Table F-15. Reported adverse events (randomized controlled trials)

| **Study** | **Adverse Events/Harms Reported** | | | **Author calculation if provided** |
| --- | --- | --- | --- | --- |
| Porpiglia et al. 201345 | Early <30 days (Clavien system minor 1–2) medical | RARP: UTI (2), transient hypoaesthesia of left arm (1), Ileus (1)  LRP: UTI (1), fever requiring antipyretics (1), delirium requiring neuroleptics (1) | | — |
| Porpiglia et al. 201345 | Early <30 days (Clavien system major 3–4) - medical | RARP: 0 cases  LRP: 0 cases | | — |
| Porpiglia et al. 201345 | Intermediate 31 to 90 days (Clavien system minor 1–2) - medical | RARP: 0 cases  LRP: transient leg edema not requiring therapy (1) | | — |
| Porpiglia et al. 201345 | Intermediate 31 to 90 days (Clavien system major 3–4) - medical | RARP: 0 cases  LRP: 0 cases | | — |
| Porpiglia et al. 201345 | Early <30 days (Clavien system minor 1–2) surgical | RARP: urine leak requiring catheterization (1), wound infection (1), lymphocele requiring puncture (1), acute urinary retention (2)  LRP: urine leak requiring catheterization (1), wound infection (1) | | — |
| Porpiglia et al. 201345 | Early <30 days (Clavien system major 3–4) – surgical | RARP: 0 cases  LRP: 0 cases | | — |
| Porpiglia et al. 201345 | Intermediate 31 to 90 days (Clavien system minor 1–2) – surgical | RARP: epididymitis (1)  LRP: distal urethral stenosis requiring urethral dilatation (1) | | — |
| Porpiglia et al. 201345 | Intermediate 31 to 90 days (Clavien system major 3–4) - surgical | RARP: 0 cases  LRP: 0 cases | | — |
| Wilt et al. 201225  PIVOT | Adverse events occurring within 30 days after surgery | Patients (N=280)  N (%) | | — |
| Wilt et al. 201225  PIVOT | Any | 60 (21.4) | | — |
| Wilt et al. 201225 | Pneumonia | 2 (0.7) | | — |
| PIVOT | Wound infection | 12 (4.3) | | — |
| Wilt et al. 201225 | Urinary tract infection | 7 (2.5) | | — |
| PIVOT | Sepsis | 3 (1.1) | | — |
| Wilt et al. 201225 | Deep vein thrombosis | 2 (0.7) | | — |
| PIVOT | Stroke | 1 (0.4) | | — |
| Wilt et al. 201225 | Pulmonary embolism | 2 (0.7) | | — |
| PIVOT | Myocardial infarction | 3 (1.1) | | — |
| Wilt et al. 201225 | Renal failure or dialysis | 1 (0.4) | | — |
| PIVOT | Bowel injury requiring surgical repair | 3 (1.1) | | — |
| Wilt et al. 201225 | Additional surgical repair | 7 (2.5) | | — |
| PIVOT | Bleeding requiring transfusion | 6 (2.1) | | — |
| Wilt et al. 201225 | Urinary catheter present >30 days after surgery | 6 (2.1) | | — |
| PIVOT | Death | 1 (0.4) | | — |
| Wilt et al. 201225  PIVOT | Other | 28 (10.0) | | — |
| Bill-Axelson et al. 201133  SPCG-4 trial | Nonfatal Surgical Complications within 1 year after Surgery among Men in the RP (N=289) Group | | | |
| Bill-Axelson et al. 201133 SPCG-4 | *Complication* | *Number of Events* | *1-Year Cumulative Incidence (95% confidence interval [CI]* | |
| Bill-Axelson et al. 201133 SPCG-4 | Urinary leakage | 93 | 32.2 (27.2–38.1) | |
| Bill-Axelson et al. 201133 SPCG-4 | Urinary obstruction | 6 | 2.1 (0.9–4.6) | |
| Bill-Axelson et al. 201133 SPCG-4 | Impotence | 168 | 58.1 (52.7–64.1) | |
| Bill-Axelson et al. 201133 SPCG-4 | Pulmonary embolism | 4 | 1.4 (0.5–3.7) | |
| Bill-Axelson et al. 201133 SPCG-4 | Deep vein thrombosis | 3 | 1.0 (0.3–3.2) | |
| Bill-Axelson et al. 201133 SPCG-4 | Myocardial infarction | 0 | Not applicable | |
