Hoffmann-La Roche, Grenzach-Wyhlen	**N screened =** NR **N randomized =** 13 **IG1 screened =** NR **IG1 randomized =** 6 **IG2 screened =** NA **IG2 randomized =** **CG screened =** NR **CG randomized =** 7 **Inclusion**: ED **Exclusion:** lifetime diagnosis of any psychiatric disorder except for sexual dysfunction; hx of alcohol or other substance abuse; current or recent evidence of sign. medical disorder; sleep disturbances; taking any drugs	**Age, mean (sd):** IG1 49.3 (SD 8.9) CG 37.8 (SD 8.2) **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR **Other:** Degree of severity of ED (Clinical Global Impression scale, mean [and standard error]) IG1 5.17 (0.31) CG 5.00 (0.37)	**Concomitant medications:** NR **Duration of ED (yr):** IG1 3.8, CG 2.8 **Underlying disease (diagnosis) (N or % of diseased/grp):** NR **Psychogenic ED**: 13 **Physiologic ED:** 0 **Mixed ED**: 0	**IG1:** moclobemide orally orally **IG2:** NA **CG:** placebo orally **IG1:** Dose: 450 mg during wk 1, 600 mg during wk 2-8 Duration: 8 wk Frequency: 1 dose/day Compliance (%): NR **IG2:** NA Dose: Duration: Frequency: Compliance (%): **CG:** Dose: placebo Duration: 8 wk Frequency: 1 dose/day Compliance (%): NR **Run In period:** NR **Wash out period:** NA **F/u duration (both on and off treatment):** 8 wk	**Primary outcome results:** Clinical Global Impression severity subscale at 8 wk (1=normal, 2=borderline ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=among most extremely ill) IG1 3.50, CG 4.50 Clinical Global Impression improvement subscale at 8 wk (–3=very much worse, –2=much worse, –1=minimally worse, 0=no change, 1=minimally improved, 2=much improved, 3=very much improved) IG1 1.50, CG 0.50 Change in mean nocturnal tumescence and rigidity of penis base and tip (averaged of the two) at 8 wk Tumescence, cm: IG1 –0.24, CG –0.13 Rigidity, %: IG1 2.58, CG 2.67 **List (narrative) other outcomes assessed:** NA **ITT analysis used for primary outcome?** **Y N/NR** N **Withdrawals/drop-outs/loss to f/u [N and/or %]:** 1 (CG) **WDAE (N and/or %):** 1 (CG) **TAE:** IG1: 4 events in 3 patients CG: 7 events in 3 patients **SAE:** 0 **Ascertainment of outcomes assessed:** RigiScan™ Rigidity Assessment System

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Meinhardt, W. (1997) [255] **Funding source:** NR	**N screened =** NR **N randomized =** 69 **IG screened =** NR **IG randomized =** 32 **CG screened =** NR **CG randomized =** 37 **Inclusion**: ED **Exclusion:** severe kidney or liver disorders, pts using anti-hypertensives or other drugs (especially alpha or beta blocking agents)	**Age, mean (range):** IG 54(26-80), CG 55(39-81) **Race (%)**: **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment (N)**: self-injections IG 5, CG 16; psychotherapy IG 1, CG 0; vacuum device IG 1, CG 1 **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR **Other:** NA	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/grp):** ED 69(100) **Psychogenic ED (N)**: IG 16, CG 20 **Physiologic ED (N):** vascular IG 5, CG 5; diabetes IG 5, CG 7; neurogenic IG 1, CG 0; peyronie's disease IG 1, CG 1; **Mixed/unknown ED**: IG 4, CG 4 **Other:** NA	**IG:** trazodone, oral **CG:** placebo, oral **IG:** Dose: 50 mg Duration: 4 or 6 wks Frequency: X3/d = 150 mg Compliance (%): NR **CG:** Dose: 50 mg Duration: 4 or 6 wks Frequency: X3/d = 150 mg Compliance (%): NR **Run In period:** 2 wks **Wash out period:** NA **F/u duration (both on and off treatment):** NA **Other:** NA	**Primary outcome results:** **Patients diary:** NR in results **Questionnaire (N [%]):** medication did not work IG 15(58), CG 20(62); it works, but insufficiently IG 6(23), CG 6(19); it works, but too many side-effects IG 1(4), CG 1(3); medication works well IG 4(15), CG 5(16) = [p> 0.05] for all **List (narrative) other outcomes assessed:** RigiScan **ITT analysis used for primary outcome?** N **Withdrawals/drop-outs/loss to f/u [N and or %]:** N=2 lost to f/u **WDAE (N and/or %):** N= 6,7 or 9 side effects **TAE:** dizziness IG 5, CG 0; sleepiness IG5, CG 2; headache IG 3, CG 1; nausea IG 3, CG 0; rash IG 0, CG 1; conjunctivitis IG 0, CG 1 **SAE:** NR **Ascertainment of outcomes assessed:** **Patients diary:** details on sexual function and complaints **Questionnaire:** opinion of treatment **Other**: NA

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Nickle (2007) [256] **Funding source:** NR	**N screened =** **N randomized =** 50 **IG, n =** 25 **CG, n =** 25 **ITT analysis used for primary outcome:** NR **Inclusion:** men > 18 y, suffering from chronic stress and anxious or depressive mood with ED **Exclusion:** psychotic disorders, organic ED, current use of cabergoline, other dopamine agonists, any kind of current anti-ED, use of antidepressants, antianxiety drugs or psychotherapy	**Age, mean (sd):** 39.3 (15.3) vs. 38.8 (12.9) y **Race: NR** **Co-morbidities, n (%):** NR **Previous ED treatment:** **Smoking status:** **Body weight:** NR **Other:** BMI: 26.1 (5.9) vs. 26.9 (5.4)	**Concomitant medications, n (%):** NR **Duration of ED:** > 6 mo **Underlying disease, n (%):** as in inclusion **Psychogenic ED, n (%):** 100% **Physiologic ED, n (%):** 0 **Mixed ED, n (%)**: NR **Other:** moderate baseline hyperprolactinemia in 38 (18 vs. 20)	**IG:** Cabergoline **CG:** Placebo **IG:** Dose: 0.5 mg Duration: 4 mo Frequency: once/d Compliance: NR **CG:** Dose: NA Duration: 4 mo Frequency: as IG Compliance: NR **Run In period:** NR **Wash out period:** NR **F/u duration:** 4 mo	**Primary outcome (EF):** Improvement from baseline (in mean): IIEF-EF: 11.7 vs. 6.9 IIEF-OF: 3.6 vs. 1.8 IIEF-IS: 5.7 vs. 2.6 IIEF-OS: 3.6 vs. 0.9 IIEF-SD: 3.5 vs. 2.0 ED-QoL change from baseline score: -16.9 vs. -9.6 **Other outcomes assessed:** SFQ partner questionnaire **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** 10 (40) vs. 9 (36) **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF domains; ED quality of life questionnaire

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Peskircioglu (1996) [257] **Funding source:** NR	**N screened** = NR **N randomized =** 36 **IG1 randomized =** 20 **CG randomized =** 16 **Inclusion**: patients with borderline arterial insufficiency **Exclusion:** patients with correctable secondary causes (endocrine, metabolic, pharmacological & Peyronie's disease)	**Age, mean (sd):** 54 (± 7) **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/ grp):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** oral pentoxifylline **CG:** placebo (vitamin B complex) **IG1:** Dose: 1.2 grams in 3 doses Duration: 2 mons Frequency: 3 doses/day Compliance (%): 100 **CG:** Dose: NA Duration: 2 mons Frequency: 3 doses/day Compliance (%): 100 **Run In period:** NR **Wash out period:** NR **F/u duration (both on and off treatment**): NR	**Primary outcome results:** Penile blood flow IG1: 12/20 ▲ (mean change = 6.25 cm) CG: 4/20 ▲ (mean change = 0.38 cm) **List (narrative) other outcomes assessed:** Potency **ITT analysis used for primary outcome?** **Withdrawals/drop-outs/loss to f/u [N and or %]:** 0 **WDAE (N and/or %):** 0 **TAE:** IG1: n =2 (nausea), n = 2 (headache) **SAE:** 0 **Ascertainment of outcomes assessed:** Penile duplex ultrasonography

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Piha J. (2003) [258] **Funding source:** Finnish Hypertension Society and Slovay Pharma/ Algol.	**N screened =** NR **N randomized =** 12 Crossover design **IG1**, n = 11 **IG1 crossover,** n = 11 **ITT analysis used for primary outcome:** **Inclusion**: Hypertensive **Exclusion:** NR	**Age:** Mean 50.5 (range 41-58) **Race:** NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Body weight:** NR **Other:** Mean IIEF-5 score: 15.8± 8.5 4= score ≥ 21 7= score <21 Mean serum T 13.1 ± 3.3 nmol/L Weekly resting Blood Pressure	**Concomitant medications:** For Hypertension (n): 2 on ACE inhibitor 5 on ACE inhibitor + beta-blocker + thiazide diuretic 1 on beta-blocker 2 on calcium cannel **Duration of ED:** NR **Underlying disease (diagnosis):** Hypertension **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR **Other:** NR	**IG1:** Moxonidine **IG1 crossover:** Metoprolol **IG1:** Moxonidine Dose: 0.4 mg ▲ 0.6mg if BP >160/100 mmHg Duration: 8 wks Frequency: daily Compliance (%): NR **IG1 crossover:** Metoprolo Dose: 100 mg ▲200 mg if needed Duration: 8wks Frequency: daily Compliance (%): NR **Run In period:** **Wash out period**: 1-3 days **F/u duration** (on and off treatment): 16 wks **Other:** NR	**Primary outcome results:** Resting vs. stimulated penile Peak artery velocity for IG1: Mean peak velocity ▲: 19.8 ± 5.8 vs. 64.0 ± 32.4 cm/sec (p=0.008) Resting vs. stimulated penile Peak artery velocity for IG1 crossover Mean peak velocity ▲: 15.6 ± 55.2 vs. 53.9 ± 26.4 cm/sec (p=0.038) Resting vs. stimulated penile diameter for IG1: ▲ diameter: 0.54 ± 0.13 vs. 0.89 ± 0.14 mm (p=0.004) Resting vs. stimulated penile diameter for IG1crossover: ▲ diameter: 0.43 ± 0.16 vs. 0.66 ± 0.14 mm (p= 0.0001) **Other outcomes assessed:** Patient reported Subjective Erectile capacity <u>improved</u>: IG1 vs. baseline: 9/11 (p<0.001). IG1 crossover vs. baseline: 9/11 reported <u>impaired</u> EF (p<0.0002) **Withdrawals/drop-outs/loss to f/u:** 1withdrawal due to not hypertensive (BP below 170/110 mmHg) **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** Stimulated erection induced by Alprostadil 10 microgram + phentolamine 0.1 mg IC. Peak systolic velocity measured via Doppler at 2 sites, mean of 4 measurements after 10-15 min **Other:** Mean Blood pressure with IG1 vs. IG1 crossover: 163.8 **(**± 16.0) / 96.2 (± 6.3) mmHg **vs**. 157.8 **(**± 19.2) / 93.6 (± 11.1) mmHg. P= not sign.

