Effective Health Care Program

Genitourinary Conditions
Urinary Incontinence

Non-surgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness

Focus of Research for Clinicians

In response to a request from the public, a systematic review of the clinical research was undertaken to determine what is known about the comparative effectiveness, benefits, and adverse effects of urinary incontinence (UI) interventions for women and the utility of methods for diagnosis and treatment evaluation. The systematic review included 905 publications presenting the results of clinical studies published from January 1990 through December 2011. The full report, listing all studies, is available at www.effectivehealthcare.ahrq.gov/ui.cfm. This summary, based on the full report of research evidence, is provided to clinicians to inform discussions of options with patients and to assist in decisionmaking along with consideration of a patient's values and preferences. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Background

UI affects women of all ages, but its prevalence increases with age. The severity of the physical, psychological, and social burdens of UI can range from mildly bothersome to debilitating.

Two predominant forms of UI are stress incontinence (sphincter failure during increases in intra-abdominal pressure, as when coughing or sneezing or with exertion) and urgency incontinence (involuntary loss of urine accompanied by a compelling urge to void, often associated with bladder detrusor muscle overactivity). Both forms can appear in one individual as the "mixed" type. Patient reports of symptoms are the typical basis for diagnosing UI, after exclusion of underlying causes (e.g., infection, urogenital prolapse). Urodynamic evaluation is not typically used in primary care, but is used for differential diagnosis, especially for patients considering surgical treatment. The comparative reliability of diagnostic methods and their value for individualizing treatment are not well understood.

Non-surgical treatments include lifestyle changes, pelvic floor muscle training (PFMT), bladder training, and drugs for urgency incontinence from overactive bladder. Effectiveness of UI interventions is typically measured by reduction in frequency of UI episodes and amounts of urine in absorbent pads, although the treatment goals valued by women with UI are not clearly established.

Conclusion

Nonpharmacological interventions (notably, PFMT or bladder training) lessen the severity of urgency, stress, and mixed UI, and promote continence in patients with stress and mixed UI, with low risk of adverse effects. For nonpharmacological interventions, reasons for discontinuation and methods to improve adherence are not understood or systematically investigated. Drug treatments for urgency UI show similar small benefits but may be differentiated by their adverse effects profiles. Withdrawal from drug treatment is typically due to adverse effects. Dry mouth and constipation are common. The long-term safety of drugs for UI has not been evaluated in clinical trials, but serious adverse effects have been associated with their use (e.g., among the elderly and in combination with other commonly prescribed drugs). Diagnosis using clinical tools available in primary care is comparable to urodynamic evaluation. Urodynamic evaluation is not associated with better outcomes with non-surgical treatments. Currently available validated tools (voiding diaries, scales measuring perception of improvement and quality of life) are effective for measuring success with treatment targets that are valued by women with UI.

Clinical Bottom Line *(Continued on next page)*

Diagnosis and Treatment Monitoring

Comparative Value of Methods for Diagnosis

- Patient reports of individual symptoms of stress or urgency have minimal or small diagnostic value when compared with both urodynamics and clinical diagnosis. ●●●
- Clinical algorithms for differentiating stress, urgency, and mixed UI (e.g., including a voiding diary and a cough stress test) have high diagnostic value when compared with urodynamics. ●●○
- Diagnosis by urodynamic examination is not associated with better outcomes with non-surgical treatments. ●●○

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Strength of Evidence Scale

High:	●●●	There are consistent results from good-quality studies. Further research is very unlikely to change the conclusions.
Moderate:	●●○	Findings are supported, but further research could change the conclusions.
Low:	●○○	There are very few studies, or existing studies are flawed.
Insufficient:	○○○	Research is either unavailable or does not permit estimation of a treatment effect.

