

Implementing AHRQ Effective Health Care Reviews

Helping Clinicians Make Better Treatment Choices

Treatments for Urinary Incontinence in Women

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This clinical content conforms to AAFP criteria for evidence-based continuing medical education (EB CME). See CME Quiz on page 678.

A collection of Implementing AHRQ Effective Health Care Reviews published in *AFP* is available at <http://www.aafp.org/afp/ahrq>.

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. A key clinical question based on the AHRQ Effective Health Care Program review is presented, followed by an evidence-based answer and an interpretation that will help guide clinicians in making treatment decisions. For the full review, clinician summary, consumer summary, and CME activity go to <http://www.effectivehealthcare.ahrq.gov/ui.cfm>.

Key Clinical Issue

What are the effectiveness, benefits, and adverse effects of options for diagnosis and treatment of urinary incontinence (UI) that are available in primary care?

Evidence-Based Answer

UI can be diagnosed in the primary care setting using the history, physical examination, voiding diaries, and validated diagnostic tools; urodynamic evaluation does not improve outcomes of nonsurgical treatments. Nonpharmacologic therapies are effective and safe. Pelvic floor muscle training (PFMT) promotes continence and reduces the severity of stress UI. Bladder training methods reduce the severity of urgency UI, but combining bladder training and PFMT is effective only for patients with mixed UI. Pharmacologic interventions for urgency (and mixed) UI provide some benefits (20 percent or less difference from placebo). Fifty percent of women discontinue drug treatment within one year, typically because of common adverse effects such as dry eye and constipation. The long-term safety of drugs for urgency UI has not been evaluated in clinical trials, but serious adverse effects have been associated with their use among older persons and in combination with other commonly prescribed drugs. Well-validated instruments are available for evaluating treatment effectiveness in terms of symptom relief and change in quality of life. (Strength of Recommendation: A, based on consistent, good-quality patient-oriented evidence.)

Practice Pointers

UI is common in women, affecting about 25 percent of younger women and increasing in frequency with age to around 75 percent of older women.¹ UI can present as stress UI,

urgency UI, or mixed UI, which has primary features of both types. Stress UI is caused by sphincter incompetence during periods of increased intra-abdominal pressure (e.g., with coughing, sneezing, or exercising). Urgency UI is caused by detrusor muscle contractions resulting in an overwhelming urge to void and leakage. Overactive bladder refers to a strong urinary urge without UI.² This AHRQ review evaluated the effectiveness of nonsurgical interventions for improving UI.¹

Patient symptom reports alone had poor diagnostic reliability compared with urodynamic testing, which was used as the diagnostic standard in most studies. Diagnostic algorithms compared favorably with urodynamics and are readily available in the primary care setting, are simple to use, and can be quickly implemented.^{1,3} Urodynamic testing did not improve nonsurgical therapeutic outcomes and should be reserved for patients considering surgical intervention.¹

Nonpharmacologic interventions are effective with low risk of adverse outcomes. PFMT for stress UI led to continence in nearly 30 percent of women and to improvement in more than 40 percent of women. Combining PFMT with biofeedback, bladder training, intravaginal electrical stimulation, intravaginal devices, or supervised training did not significantly improve results.¹ A Cochrane review found insufficient evidence to determine the best approach to PFMT.⁴

Intravaginal and intraurethral devices were associated with more adverse events than PFMT. Bladder training resulted in improvement in 43 percent of persons with urgency UI. Adding PFMT to bladder training did not improve outcomes. Electrical and magnetic stimulation alone were effective for stress UI. In women who are obese, exercise and weight loss were associated with improved

Clinical Bottom Line: Urinary Incontinence in Women

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 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 compared with urodynamics. ●●○

Diagnosis by urodynamic examination is not associated with better outcomes with nonsurgical treatments. ●●○

Treatment monitoring

Multiple validated instruments can be used to monitor treatment success by detecting meaningful changes in symptoms and quality of life, as identified by women with UI. ●●●

- Clinical success is perceived by women when episode frequency is reduced by 50 percent or more.
- Improvements in quality of life 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).