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Reiter, WJ (1998) [259] **Funding source:** NR	**N screened =** NR **N randomized =** 40 **IG1, n =** 20 **CG, n =** 20 **ITT analysis used for primary outcome:** N **Inclusion**: hx of ED > 6 mos., serum levels of testosterone, PRL, and PSA within normal range, and serum DHEAS level < 1.5 µmol/L, International Prostate Symptom Score < 7, full erection after intracavernosal administration of 10 µg PGE1 **Exclusion:** well known causes of ED (hypertension, DM, ischemic heart disease, hyperlipidemia, neurological disorders, veno-occlusive dysfunction, and hx of radical prostatectomy)	**Age [mean yr (range)]:** IG 56.6(43-68), CG 56.4(41-69) **Race:** NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status [N (%)]**: non-smokers 40(100) **Body weight**: NR	**Concomitant medications:** NR **Duration of ED:** NR **Underlying disease (diagnosis)[N (%)]:** ED 40(100) **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** oral dehydroepiandrosterone (DHEA) **CG:** oral placebo DHEA **IG1:** Dose: 50 µg Duration: 24 wks Frequency: 1X/d Compliance: NR **CG:** Dose: 50 µg Duration: 24 wks Frequency: 1X/d Compliance: NR **Run In period:** NA **Wash out period:** NA **F/u duration** (on and off treatment)**:** 24 wks (0, 8, 16, and 24 wks)	**Primary outcome results:** IIEF (~mean score /30): EF IG scored higher ~29 vs. CG ~8; OF IG scored higher ~10 vs. CG ~2; SD IG scored higher ~8 vs. CG ~2; intercourse satisfaction IG scored higher ~14 vs. CG ~4; OS IG scored higher ~9 vs. CG ~4 (no indication of sign.)(data provided in Figure 2) Testosterone serum levels (~ mean ng/ml): IG ~4.6 vs. CG ~3.6 no sign. difference (p >0.05)(data provided in Figure 1) DHEA serum levels (~ mean µg/ml): IG levels ▲~2.4 vs. CG ~1.0 (no indication of sign.)(data provided in Figure 1) **Other outcomes assessed:** PRL and PSA serum levels **Withdrawals/drop-outs/loss to f/u (N):** insufficient response IG 0, CG 6; inadequate PSA IG 0, CG 1 **WDAE:** NR **TAE:** NR **SAE:** NR **Ascertainment of outcomes assessed:** IIEF: 15-item questionnaire, questions rated 0-5. Testosterone serum levels: via blood sample. DHEA serum levels: via blood sample.

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Safarinejad (2001) [260] **Funding source:** NR	**N screened =** 44 **N randomized =** 44 **IG1 screened =** 44 **IG1 randomized =**44 **CG screened:** 44 **CG randomized:** 44 **Inclusion**: No organic diseases, laboratory findings were normal, peak flow values on Duplex ultrasonaography were > 30cm/s in both cavernous arteries, the end diastolic flow on duplex Doppler ultrasonography was < 2cm/s, intra cavernous injection test produced good rigidity, neurologic findings were normal. **Exclusion:** clinically obvious psychogenic impotence, verified or suspected malignancy, diabetes, neurological problems such as parkinsonism and paraplegia, impotence of clearly arterial or venous origin, genital anomoly or disease, cardiovascular disorders	**Age , mean (range):** 42 (28-55) y **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment:** NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant Medications (n/grp): NR** **Duration of ED (yr):** NR **Underlying disease (diagnosis) (N or % of diseased/grp): NR** **Physiologic ED:** NR **Psychogenic ED:** NR **Mixed ED**: 44	**IG1:** isoxsuprine hydrochloride, oral medication (pill form) **CG:** oral medication (pill form) **IG1:** Dose: 60 milligrams Duration: 30 days Frequency: 1x/day Compliance (%): NR **CG:** Dose: NA Duration:30 days Frequency: 1x/day Compliance (%): 82 **Run In period:** NR **Wash out period:** 2 wks **F/u duration (both on and off treatment):** NR	**Primary outcome results:** Erectile response for IG1: n (%) - Complete: 3 (8.3); Partial: 3 (8.3); None: 27 (75); Worse: 3 (8.3) Erectile response for CG: n (%) - Complete: 3 (8.3); Partial: 4 (11); None: 29 (80.5); Worse: 0 **List (narrative) other outcomes assessed:** Pulse rate, blood pressure, Libido, orgasm, duration of erection, rigidity of penis **ITT analysis used for primary outcome?** **Y N/NR:** No **Withdrawals/drop-outs/loss to f/u [N and/or %]:** 6 **WDAE (N and/or %):** 2 (IG1, hypotension) **TAE:** 47 IG1: n (%) - ▼ arterial pressure: 8 (22.2); Headache: 7 (19.4) Trembling: 3 (8.3); Nervousness: 4 (11.1); Gastrointestinal problems: 9 (25) Skin rash: 4 (11.1); Facial redness: 4 (11.1); Tachycardia: 2 (5.55) CG: n (%) - Headache: 2 (5.55); Skin rash: 2 (5.55); Tachychardia: 3 (8.3) **SAE:** 0 **Ascertainment of outcomes assessed:** Doppler ultrasonography, patient perception questionnaire, laboratory tests

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sommer (2006) [261] **Funding source:** NR (medication by LO.LI Pharma Co. Italy)	**N screened =** NR **N randomized =** 176 **IG, n =** NR **CG, n =** NR **ITT analysis used for primary outcome:** NR **Inclusion:** men with diagnosed DM type II and ED of longer than 6 mo who were in stable relationships **Exclusion:** current or recent ED treatment (including vacuum devices, IC or IU injections)	**Age, range:** 50-70 y **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** BMI, mean (sem) 26.2 (3.5) vs. 27.4 (3.0) kg/m^2	**Concomitant medications, n (%):**NR **Duration of ED:** > 6 mo **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** 0 **Physiologic ED, n (%):** 100% **Mixed ED, n (%)**: NR	**IG:** Myoinositol/folic acid combination (oral) **CG:** Placebo **IG:** Dose: 4 g/400 µg Duration: 12 wks Frequency: once/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 2 wks **Wash out period:** NA **F/u duration:** 90 d	**Primary outcome results:** IIEF-5 score, mean (sem): Baseline: 12 (5) vs. 14 (4) Post tx: 20 (3) vs. 13 (4) Sexual function, mean (sem) Baseline: 8 (3) vs. 9 (2) Post tx: 11 (1) vs. 9 (1) Sexual diary, mean (sem) Baseline: 1 (1) vs. 1 (1) Post tx: 6 (1) vs. 3 (1) **Other outcomes assessed:** PSV, EDV and RI (resistance index); results indicated sign. improvement in PSV and EDV after tx in IG only ($p<0.05$) **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** NR **SAE, n (%):** NR **Ascertainment of outcomes assessed:** IIEF-5, pts diary

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sommer (2006) [262] **Funding source:** NR	**N screened =** 237 **N randomized =** 68 (cross over design) **IG/CG, n =** 68 **ITT analysis used for primary outcome:** NR **Inclusion:** men 18 or older, with diagnosed depressive disorder and ED of longer than 6 mo who were in stable relationships **Exclusion:** other axis I psychiatric disorder (i.e. substance abuse or dependence), use of any antidepressant medication, abnormal serum hormone levels, hx of major organ disease or poorly controlled DM	**Age, mean (sd):** 36.1 (6.7) vs. 35 (8.3) **Race:** NR **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** NR **Other:** BMI, mean (sem) 26.2 (3.5) vs. 27.4 (3.0) kg/m^2	**Concomitant medications, n (%):** NR **Duration of ED:** 6.5 (1.4) VS. 7.2 (1.5) y **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** 100% **Physiologic ED, n (%):**0 **Mixed ED, n (%)**: NR	**IG:** Tianeptine (oral) **CG:** Placebo **IG:** Dose: NR Duration: 8 wks Frequency: once/d Compliance: NR **CG:** Dose: NA Duration: as IG Frequency: as IG Compliance: NR **Run In period:** 4 wks **Wash out period:** NR **F/u duration:** 8 and 16 wks (end of each cross over tx phase)	**Primary outcome results:** Brief Sexual Inventory score for erection, mean (sd): Baseline: 5.4 (1.9) vs. 4.1 (2.3) Post tx: 8.5 (2.4) vs. 5.7 (1.1), p<0.05 GAQ, % yes (successful sexual intercourse): 89.4% vs. 50% Responders: 48 (72.2%) vs. 19 (27.9%) **Other outcomes assessed:** depressive scores (ED improvement highly correlated with changes in depressive symptoms) **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** 5 (3.4) vs. 1 (1.5) including headache, GI or CNS symptoms **SAE, n (%):** NR **Ascertainment of outcomes assessed:** Anxiety Depression Scale, Brief Sexual Inventory, and QoL and erection questionnaire; GAQ

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Sommer (2006) [263] **Funding source:** NR	**N screened =** NR **N randomized =** 18 (likely parallel) **IG1, n =** NR **IG2, n =** NR **CG, n =** NR **ITT analysis used for primary outcome:** yes **Inclusion:** men 21-62 y; diagnosed with ED (by IIEF-EF) **Exclusion:** ED due to any neurological on endocrine causes, an anatomical deformity such as severe penile fibrosis, SCI or radical prostatectomy, DM, other relevant co morbidities, major psychiatric illness or concomitant tx	**Age, mean (sd):** 41.6 (11.9) y **Race:** 100% White **Co-morbidities, n (%):** NR **Previous ED treatment:** NR **Smoking status:** NR **Body weight:** 78.8 (7.9) kg **Other:** IIEF-EF baseline: range 14-19	**Concomitant medications, n (%):** NR **Duration of ED:** NR **Underlying disease, n (%):** NR **Psychogenic ED, n (%):** NR **Physiologic ED, n (%):** NR **Mixed ED, n (%)**: NR	**IG1-2:** Tetrahydobiopterine (BH_4) + VSS **CG:** Placebo **IG1/2:** Dose: 200 mg or 500 mg Duration: NA Frequency: single dose Compliance: 100% **CG:** Dose: NA Duration: NA Frequency: as IG Compliance: 100% **Run In period:** NR **Wash out period:** NR **F/u duration:** NR	**Primary outcome results:** Time, base rigidity 60-100%, mean (sd): 71.6 (40.5) vs. 74.2 (44.1) vs. 38.1 (26.4) min Duration of event at base, mean (sd): 74.1 (36.1) vs. 77.9 (41.1) vs. 51.2 (26.9) Time, tip rigidity 60-100%, mean (sd): 54.6 (33.4) vs. 58.9 (46.1) vs. 25.2 (22.3) min Duration of event at tip, mean (sd): 67.2 (37.2) vs. 78.9 (42.2) vs. 37.7 (29.8) min **Other outcomes assessed:** Other RigiScan measures (base and tip RAU, time rigidity of 80-100%, TAU, average event rigidity, average event tumescence) **Withdrawals/drop-outs/loss to f/u, n (%):** NR **WDAE, n (%):** NR **TAE, n (%):** 2 () vs. 1 () vs. 1 () **SAE, n (%):** 0 **Ascertainment of outcomes assessed:** RigiScan

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Speel (2005) [264] **Funding source:**	**N screened =** 59 **N randomized =** 59 **IG1, n =** 30 **CG, n =** 29 **ITT analysis used for primary outcome:** None **Inclusion**: Patients with complaints of ED and impaired cavernosal perfusion as demonstrated with PPDU. Patients between 35 to 75yrs. **Exclusion:** Men with penile implants; heart failure or low ejection fraction; uncontrolled hypertension; hypotension; nephropathy or renal artery stenosis; abnormal kidney function; dehydration; taking diuretic; myocardial infraction or stroke within 4 wks; hypersensibility for ACE, participating in any other trial; has medical, psychiatric or substance abuse disorders, hx of malignancy.	**Age, mean (sd);** 60 (6.8) yrs **Race:** NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C):** NR **Previous ED treatment**: None **BMI (kg/m^2)**: NR **Smoking status**: NR **Body weight:** NR	**Concomitant medications:** Sildenafil, self – injection with papaverine/ phentolamine prior to sexual intercourse. (70% used) **Duration of ED, mean (95% CI) mo** IG1: 40 (25-55) CG: 48 (29-67) **Underlying disease (diagnosis):** n (%) IG1: 9 (30) CG: 3 (10.3) suffered from diabetes **Psychogenic ED**: None **Physiologic ED:** None **Mixed ED**: None	**IG1:** Quinapril **CG:** Placebo **IG1:** Dose: 20mg Duration: 26 – 46 wks Frequency:once a day Compliance (%): (87) **CG:** Dose: Duration: 26 – 46 wks Frequency: once a day Compliance (%): (93) **Run In period:** None **Wash out period:** None **F/u duration** (on and off treatment)**:** day 14, wk 4, and 2 mo	**Primary outcome (EF)**: Change AT: -13 vs.-18 Change IMT: 0.03 vs. 0.01 Sexual Activity (% change): 8 vs. 20 Severe ED (% change): -32 vs. -35 **Other outcomes assessed:** IIEF score erection domain (who were sexually active) n (%) >19 (mild): 4 (25) vs. 4 (24) 13-18 (moderate): 7 (44) vs. 6 (35) 5-12 (severe): 5 (31) vs.7 (41) **Withdrawals/drop-outs/loss to f/u:** n (%). IG1: 2 (6.7) were exclude for lack of compliance. CG: 2 (6.9) Lack of compliance **WDAE:** n (%). IG1: 2 (6.7) dropped out because of discomfort in the epigastria region. CG: 1 (3.4) had a stroke during study 1 (3.4) died during study because of cerebral hemorrhage. **TAE:** n (%). IG1: 3 (10) dry cough, 4 (13.3) nausea, 3 (10) joint and muscle pain, and 1 (3.3) twinkle feeling in feet. CG: 2 (6.9) epigastric pain, 1 (3.4) dry cough, 1 (3.4) nausea, 1 (3.4) headache. **SAE:** n (%). CG: 1 (3.4) had a stroke during study. 1 (3.4) died during study because of cerebral hemorrhage. **Ascertainment of outcomes assessed:** Cavernosal acceleration time measures during PPDU, IMT, and EF determined by the erection domain of the IIEF questionnaire. (Physician and vascular technologist)