| Giberti et al. 200944 | RRP: 100 patients | BT: 100 patients | — | |
| Urinary incontinence | 18.4% (severe in 5.4% and mild in 13.0%) at 6‑month‑followup | Not reported | — | |
| Anastomotic urethral stricture | 6.5% at 6-month-followup | Not reported | — | |
| Irritative urinary symptoms | 5.0% at 6-month-followup | 80% at 6-month followup  20% at 1-year followup | — | |
| Erectile function | Significant worsening of the QLQ-PR25 and IIEF was reported by both groups at 6-month-followup | | — | |
| Erectile function and urinary disorders at 5-year followup. | There was no differences in erectile function and urinary disorders at the 5‑year followup period in both study groups. | | — | |
| Jones et al. 201143 | EBRT: 992 patients | EBRT plus ADT: 987 | — | |
| Incidence of grade 3 or higher acute and late gastrointestinal toxic effects up to 90 days after the start of EBRT | 3% | 1% | — | |
| Acute grade 3 of higher genitourinary toxic effects up to 90 days after the start of EBRT | 2% | 2% | — | |
| Deaths | Colonic obstruction: 2 patients | Colorectal bleeding: 1 patient | — | |
| Donnelly et al. 201047 | EBRT: 122 patients | Cryotherapy: 122 patients | — | |
| Adverse events at 3 years were classified according to the codes of the National Cancer Institute of Canada Common Toxicity Criteria (version 2,0) | 14 patients suffered 16 grade 3 adverse events | 12 patients suffered 13 grade 3 adverse events | — | |
| D’Amico et al. 200835 | — | EBRT: 103 patients at median followup of 4.52 years | EBRT plus ADT: 98 patients at median followup of 4.52 years | |
| D’Amico et al. 200835 | Hematuria | Grade 1: 6  Grade 2: 5  Grade 3: 3  Grade 4: 0 | Grade 1: 7  Grade 2: 6  Grade 3: 3  Grade 4: 0 | |
| D’Amico et al. 200835 | Diarrhea | Grade 1: 19  Grade 2: 8  Grade 3: 3  Grade 4: 0 | Grade 1: 18  Grade 2: 9  Grade 3: 1  Grade 4: 0 | |
| D’Amico et al. 200835 | Rectal bleeding | Grade 1: 34  Grade 2: 18  Grade 3: 2  Grade 4: 0 | Grade 1: 26  Grade 2: 16  Grade 3: 3  Grade 4: 0 | |
| D’Amico et al. 200835 | Anal fibrosis | Grade 1: 1  Grade 2: 0  Grade 3: 0  Grade 4: 0 | Grade 1: 1  Grade 2: 0  Grade 3: 0  Grade 4: 0 | |
| D’Amico et al. 200835 | Gynecomastia | Grade 1: 1  Grade 2: 2  Grade 3: 0  Grade 4: 0 | Grade 1: 14  Grade 2: 4  Grade 3: 0  Grade 4: 0 | |
| D’Amico et al. 200835 | Liver dysfunction | Grade 1: 0  Grade 2: 0  Grade 3: 1  Grade 4: 1 | Grade 1: 0  Grade 2: 0  Grade 3: 0  Grade 4: 0 | |
| Martis et al. 200746 | — | RPP: 100 patients | RRP: 100 patients | p-value |
| Martis et al. 200746 | Urinary continence at 6 months (number, %) | 74 (74) | 76 (76) | p=0.85 |
| Martis et al. 200746 | Urinary continence at 24 months (number, %) | 96 (96) | 95 (95) | p=1 |
| Martis et al. 200746 | Erectile function at 6 months (number, %) | 30 (30) | 45 (45) | p=0.07 |
| Martis et al. 200746 | Erectile function at 24 months (number, %) | 42 (42) | 60 (60) | p=0.03 |

**Abbreviations:** ADT=Androgen-deprivation therapy; BT=brachytherapy; CI=confidence interval; EBRT=external beam radiation therapy; LRP=laparoscopic radical prostatectomy; PIVOT= Prostate Intervention Versus Observation Trial; RARP= robot-assisted radical prostatectomy; RP=radical prostatectomy; RPP=radical perineal prostatectomy; RRP=radical retropubic prostatectomy; SPCG-4=Scandinavian Prostate Cancer Group-4; UTI=urinary tract infection.