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Treatment Monitoring

- Multiple validated instruments can be used to monitor treatment success by detecting meaningful changes in symptoms and quality of life (QoL), as identified by women with UI. ●●●
  - Clinical success is perceived by women when episode frequency is reduced by 50 percent or more.
  - QoL improvements are perceived by women at a 70 percent reduction in frequency (as measured by the Incontinence Quality of Life Questionnaire and the Global Perception of Improvement and Incontinence Impact Questionnaire).

Nonpharmacological Interventions

Benefits

- Some nonpharmacological interventions can promote continence and improve severity for patients with stress, urgency, or mixed forms of UI, with limited risk of adverse effects. (See Table 1 for details.)

Table 1. Outcomes of Nonpharmacological Interventions for UI

The ability of interventions to achieve continence or clinically important improvement was compared with placebo or no active treatment. Meta-analytic results are presented as the number of reported events attributable to treatment per 1,000 patients (calculated from the difference between treatment-group and control-group event rates).

Indication	Intervention	Continence (Reports per 1,000 treated)	Improvement (Reports per 1,000 treated)
Stress UI	PFMT	299 ●●●	412 ●●○
	PFMT plus biofeedback	NSD ●○○	390 ●●●
	Electrical stimulation	162 ●●●	156 ●●●
	Magnetic stimulation	NSD ●●○	265 ●●○
Urgency UI	Bladder training	○○○	430 ●○○
	Percutaneous tibial nerve stimulation	NR	308 ●●○
Mixed UI	PFMT plus bladder training	166 ●●●	387 ●●●
	Maintained weight loss and exercise	○○○	273 ●●○
All training regimens of PFMT increase rates of continence and improvement in stress UI. ●●●			

NSD = no statistically significant difference; NR = not reported

Comparative Effectiveness of Nonpharmacological Interventions

For Stress and Mixed UI

- PFMT alone is as effective as adding:
  - Biofeedback, supervision, or bladder training. ●●●
  - Intravaginal electrical stimulation or intravaginal devices. ●●○
- Intravaginal and intraurethral devices and bulking agents are not superior to PFMT and have adverse effects. ●○○

For Urgency UI

- Bladder training alone is as effective as bladder training with PFMT. ●●●

Pharmacological Interventions for Urgency UI

Benefits

- Drug treatments for urgency UI each show a 20 percent or less difference from placebo in the rate of achieving continence (oxybutynin, solifenacin, tolterodine, or trospium ●●●; fesoterodine ●○○; darifenacin, not reported) or improvement (darifenacin, fesoterodine, or tolterodine ●●●; oxybutynin ●●○; solifenacin or trospium ●○○). The number of reports of continence or improvement attributable to treatment ranges from 85–180 per 1,000 patients.
- Benefits are greater with larger doses of fesoterodine and solifenacin (●●●), as well as with oxybutynin (●○○).
- Larger doses of darifenacin (30 mg/day) do not provide greater benefits. ●●●

Adverse Effects

- Tolerability of pharmacological interventions, represented by the rate of discontinuation of treatment due to adverse effects during clinical trials, ranges from no statistically significant difference from placebo (darifenacin, tolterodine) to less than 10 percent difference from placebo (discontinuations per 1,000: solifenacin, 13; trospium, 18; fesoterodine, 31; oxybutynin, 63). ●●●
- In treatment of stress UI with duloxetine (an off-label indication), discontinuation due to adverse effects (129 per 1,000) is more likely than benefits (75 per 1,000). ●●●
- 50 percent of women stop treatment with drugs within 1 year. ●●○
- The rate of adverse effects increases with increased doses of darifenacin, fesoterodine, oxybutynin, and solifenacin (●●●). The influence of increased doses of other drugs is not known.
- Transdermal and controlled-release forms of oxybutynin have lower rates of adverse effects, but a dose response for adverse effects is still found with these formulations. ●○○

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- Dry mouth is the most common adverse effect (106 to 347 reports per 1,000), followed by constipation (12 to 80 reports per 1,000), blurred vision (17 reports per 1,000), and dry eye (14 to 28 reports per 1,000). ●●●
- Evidence about long-term safety of drug treatments for UI is insufficient to permit conclusions about the magnitude of risk.
- Postmarketing surveillence has revealed increased risks of ventricular arrhythmias or sudden death when UI medications are used in older people who are also using antihistamines/cytochrome inhibitors. Tolterodine is associated with an increased risk of hallucinations.