Author Funding	N; study design; eligibility	Participants characteristics	Diagnosis details	Intervention	Outcomes
Van Ahlen (1995) [265] **Funding source:** NR	**N screened =** NR **N randomized =** 20 **IG1 randomized =** 20 **IG2 randomized** = 20 **CG randomized =** 20 **Inclusion**: normal results for evaluation of pharmacotesting, evaluation of relevant hormones, pharmaco-Doppler studies and nocturnal penile tumescence **Exclusion:** severe organic causes of ED, severe cardiac disease, hypertension, DM, elevated liver enzyme concentrations.	**Age, mean (sd):** 46.3 (±2.7) **Race (%)**: NR **Co-morbidities (unrelated to disease):** NR **Blood glucose (or HbA1C)(%):** NR **Previous ED treatment**: NR **BMI (kg/m^2)**: NR **Smoking status**: NR **Initial body weight:** NR	**Concomitant medications:** NR **Duration of ED (yr) SD:** 3.6 (± 0.5) **Underlying disease (diagnosis) (N or % of diseased/ grp):** NR **Psychogenic ED**: NR **Physiologic ED:** NR **Mixed ED**: NR	**IG1:** oral naltrexone **IG2:** oral naltrexone **CG:** oral placebo **IG1:** Dose: 25 milligrams (phase 1) Duration: 4wks Frequency: 1x/day Compliance (%): 90 **IG2:** Dose: 25 milligrams (50 total) Duration: 4wks (phase 2) Frequency: 2x/day Compliance (%): 90 **CG:** Dose: matching to treatment Duration: 8 wks Frequency: matching IG1 & IG2 Compliance (%): 90 **Run In period:** 4 wks **Wash out period:** NR **F/u duration (both on and off treatment):** NR	**Primary outcome results:** Intercourse (non-sig), libido (non-sig) Spontaneous early morning erections Baseline: 2.83 ± 0.28 IG1: 4.22 ± 0.31 IG2: 3.78 ± 0.31 **List (narrative) other outcomes assessed:** None **ITT analysis used for primary outcome?** NR **Withdrawals/drop-outs/loss to f/u [N and or %]:** IG1: 1 = psychological reasons IG2: 1= psychological reasons **WDAE (N and/or %): 0** **TAE: 0** **SAE:** 0 **Ascertainment of outcomes assessed:** Daily patient questionnaire, hormonal measurements – no objective evaluations

List of abbreviations: %=percent, ▲=increased, ▼=decreased, AE=adverse event, SAE=serious adverse event, BMI=body mass index, CC=controlled clinical trials, CG=comparator/control group, ctrls=controls, DM=diabetes mellitus, E_1 IC=intracavernosal injection, ECG=electrocardiograms, ED=erectile dysfunction, EDV=end-diastolic velocity, f/u=follow-up, FMD=flow mediated dilation, GAQ=global assessment question, GEQ=global efficacy question, grp=group/s, HbA1C=haemoglobin, hr=hour(s), hx=history, IG=intervention group, IIEF= international index of erectile function (EF=erectile function, OF=orgasmic function, OS=overall satisfaction, SD=sexual desire), ITT=intent-to-treat (Y = yes, N = no, NR = not reported), IU=intraurethral, kg=kilograms, lbs=pounds, LUTS=lower urinary tract symptoms, M=male, max=maximum, mo=month(s), NA=not applicable, PADAM=partial androgen deficiency of the aging male, PgE_1=Prostagladin, PRL=prolactin, PSA=prostate-specific antigen, RAU=rigidity activity unit, RCT=randomized control trial, SBP=systolic blood pressure, sign.=significant; TAE=total adverse events, TAU=tumescence activity unit, vs.=versus, WDAE=withdrawals resulting from adverse events, wk=week(s), yr=year(s).

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The UO-EPC gratefully acknowledges the following individuals who reviewed the initial draft of this evidence report, and provided constructive feedback. Acknowledgements not reflect endorsement of this report.

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Appendix F. Quality Assessment

Randomized Controlled Trials (RCTs)