Comparative Effectiveness of Pharmacological Interventions

- When compared with tolterodine, fesoterodine achieves higher rates of continence (55 reports per 1,000 ●○○) and improvement (28 reports per 1,000 ●●●).
- No statistically significant difference in improvement rates is found in comparisons of oxybutynin and tolterodine. ●●○
- Discontinuation rates due to adverse effects are higher with fesoterodine (a difference of 17 reports per 1,000 ●●○) and oxybutynin (a difference of 71 reports per 1,000 ●●●) when compared with tolterodine.
- No statistically significant difference in discontinuation rate was found in comparisons of solifenacin and tolterodine. ●●○
- The evidence from other head-to-head comparisons reported in the literature is insufficient to permit conclusions about comparative benefits or adverse effects.

Modifiers of Pharmacological Treatment

- Age does not modify continence or improvement outcomes of oxybutynin, trospium, or darifenacin. ●●○
- Trospium is more effective than placebo in both obese and nonobese women (●●●). The effect of obesity on outcomes with other drugs is not known.
- The effectiveness of trospium is not affected by concomitant medications, but adverse effects are more common when trospium is taken with seven or more concomitant medications. ●●○
- Solifenacin is effective regardless of response to previous treatment, even in those patients who did not respond to higher doses of other drugs. ●●●
- Tolterodine and solifenacin outcomes are not affected by mixed or pure urgency types of UI. ●●○
- Patients with mixed UI may require a larger dose and longer treatment with solifenacin. ●○○
- Baseline frequency of UI does not influence clinical outcomes of any drug. ●○○

Gaps in Knowledge

The systematic review identified areas where evidence about treatments for UI is limited or absent, including:

- Evidence is insufficient to permit conclusions about the effectiveness of nonpharmacological interventions when compared with drugs or combined modalities.
- The reasons for discontinuation from treatment with nonpharmacological interventions and methods to improve adherence are not understood nor well investigated.
- Evidence is inadequate to determine whether increasing drug dosage leads to greater improvement or likelihood of achieving continence.
- Evidence about how patient characteristics influence treatment benefits or adverse effects is incomplete and of limited value to guide decisionmaking (e.g., baseline frequency, age, race, type of UI, prior treatment, comorbidities, and obesity).

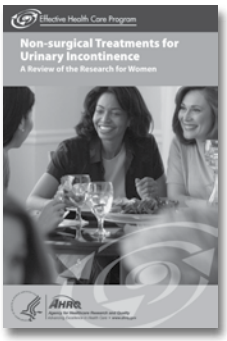
What To Discuss With Your Patients

- The roles of nonpharmacological, pharmacological, and surgical interventions.
- The trade-offs between the likelihood of benefits and the types and severity of adverse effects associated with UI drug treatments.
- The importance of adherence to exercise protocols to achieve continence or improve severity of UI.
- The benefits and low risk of adverse effects from nonpharmacological UI treatments, such as special exercises.

Resource for Patients

Non-surgical Treatments for Urinary Incontinence, A Review of the Research for Women is a free companion to this clinician research summary. It covers:

- The types of UI and procedures for diagnosis



- The types of drug and nondrug interventions that are available for treating stress, urgency, and mixed UI
- The potential for benefits and the risks of adverse effects when drug or nondrug treatments are chosen
- Questions to ask when making decisions about UI treatment options

Ordering Information

For electronic copies of *Non-surgical Treatments for Urinary Incontinence, A Review of the Research for Women*, this clinician research summary, and the full systematic review, visit www.effectivehealthcare.ahrq.gov/ui.cfm. To order free print copies, call the AHRQ Publications Clearinghouse at 800-358-9295.

Source

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