Table F-1. Quality Assesment of RCTs

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
Palmer 2000[1]	1	0	0	1	0	2	Unclear
Seidman 2001[2]	1	0	1	1	1	4	Unclear
Kongkanand 2003[3]	1	0	1	1	1	4	Unclear
Stuckey 2003[4]	1	1	1	1	1	5	Adequate
Choi 2003[5]	1	0	1	1	1	4	Unclear
Levinson 2003[6]	1	0	1	0	1	3	Unclear
DeBusk 2004[7]	1	1	1	0	1	4	Unclear
Boolell 1996[8]	1	0	1	0	1	3	Unclear
Goldstein 1998[9]	1	0	1	1	1	4	Unclear
Tan 2000[10]	1	0	1	1	1	4	Unclear
Meuleman 2001[11]	1	0	1	1	1	4	Unclear
Eardley 2001[12]	1	-1	1	1	0	2	Unclear
Young 2002[13]	1	0	1	1	0	3	Unclear
von Keitz 2002[14]	1	-1	1	0	1	2	Unclear
Goldstein 2003[15]	1	0	1	0	1	3	Unclear
Nurnberg 2003[16]	1	1	1	1	1	5	Adequate
Incrocci 2003[17]	1	0	1	0	1	3	Unclear
Hellstrom 2003[18]	1	1	1	0	1	4	Adequate
Price 1998[19]	1	0	1	0	1	3	Unclear
Rendell 1999[20]	1	1	1	1	1	5	Adequate
Christiansen 2000[21]	1	1	1	1	1	5	Adequate
Olsson 2000[22]	1	0	1	0	1	3	Unclear
Chen 2001[23]	1	0	1	1	1	4	Unclear
Boulton 2001[24]	1	0	1	1	0	3	Unclear
Hussain 2001[25]	1	0	1	0	0		Unclear
Lewis 2001[26]	1	0	1	0	0	2	Unclear
Brock 2002[27]	1	0	0	0	1	2	Unclear
Porst 2003[28]	1	0	1	0	0	2	Unclear
Montorsi 2004[29]	1	0	1	0	1	2	Unclear
Safarinejad 2004[30]	1	1	1	0	1	4	Adequate
Webster 2004[31]	1	-1	1	0	1	2	Unclear
Giuliano 2005[32]	1	-1	1	0	0	1	Unclear
Hatzichristou 2005[33]	1	-1	1	0	0	2	Unclear
Eardley 2005[34]	1	0	0	0	1	2	Unclear
Cavallini 2005[35]	1	-1	1	1	1	3	Unclear
Diamond 2005[36]	1	0	1	0	1	3	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
Hellstrom 2005[37]	1	0	1	0	0	2	Unclear
Melman 2005[38]	0	0	0	0	0	0	Unclear
Valiquette 2005[39]	1	0	1	0	1	3	Unclear
Shabsigh 2005[40]	1	0	1	0	0	2	Unclear
Ardicoglu 2005[41]	0	0	0	0	0	0	Unclear
Melnik 2005[42]	1	1	0	0	1	3	Adequate
Seyam 2005[43]	1	0	0	0	1	2	Unclear
Mirone 2005[44]	1	0	0	0	1	2	Unclear
Nehra 2005[45]	1	1	1	0	1	4	Unclear
Young 2005[46]	1	-1	1	0	0	1	Unclear
McMahon 2005[47]	1	1	1	1	1	5	Unclear
Fowler 2005[48]	1	1	1	1	0	4	Adequate
Haren 2005[49]	1	1	1	1	0	4	Unclear
Carson 2005[50]	1	0	1	0	1	3	Unclear
Mahon 2005[51]	1	0	1	1	0	3	Unclear
Rosano 2005[52]	1	0	1	1	1	4	Unclear
Kirby 2005[53]	1	0	1	1	1	4	Unclear
De Rose 2005[54]	1	1	0	0	1	3	Adequate
Gontero 2005[55]	1	1	1	1	1	5	Adequate
Katz 2005[56]	1	1	1	0	1	4	Unclear
Carson 2004[50]	1	-1	1	1	1	4	Unclear
Fonseca 2004[57]	1	0	1	0	0	2	Unclear
Wheatley 2004[58]	1	1	1	1	0	4	Adequate
Abdel-Naser 2004[59]	1	0	0	0	1	2	Unclear
Parsons 2004[60]	1	1	1	0	0	3	Inadequate
Deveci 2004[61]	1	0	1	0	0	2	Unclear
Seftel 2004[62]	1	0	0	0	0	1	Inadequate
Eardley 2004[63]	1	0	0	0	0	1	Unclear
Gentile 2004[64]	1	-1	1	0	0	2	Unclear
Staab 2004[65]	1	-1	1	1	1	3	Adequate
Montorsi 2004[66]	1	0	1	1	0	3	Unclear
Skoumal 2004[67]	1	1	1	1	1	5	Unclear
Rosen 2004[68]	1	-1	1	0	1	2	Unclear
Shabsigh 2004[69]	1	0	1	1	0	3	Unclear
Seftel 2004[70]	1	1	1	1	1	5	Unclear
Nagao 2004[71]	1	-1	1	1	1	3	Adequate
Perimenis 2004[72]	1	-1	1	-1	1	1	Unclear
Tignol 2004[73]	1	0	0	0	0	1	Unclear
Perimenis 2004[74]	1	1	1	1	1	5	Unclear
Carson 2004[75]	1	1	0	0	1	3	Unclear
Eardley 2004[76]	1	0	1	0	1	3	Unclear
Stief 2004[77]	1	1	0	0	0	2	Unclear
Hatzichristou	1	0	1	1	1	4	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
2004[78]							
Cavallini 2004[79]	1	1	1	1	1	5	Adequate
Rosen 2004[80]	1	1	0	0	0	2	Adequate
von Keitz 2004[81]	1	0	1	1	0	3	Unclear
Leder 2004[82]	1	0	1	1	1	4	Unclear
Diamond 2004[83]	1	1	1	0	0	3	Unclear
Mancini 2004[84]	1	0	1	1	0	3	Unclear
Perimenis 2004[85]	1	0	1	0	1	3	Unclear
Govier 2003[86]	1	-1	0	0	0	1	Unclear
Fox 2003[87]	1	0	0	0	1	2	Unclear
Brock 2003[88]	1	-1	1	0	1	2	Unclear
Padma-Nathan 2003[89]	1	0	1	1	0	3	Unclear
Hellstrom 2003[90]	1	1	1	1	1	5	Adequate
Montorsi 2003[91]	1	0	1	1	1	4	Unclear
Porst 2003[92]	1	-1	0	0	1	1	Unclear
Boyanov 2003[93]	1	0	1	0	0	2	Unclear
Anderson 2003[94]	1	1	1	1	1	5	Unclear
Steidle 2003[95]	1	0	0	0	1	2	Unclear
Gontero 2003[96]	1	1	0	0	1	3	Unclear
Aversa 2003[97]	1	-1	0	0	0	0	Unclear
Hagemann 2003[98]	1	0	0	0	0	1	Unclear
Montorsi 2003[99]	1	0	0	0	0	1	Unclear
McNicholas 2003[100]	1	0	0	0	0	1	Unclear
Padma-Nathan 2003[101]	1	0	1	0	0	2	Unclear
Harding 2002[102]	1	-1	1	0	0	2	Unclear
Steidle 2002[103]	1	0	1	0	0	2	Unclear
Thadani 2002[104]	1	0	1	0	1	3	Unclear
Saenz, I 2002[105]	1	1	1	0	0	3	Inadequate
Hellstrom 2002[106]	1	0	1	0	1	3	Unclear
Seibel 2002[107]	1	0	1	0	1	3	Unclear
Bocchi 2002[108]	1	0	1	0	1	3	Unclear
Ugarte 2002[109]	1	1	1	0	1	4	Adequate
Gomez 2002[110]	1	1	1	1	1	5	Adequate
Becher 2002[111]	1	0	1	0	1	3	Unclear
Glina 2002[112]	1	0	0	0	0	1	Unclear
Schanz 2002[113]	1	0	1	1	1	4	Unclear
Padma-Nathan 2002[114]	1	0	1	0	1	3	Unclear
Lebret 2002[115]	1	0	1	1	0	3	Unclear
Lindsey 2002[116]	0	0	0	0	0	0	Unclear
Lim 2002[117]	0	0	0	0	1	1	Unclear
van der Windt	1	1	1	0	0	3	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
2002[118]							
Kunelius 2002[119]	1	1	1	1	1	5	Unclear
Lammers 2002[120]	1	0	1	1	1	4	Unclear
De Rose 2002[121]	1	0	0	0	1	2	Unclear
Eardley 2002[122]	1	1	1	1	1	5	Inadequate
Hatzichristou 2001[123]	1	0	1	0	0	2	Unclear
Incrocci 2001[124]	1	1	0	0	1	3	Adequate
Stark 2001[125]	1	0	1	1	1	4	Unclear
Choppin 2001[126]	0	0	1	1	1	3	Unclear
Porst 2001[127]	1	0	1	0	1	3	Unclear
Mann 2001[128]	1	0	1	0	0	2	Unclear
Dula 2001[129]	1	0	0	0	0	1	Unclear
Safarinejad 2001[130]	1	0	1	1	1	4	Unclear
Gomaa 2001[131]	1	0	1	0	1	3	Unclear
Olsson 2001[132]	1	0	1	0	0	2	Unclear
Padma-Nathan 2001[133]	1	0	1	0	0	2	Unclear
Klotz 2001[134]	1	0	1	1	0	3	Adequate
Goldstein 2001[135]	1	0	1	0	0	2	Unclear
Kloner 2001[136]	1	0	1	0	0	2	Unclear
Fu 2000[137]	1	0	1	0	0	2	Unclear
Montorsi 2000[138]	1	-1	1	1	1	3	Unclear
Enzlin 2000[139]	1	0	1	0	0	2	Unclear
Baum 2000[140]	1	0	0	0	0	1	Unclear
Wessells 2000[141]	1	0	1	1	1	4	Unclear
Cappelleri 2000[142]	1	0	1	0	1	3	Unclear
Ekman 2000[143]	1	0	0	0	0	1	Unclear
Dula 2000 [144]	1	0	1	0	1	3	Unclear
Rabkin 2000[145]	1	0	1	0	0	2	Unclear
Shabsigh 2000[146]	1	0	0	0	0	1	Unclear
Anderson 1999[147]	1	0	1	1	1	4	Unclear
Palmer 1999[148]	1	1	1	1	1	5	Adequate
Shokeir 1999[149]	1	1	0	0	0	2	Unclear
Le Roux 1999[150]	1	0	0	0	1	2	Unclear
Sandhu 1999[151]	1	0	1	1	1	4	Unclear
Costabile 1999[152]	1	0	0	0	1	2	Unclear
Dinsmore 1999[153]	1	0	1	1	1	4	Adequate
Chen 1999[154]	1	0	1	0	0	2	Unclear
Montorsi 1999[155]	1	1	1	0	0	3	Unclear
Dinsmore	1	0	1	0	0	2	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
1999[156]							
Gramkow 1999[157]	1	0	1	0	1	3	Unclear
Klotz 1999[158]	1	0	1	1	1	4	Unclear
Eardley 1999[159]	1	0	1	1	0	3	Unclear
Hartmann 1999[160]	1	0	1	0	0	2	Unclear
Feldman 1999[161]	1	-1	0	0	0	1	Unclear
Young 1999[162]	1	0	1	0	0	2	Unclear
Padma-Nathan 1998[163]	1	0	1	0	1	3	Unclear
Williams 1998[164]	1	0	1	0	0	2	Unclear
Foldvari 1998[165]	1	0	1	0	0	2	Unclear
Costabile 1998[166]	1	0	1	1	1	4	Unclear
Williams 1998[167]	1	-1	1	0	0	1	Unclear
Engel 1998[168]	1	0	1	1	0	3	Unclear
Peterson 1998[169]	1	0	1	0	0	2	Unclear
Becker 1998[170]	1	-1	1	0	0	2	Unclear
Buvat 1998[171]	1	0	1	0	0	2	Unclear
Montorsi 1998[172]	1	0	1	0	0	2	Unclear
Sogari 1997[173]	1	0	1	0	1	3	Unclear
Meinhardt 1997[174]	1	0	1	1	1	4	Unclear
Vogt 1997[175]	1	0	0	0	0	1	Unclear
Montorsi 1997[176]	1	0	0	0	0	1	Unclear
Soderdahl 1997[177]	1	0	1	1	1	4	Unclear
Schiavi 1997[178]	1	0	1	0	1	3	Unclear
Bechara 1997[179]	1	0	0	0	0	1	Unclear
Kunelius 1997[180]	1	-1	0	0	0	0	Unclear
Rowland 1997[181]	1	0	1	0	0	2	Unclear
Padma-Nathan 1997[182]	1	0	1	0	1	3	Unclear
Aversa 1996[183]	1	0	1	0	0	2	Unclear
Hellstrom 1996[184]	0	0	1	1	0	2	Adequate
Colli 1996[185]	1	0	1	0	1	3	Unclear
Godschalk 1996[186]	1	0	0	0	0	1	Unclear
Mann 1996[187]	1	0	1	0	0	2	Unclear
Gheorghiu 1996[188]	1	0	1	0	0	3	Unclear
Peskircioglu 1996[189]	1	1	1	0	1	4	Unclear
Gomaa 1996[190]	1	0	1	0	1	3	Unclear
Linet 1996[191]	1	0	1	0	0	2	Unclear
Bechara 1996[192]	1	0	0	0	0	1	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
Knoll 1996[193]	1	0	1	0	0	2	Unclear
Wegner 1995[194]	1	0	1	1	1	4	Unclear
van Ahlen 1995[195]	1	0	0	0	0	1	Unclear
Guay 1995[196]	1	0	0	0	0	1	Unclear
Vanderschueren 1995[197]	1	1	1	1	0	4	Unclear
Georgitis 1995[198]	1	0	1	0	1	3	Unclear
el-Saleh 1995[199]	1	1	1	1	0	4	Unclear
Ogrinc 1995[200]	1	0	1	0	0	2	Unclear
Kattan 1995[201]	1	0	1	0	0	2	Unclear
Martinez-Pineiro 1995[202]	1	1	0	0	0	2	Unclear
Cavallini 1994[203]	1	0	1	0	0	2	Unclear
Lazzeri 1994[204]	1	0	1	1	1	4	Unclear
Wegner 1994[205]	1	0	0	0	0	1	Unclear
Montorsi 1994[206]	1	1	1	0	0	3	Unclear
Schramek 1994[207]	1	0	0	0	0	1	Unclear
Kurt 1994[208]	1	-1	0	0	0	1	Unclear
Godschalk 1994[209]	1	0	1	1	1	4	Adequate
Brennemann 1993[210]	1	0	1	1	0	3	Unclear
von Heyden 1993[211]	1	0	1	0	1	3	Unclear
Moriel 1993[212]	1	0	1	0	1	3	Unclear
Porst 1993[213]	1	-1	1	1	1	3	Unclear
Korenman 1993[214]	1	0	0	0	0	1	Unclear
Costa 1993[215]	1	0	1	1	0	3	Unclear
Allen 1992[216]	1	0	0	0	0	1	Unclear
Mahmoud 1992[217]	1	0	1	0	0	2	Unclear
Cavallini 1991[218]	1	1	1	0	1	4	Unclear
Kattan 1991[219]	1	1	1	-1	0	2	Unclear
Segraves 1991[220]	1	0	1	0	0	2	Unclear
Floth 1991[221]	1	1	1	0	0	3	Unclear
Sonda 1990[222]	1	0	1	1	0	3	Unclear
Roy 1990[223]	1	0	1	1	0	3	Unclear
Earle 1990[224]	1	0	0	0	0	1	Unclear
van Ahlen 2005[225]	0	0	1	1	1	3	Unclear
Goldstein 2005[226]	1	0	1	0	1	3	Unclear
Fisher 2005[227]	1	-1	0	0	0	0	Unclear
Carrier 2005[228]	1	0	1	1	1	4	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
Moncada 2005[229]	1	1	1	1	1	5	Unclear
Hatzichristou 2005[230]	1	1	1	1	1	5	Unclear
Patterson 2005[231]	1	-1	1	1	1	3	Unclear
Albuquerque 2005[232]	1	0	0	0	0	1	Unclear
Yonessi 2005[233]	1	0	1	0	1	3	Unclear
Shamloul 2005[234]	1	0	1	1	1	4	Unclear
McMahon 2005[235]	1	1	1	1	1	5	Unclear
Speel 2005[236]	1	1	1	0	0	3	Unclear
Chen 2004[237]	1	0	0	0	0	1	Unclear
Rosen 2004[238]	1	1	0	0	1	3	Unclear
Donatucci 2004[239]	1	0	0	0	1	2	Unclear
Gingell 2004[240]	1	1	1	0	1	4	Unclear
Montorsi 2004[241]	1	-1	1	0	1	3	Unclear
Pickering 2004[242]	1	-1	1	0	0	2	Unclear
Pavone 2004[243]	1	0	1	-1	1	3	Unclear
Bawa 2004[244]	1	-1	1	1	1	3	Unclear
Petrov 2003[245]	1	0	1	0	1	3	Unclear
Dunzendorfer 2002[246]	1	0	0	0	1	2	Unclear
Glina 2001[247]	1	0	1	0	0	2	Unclear
Giammusso 1996[248]	1	0	0	0	1	2	Unclear
Garceau 1996[249]	1	0	0	0	0	1	Unclear
Claes 1992[250]	1	0	1	1	1	4	Unclear
Valiquette 2005[251]	1	0	1	0	0	2	Unclear
Reiter 1999[252]	1	0	1	0	0	2	Unclear
Kunelius 1998[253]	1	0	1	0	0	2	Unclear
Haslam 1992[254]	1	1	1	0	0	3	Unclear
Rosen 2006[255]	1	1	0	0	1	4	Unclear
Korenman 1994[256]	1	-1	1	0	0	1	Unclear
Clopper 1993[257]	1	0	1	1	1	4	Unclear
Wang 2000[258]	1	0	1	1	0	3	Unclear
Nickel 2007[259]	1	0	1	1	0	3	Unclear
Yassin 2006[260]	1	0	0	0	0	1	Unclear
Martin-Morales 2007[261]	1	0	1	0	1	3	Unclear
Heiman 2007[262]	1	0	1	1	0	2	Unclear
Bank 2006[263]	1	0	0	0	1	2	Unclear
McVary 2007[264]	1	0	1	0	0	2	Unclear

Author Year	Jadad Q-1	Jadad Q-2	Jadad Q-3	Jadad Q-4	Jadad Q-5	Total Scores	Allocation Concealment
Saylan 2006[265]	1	1	1	0	1	4	Inadequate
Zinner 2007[266]	1	0	1	1	0	3	Unclear
Edwards 2006[267]	1	0	1	0	1	3	Unclear
Rajfer 2007[268]	1	0	1	0	1	3	Unclear
Valiquette 2006[269]	1	0	1	0	0	2	Unclear
Wespes 2007[270]	1	0	1	0	1	3	Unclear
Porst 2006[271]	1	0	1	0	1	3	Unclear
Yip 2006[272]	1	0	1	1	0	3	Unclear
Safarinejad 2006[273]	1	0	0	0	0	1	Unclear
Agostini 2006[274]	1	0	1	0	1	3	Unclear
Mazo 2006[275]	1	0	1	0	1	3	Unclear
El-Shafey 2006[276]							
Tolra 2006[277]	1	0	1	1	0	3	Unclear
Ziegler 2006[278]	1	0	1	0	0	2	Unclear
Ishii 2006[279]	1	0	1	0	0	2	Unclear
Guo 2006[280]	1	0	0	0	1	2	Unclear
Nagao 2006[281]	1	0	1	1	1	4	Unclear
Padma-Nathan 2006[282]	1	0	1	1	1	4	Unclear
Dean 2006[283]	1	0	1	0	1	3	Unclear
Seidman 2006[284]	1	0	1	0	1	3	Unclear
Demir 2006[285]	1	1	1	0	0	3	Unclear
Althof 2006[286]	1	0	0	0	0	1	Unclear
Buvat 2006[287]	1	0	0	0	1	2	Unclear
McMahon 2006[288]	1	0	0	0	0	1	Unclear
Fava 2006[289]	1	0	1	0	1	3	Unclear
Gopalakrishnan 2006[290]	1	0	0	0	0	1	Unclear
Herrmann 2006[291]	1	1	1	0	1	4	Unclear
Titta 2006[292]	1	1	1	0	1	4	Unclear
Sommer 2006[293]	1	1	1	1	1	5	Inadequate
Rochira 2006[294]	1	0	1	1	0	3	Unclear
O'Leary 2006[295]	1	0	0	0	0	1	Unclear
Viswaroop 2005[296]	1	0	1	0	0	2	Unclear
Carson 2005[297]	1	0	0	0	0	1	Unclear
Kaplan 2007[298]	1	1	1	0	0	3	Unclear
Choi 2006[299]	1	1	0	0	0	2	Unclear
Gomaa 2006[300]	1	0	1	0	0	2	Unclear

Quality Assessment of Observational Studies

Table F-2. Quality assessment on 8 Out of 14 QUADAS questions for each included study

STUDY ID	Q1: Spectrum	Q2. Selection criteria	Q5. Reference standard?	Q8. Details of index test described	Q10. Index test interpreted without knowledge of RS	Q12. Same clinical data available	Q13. Uninterpretable test results reported	Q14. Withdrawals explained	TOTAL ("YES")
Jaffe 1996[301]	yes	no	no	yes	yes	yes	No	no	4
Netto 1993[302]	yes	no	no	yes	yes	yes	No	no	4
Citron 1996[303]	no	yes	yes	yes	yes	no	No	no	4
Hatzichristou 2002[304]	yes	yes	no	yes	yes	yes	No	no	5
Martinez-Jabaloyas 2006[305]	yes	no	no	yes	yes	yes	no	no	4
Acar 2004[306]	unclear	no	no	yes	yes	yes	no	no	3
Earle 2003[307]	yes	no	no	yes	yes	yes	no	no	4
Rhoden 2002[308]	no	yes	no	yes	yes	no	no	no	3
Bunch 2002[309]	yes	yes	unclear	yes	yes	yes	no	no	5
Fahmy 1999[310]	yes	no	no	yes	yes	yes	no	no	4
Buvat 1997 [311]	yes	no	no	yes	yes	yes	no	no	4
Akpunonu 1994[312]	unclear	yes	yes	yes	unclear	yes	no	yes	5
Drinka 1993[313]	no	yes	no	yes	yes	yes	no	yes	5
Johnson 1992[314]	yes	no	no	yes	yes	yes	no	no	4
El-Sakka 2005[315]	no	yes	no	yes	yes	yes	No	no	4
Tsujimura 2005[316]	yes	yes	no	yes	yes	yes	No	no	5
Guay 1991[317]	no	yes	no	yes	yes	no	No	no	3
Forsberg 1990[318]	yes	yes	no	yes	yes	yes	No	no	5

STUDY ID	Q1: Spectrum	Q2. Selection criteria	Q5. Reference standard?	Q8. Details of index test described	Q10. Index test interpreted without knowledge of RS	Q12. Same clinical data available	Q13. Uninterpretable test results reported	Q14. Withdrawals explained	TOTAL ("YES")
Reyes-Vallejo 2006[319]	no	yes	no	yes	yes	no	No	no	3
El-Sakka 2006[320]	no	yes	no	yes	yes	yes	No	no	4
Hwang 2007[321]	yes	no	no	yes	yes	yes	No	no	4
Low 2006[322]	yes	yes	no	yes	yes	yes	No	no	5
Guay 2007[323]	unclear	no	no	no	yes	yes	No	no	2
Zohdy 2007[324]	unclear	yes	yes	yes	unclear	yes	No	no	4

Appendix G. Funnel Plots

Sildenafil

Figure G-1. Sildenafil (any dose) vs. Placebo: mean IIEF-Q3 score

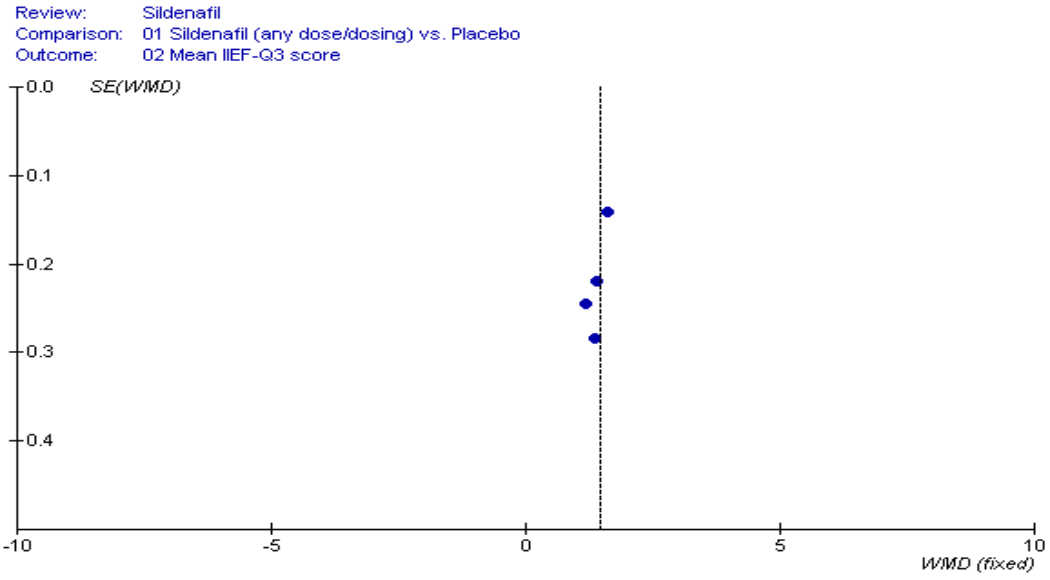


Figure G-2. Sildenafil (any dose) vs. Placebo: mean IIEF-Q4 score

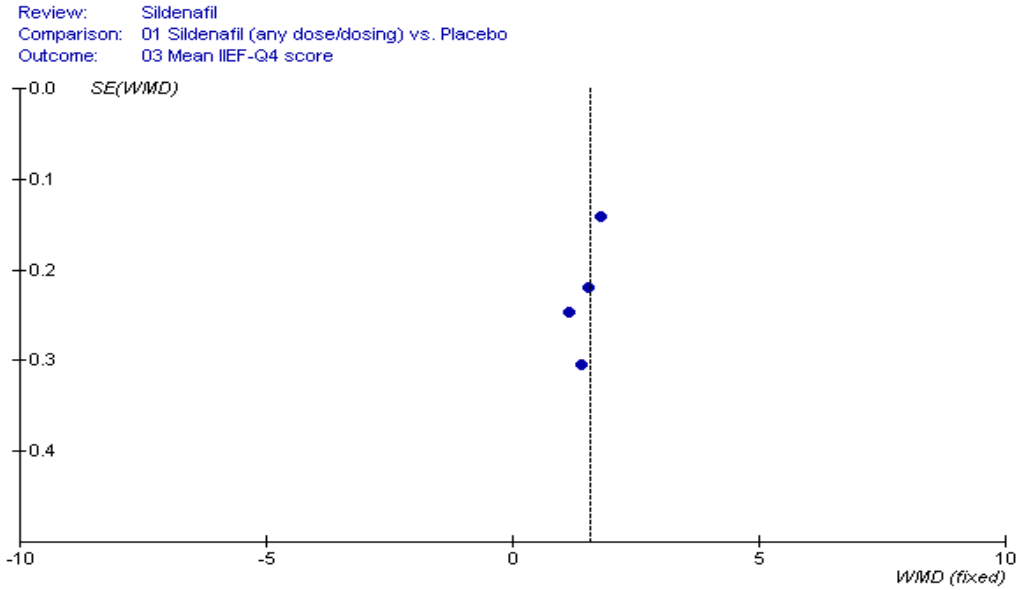


Figure G-3. Sildenafil (any dose) vs. Placebo: participants with improved erection (GEQ-Q1)

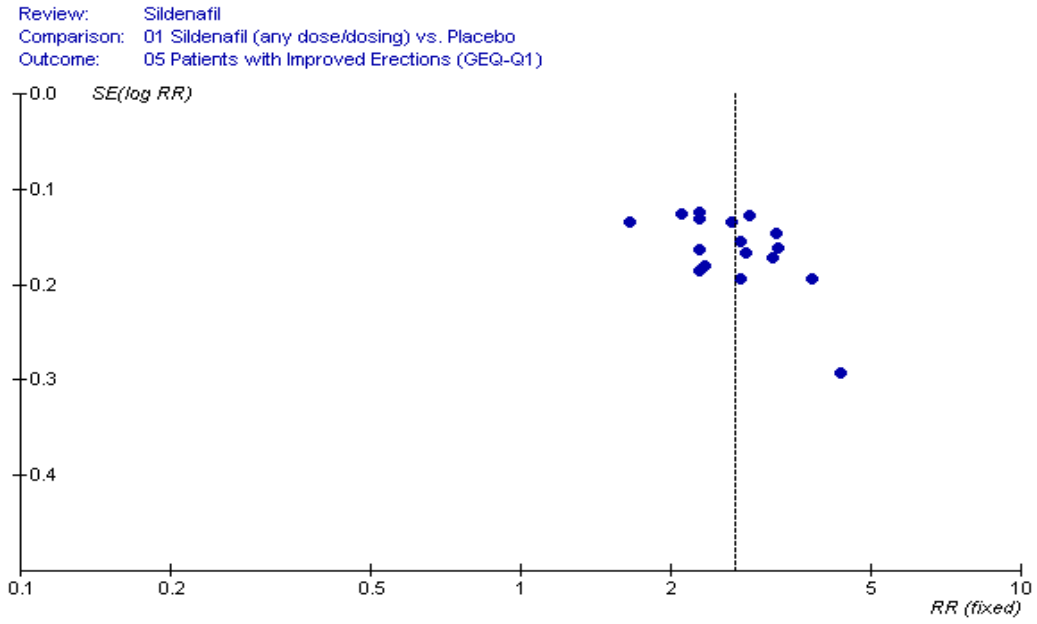


Figure G-4. Sildenafil (any dose) vs. Placebo: mean IIEF-Q3 score

Participants with type I-II diabetes

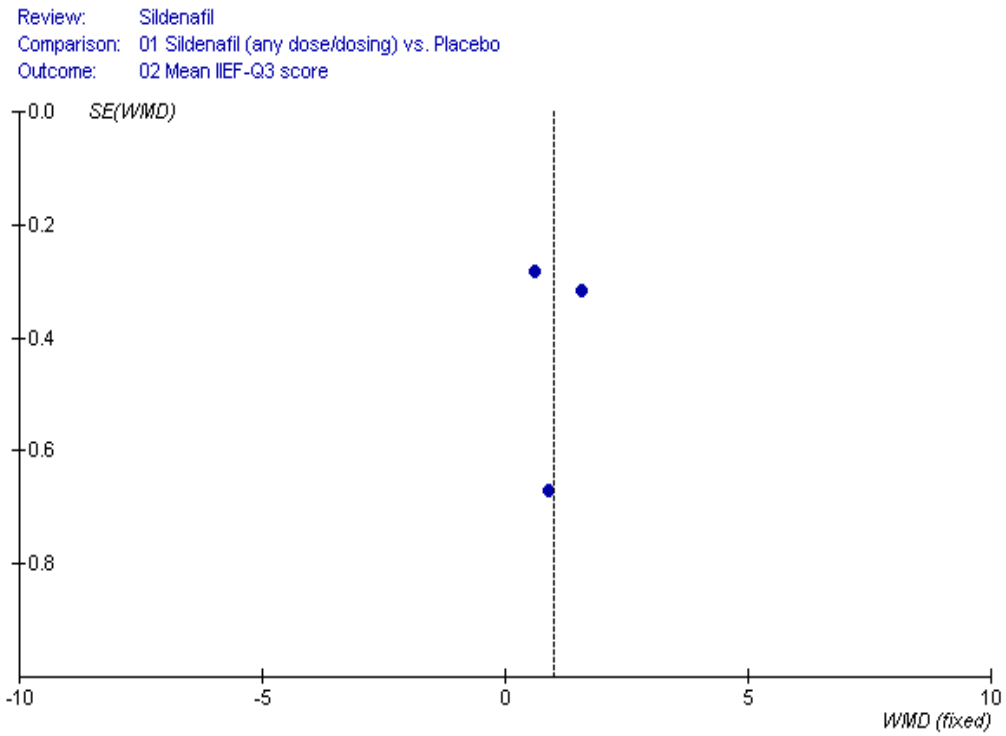


Figure G-5. Sildenafil (any dose) vs. Placebo: mean IIEF-Q4 score

Participants with type I-II diabetes

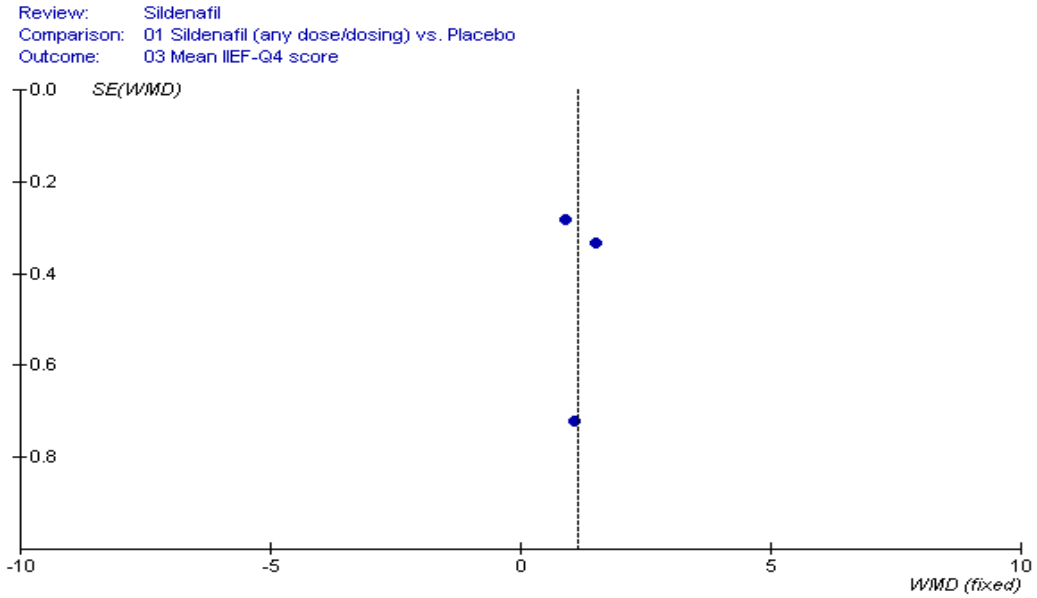


Figure G-6. Sildenafil (any dose) vs. Placebo: patients with improved erection (GEQ-Q1)
Participants with type I-II diabetes

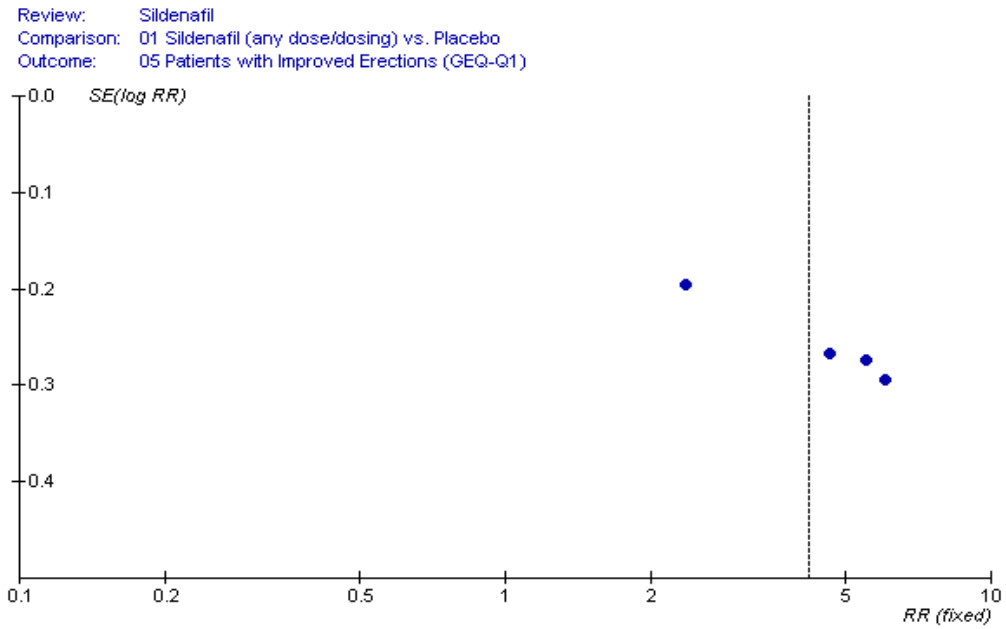


Figure G-7. Sildenafil (any dose) vs. Placebo: participants with improved erection (GEQ-Q1)
Participants with type II diabetes

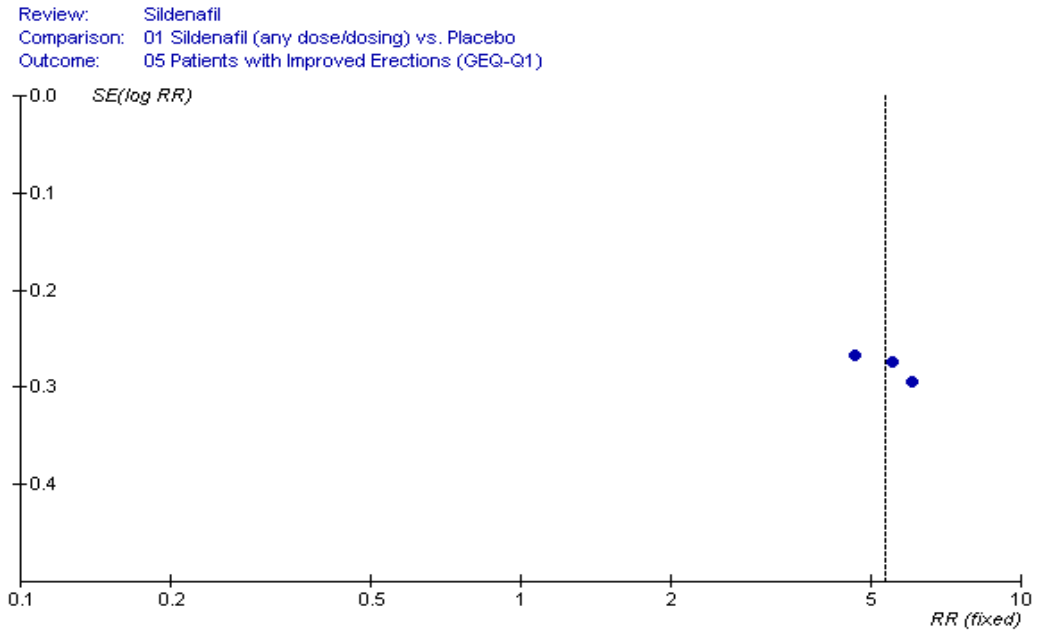
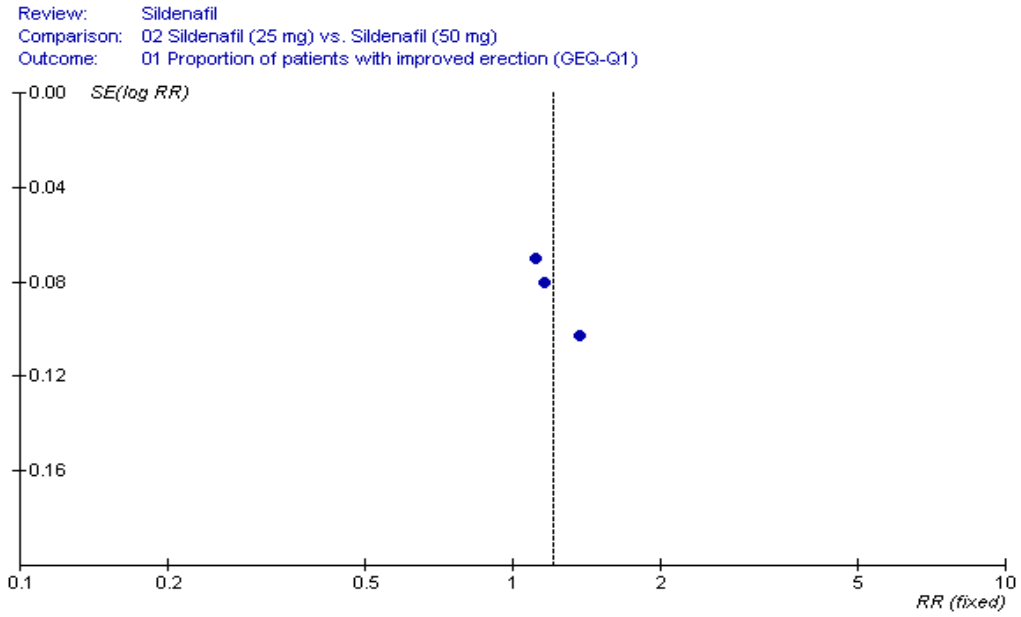


Figure G-8. Sildenafil (25 mg) vs. Sildenafil (50 mg): participants with improved erection (GEQ-Q1)



Vardenafil

Any dose vs. Placebo

Figure G-9. Vardenafil (any dose) vs. Placebo: mean IIEF 'EF domain' score at week 12

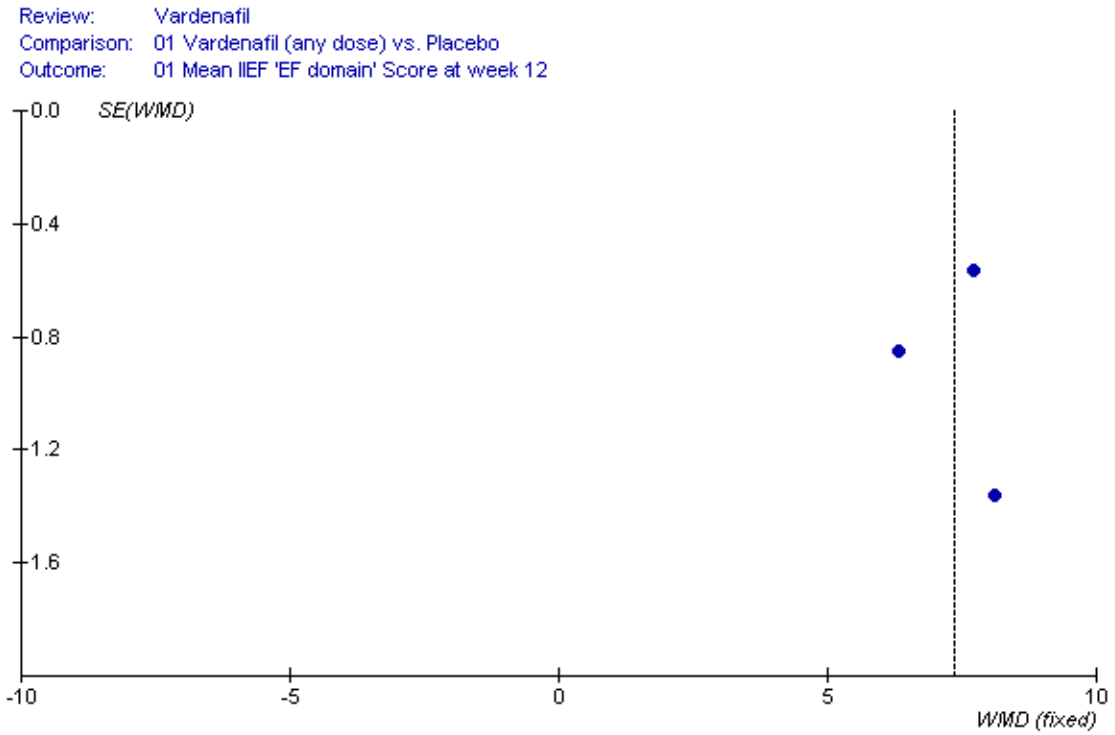


Figure G-10. Vardenafil (any dose) vs. Placebo: patients with mean IIEF 'EF domain' score ≥ 26

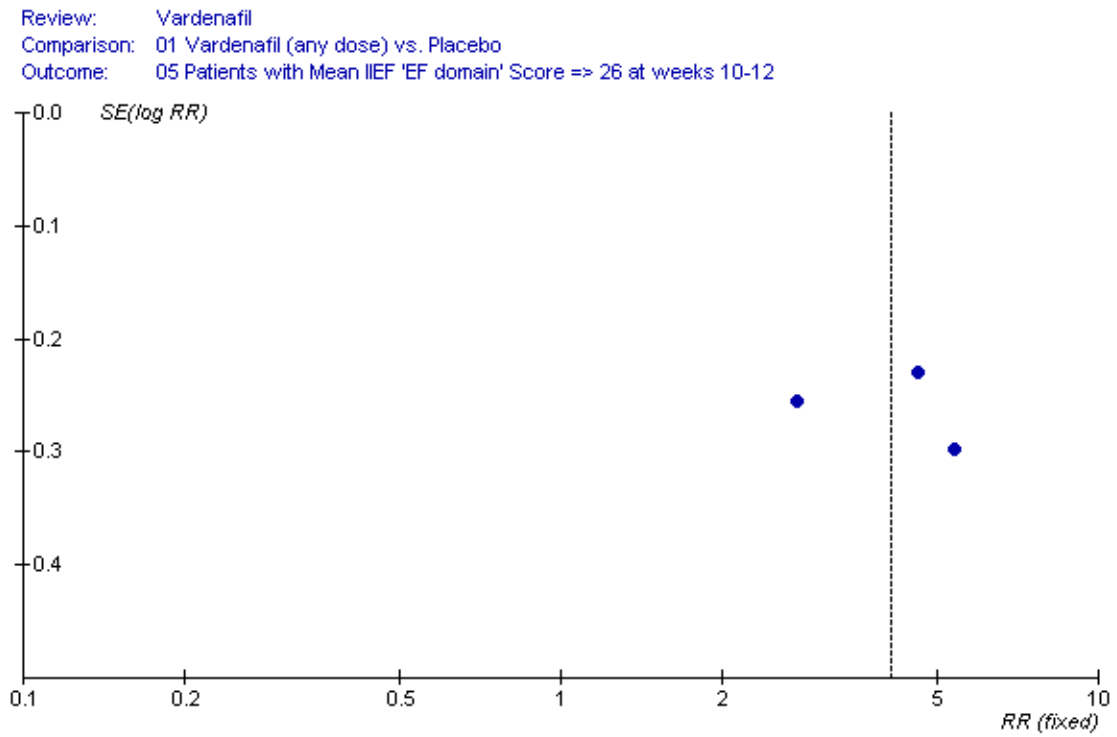
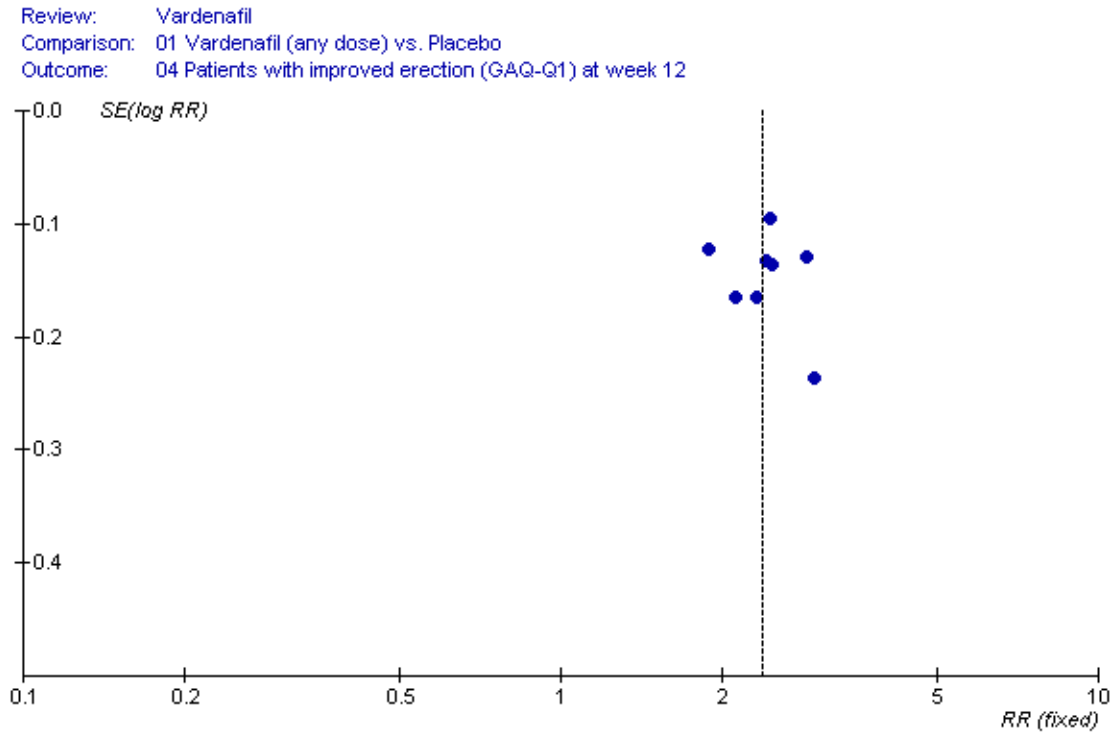


Figure G-11. Vardenafil (any dose) vs. Placebo: patients with improved erection (GAQ-Q1)



Tadalfil

20 mg vs. Placebo

Figure G-12. Tadalafil (20 mg) vs. Placebo: mean IIEF-'EF domain' score change

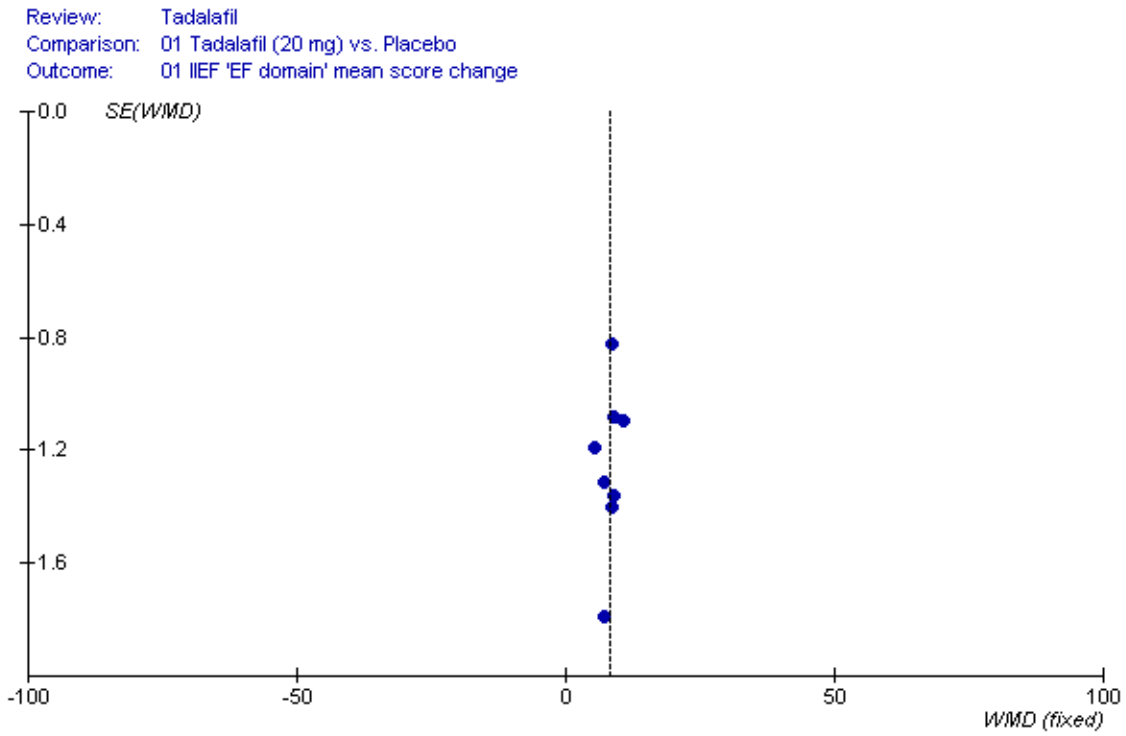


Figure G-13. Tadalafil (20 mg) vs. Placebo: % mean SEP-Q2 score change

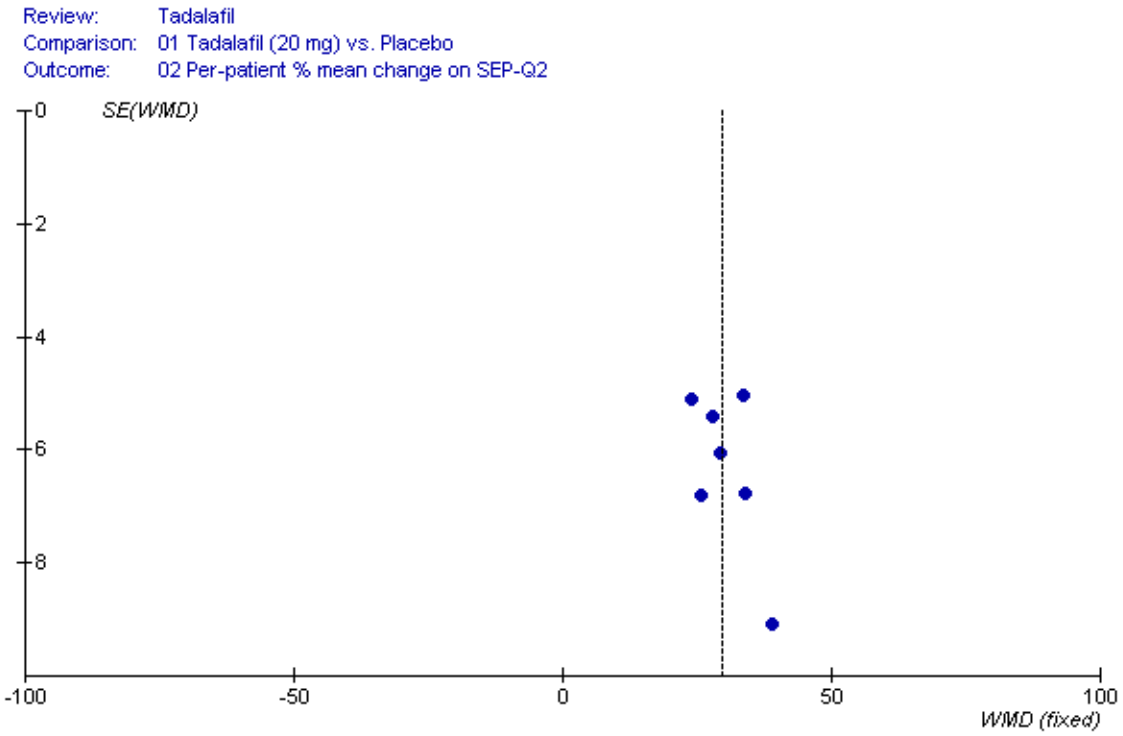
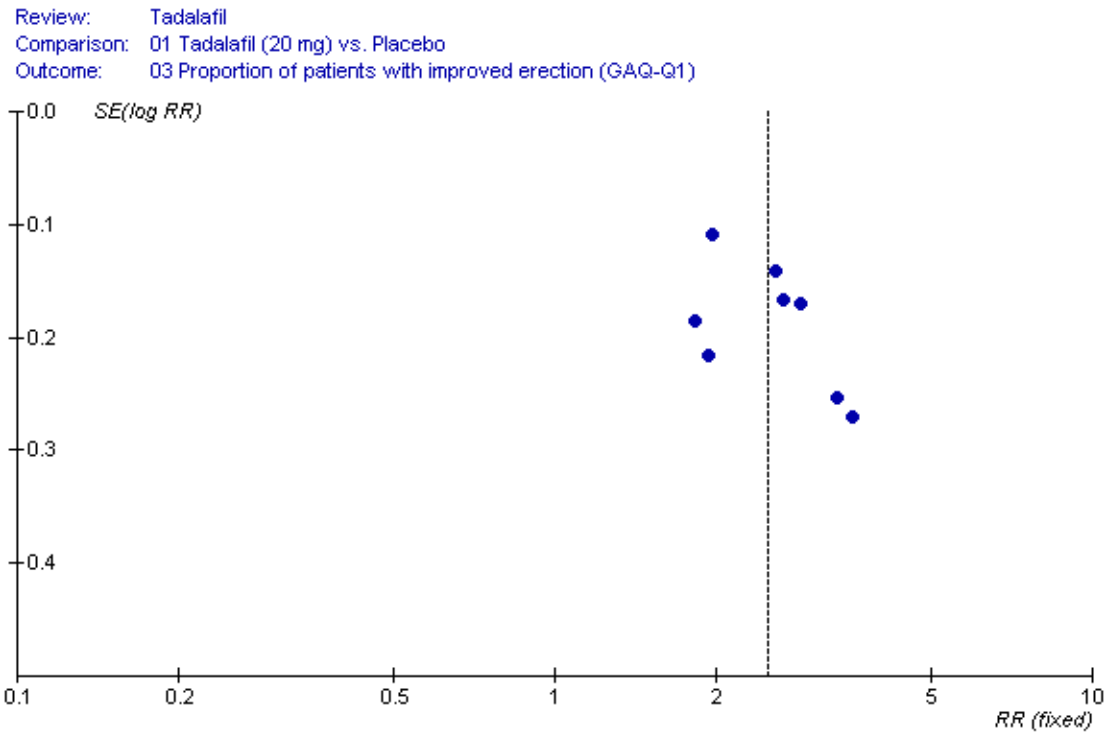


Figure G-14. Tadalafil (20 mg) vs. Placebo: patients with improved erection (GAQ-Q1)



20 mg vs. 10 mg

Figure G-15. Tadalafil (20mg) vs. Tadalafil (10mg): mean IIEF 'EF domain' score

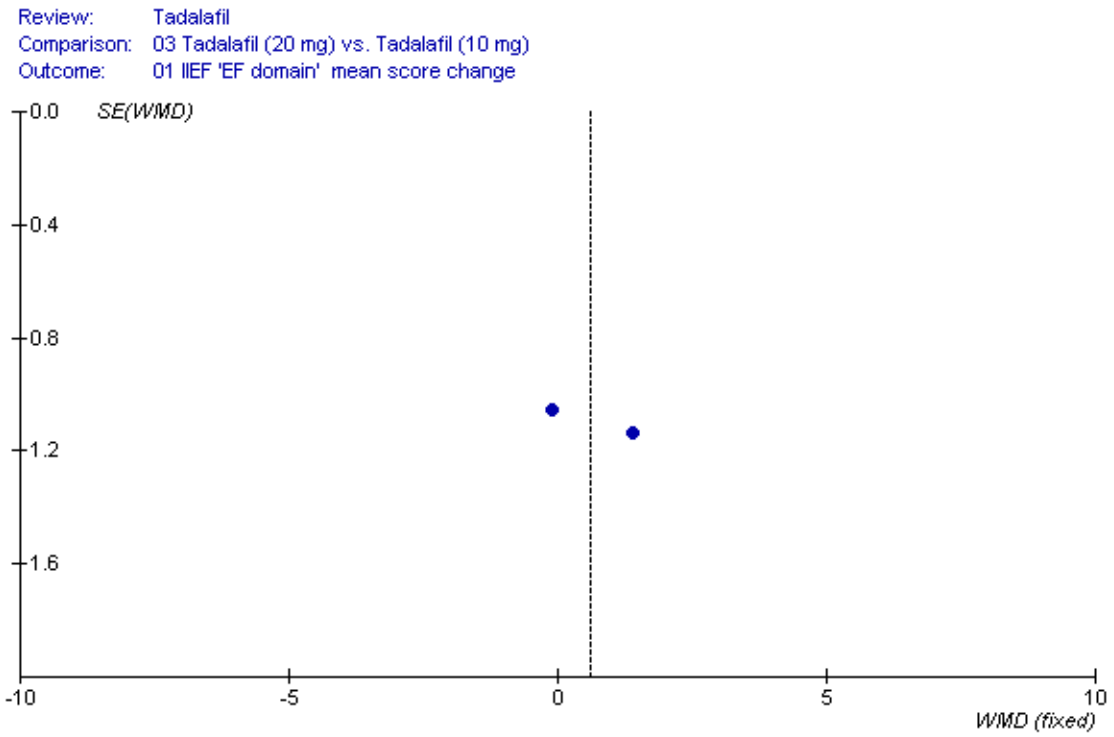
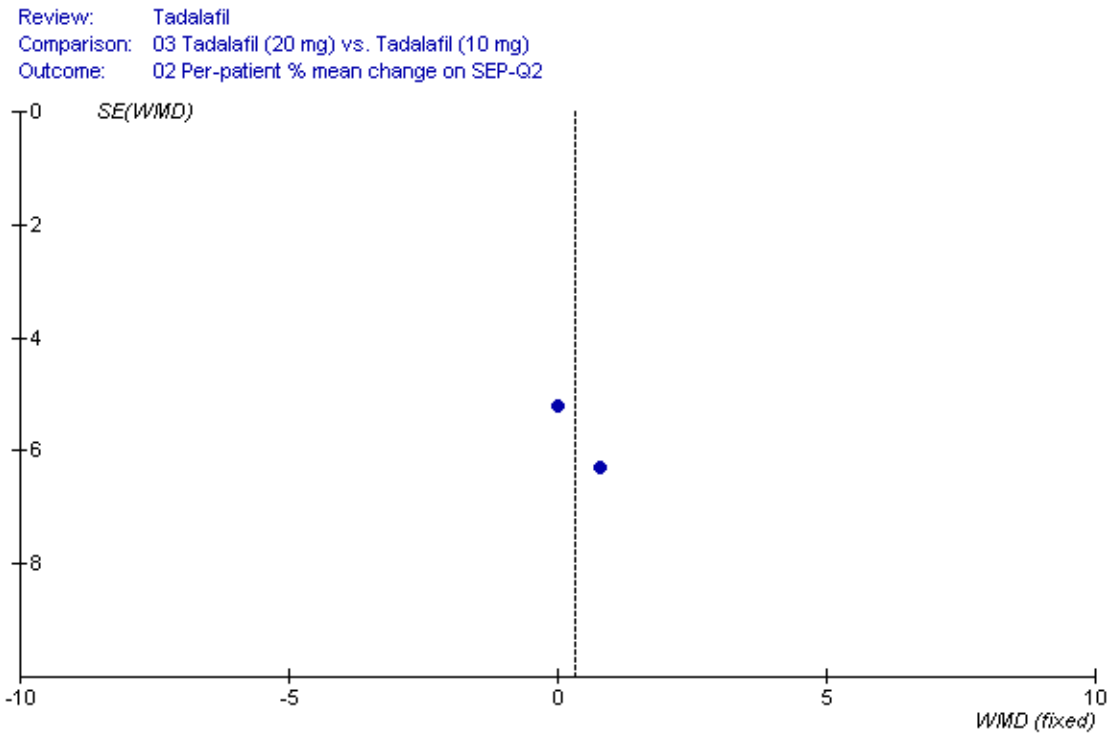


Figure G-16. Tadalafil (20mg) vs. Tadalafil (10mg): % mean SEP-Q2 score change



Appendix H. Instruments Used in the Assessment of Treatment Outcomes

International Index of Erectile Function (IIEF)

Individual items of International Index of Erectile Function Questionnaire ***and response options (US version)*:***

Q1: How often were you able to get an erection during sexual activity?
0 = No sexual activity
1 = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q2: When you had erections with sexual stimulation, how often were your erections hard enough for penetration?
0 = No sexual activity
1 = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q3: When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?
0 = Did not attempt intercourse
I = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q4: During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?
0 = Did not attempt intercourse
I = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q5: During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?
0 = Did not attempt intercourse
1 = Extremely difficult
2 = Very difficult
3 = Difficult
4 = Slightly difficult
5 = Not difficult

Q6: How many times have you attempted sexual intercourse?
0 = No attempts
1 = One to two attempts
2 = Three to four attempts
3 = Five to six attempts
4 = Seven to ten attempts

5 = Eleven+ attempts

Q7: When you attempted sexual intercourse, how often was it satisfactory for you?
0 = Did not attempt intercourse
1 = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q8: How much have you enjoyed sexual intercourse?
0 = No intercourse
1 = No enjoyment
2 = Not very enjoyable
3 = Fairly enjoyable
4 = Highly enjoyable
5 = Very highly enjoyable

Q9: When you had sexual stimulation or intercourse, how often did you ejaculate?
0 = No sexual stimulation/intercourse
1 = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q10: When you had sexual stimulation or intercourse, how often did you have tile feeling of orgasm or climax?
0 = No sexual stimulation/intercourse
1 = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q11: How often have you felt sexual desire?
1 = Almost never/never
2 = A few times (much less than half the time)
3 = Sometimes (about half the time)
4 = Most times (much more than half the time)
5 = Almost always/always

Q12: How would you rate your level of sexual desire?
1 = Very low/none at all
2 = Low
3 = Moderate
4 = High
5 = Very high

Q13: How satisfied have you been with your overall sex life?
1 = Very dissatisfied
2 = Moderately dissatisfied
3 = About equally satisfied and dissatisfied
4 = Moderately satisfied
5 = Very satisfied

Q14: How satisfied have you been with your sexual relationship with your partner?

1 = Very dissatisfied
2 = Moderately dissatisfied
3 = About equally satisfied and dissatisfied
4 = Moderately satisfied
5 = Very satisfied

Q15: How do you rate your confidence that you could get and keep an erection?
1 = Very low
2 = Low
3 = Moderate
4 = High
5 = Very high

** All questions are preceded by the phrase "Over the past 4 weeks."*

IIEF domains and the scoring

Domain	Items	Score Range	Minimum Score	Maximum Score
Erectile Function	1,2, 3, 4, 5, 15	0 (or 1)-5	1	30
Orgasmic Function	9, 10	0-5	0	10
Sexual Desire	11, 12	1-5	2	10
Intercourse Satisfaction	6, 7, 8	0-5	0	15
Overall Satisfaction	13, 14	1-5	2	10

IIEF-5 scoring system

Question	Score				
Over the past six months:	**1**	**2**	**3**	**4**	**5**
How do you rate your confidence that you could get and keep an erection?	Very low	Low	Moderate	High	Very high
When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never or never	Much less than half the time	About half the time	Much more than half the time	Almost always or always
During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	Almost never or never	Much less than half the time	About half the time	Much more than half the time	Almost always or always
During sexual intercourse how difficult was it to maintain your erection to the completion of intercourse?	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never or never	Much less than half the time	About half the time	Much more than half the time	Almost always or always

The IIEF-5 score is the sum of questions 1 to 5. The lowest score is 5 and the highest score 25.

Sexual Encounter Profile (SEP- Questions 2 and 3)

SEP-Q2: Were you able to insert your penis into your partner's vagina?

SEP-Q3: Did your erection last long enough for you to have successful intercourse?

Global Assessment Question (GAQ)

GAQ-Q1: Has the treatment you have been taking improved your erectile function?

GAQ-Q2: If yes, has the treatment improved your ability to engage in sexual activity?

Appendix I. List of Unobtained Articles

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