Effectiveness of nonpharmacologic interventions for UI

Indication	Intervention	Continence (reports per 1,000 treated)	Improvement (reports per 1,000 treated)
Stress UI	Pelvic floor muscle training	299 ●●●	412 ●●○
	Pelvic floor muscle training plus biofeedback	NSD ●○○	390 ●●●
	Electrical stimulation	162 ●●●	156 ●●●
	Magnetic stimulation	NSD ●●○	265 ●●○
Urgency UI	Bladder training	○○○	430 ●○○
	Percutaneous tibial nerve stimulation	Not reported	308 ●○○
Mixed UI	Pelvic floor muscle training plus bladder training	166 ●●●	387 ●●●
	Maintained weight loss and exercise	○○○	273 ●○○

All training regimens of pelvic floor muscle training increase rates of continence and improvement in stress UI. ●●●

Comparative effectiveness of nonpharmacologic interventions

For stress and mixed UI

Pelvic floor muscle training 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 pelvic floor muscle training and have adverse effects. ●○○

For urgency UI

Bladder training alone is as effective as bladder training with added pelvic floor muscle training. ●●●

Pharmacologic 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 to 180 per 1,000 patients.

Comparative effectiveness of pharmacologic interventions

Oxybutynin and tolterodine provide similar improvement rates (●●○), but fesoterodine is more effective than tolterodine for improving severity (●●●).

Discontinuation because of adverse effects is greater with fesoterodine (●●○) and oxybutynin (●●●), compared with tolterodine. Solifenacin and tolterodine have similar discontinuation rates (●●○).

Adverse effects

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). ●●●

Tolerability of pharmacologic interventions, represented by the rate of discontinuation of treatment because of 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). ●●●

50 percent of women stop drug treatment within one year. ●●○

Postmarketing surveillance has revealed increased risks of ventricular arrhythmias or sudden death when UI medications are used in older persons who are also using antihistamines/cytochrome inhibitors. Tolterodine is associated with an increased risk of hallucinations.

Evidence about long-term safety of drug treatments for UI is insufficient to permit conclusions about the magnitude of risk.

Clinical Bottom Line: Urinary Incontinence in Women (continued)

Modifiers of pharmacologic treatment

Drug administration

Dosage: Benefits are greater with larger doses of fesoterodine and solifenacin, but not with darifenacin (30 mg per day). ●●● 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.

Concomitant medications: Trospium effectiveness is not modified by concomitant medications, but adverse effects are more common when trospium is taken with seven or more other drugs. ●●○

Patient characteristics

Age: Treatment responses are similar across age groups. ●●○ In older women, oxybutynin, trospium, and darifenacin improve UI (●●○), and solifenacin increases continence rates (●●●).

Obesity: Trospium is effective in women who are obese, as well as in women who are not obese. ●●●

Response to previous treatment: Solifenacin is effective even when the patient's condition did not respond to increased doses of other drugs. ●●●

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.

NSD = no statistically significant difference; UI = urinary incontinence.

Adapted from the Agency for Healthcare Research and Quality, Effective Health Care Program. Non-surgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Clinician research summary. Rockville, Md.: Agency for Healthcare Research and Quality; April 2012. http://effectivehealthcare.ahrq.gov/ehc/products/169/1031/uj_clin_fin_to_post.pdf. Accessed January 23, 2013.

mixed UI.¹ Some invasive nonsurgical treatments for UI, such as botulinum toxin injections,⁵ midurethral slings, and radiofrequency ablation, lack sufficient evidence of benefit or are beyond the scope of this review.¹

All drugs studied for urgency UI were superior to placebo, although the overall effectiveness was low, with less than 20 percent of patients achieving continence. Indirect comparison between drugs suggested that all common UI drugs are similarly effective. In direct comparisons, fesoterodine (Toviaz) was more effective than tolterodine (Detrol), but had a higher discontinuation rate because of adverse effects. Oxybutynin (Ditropan) and tolterodine had similar effectiveness, although tolterodine was associated with fewer adverse effects. Patient characteristics such as age, race, comorbidities, and baseline severity of UI could not be shown to modify the outcomes of any medication.¹

Adverse effects were relatively common and generally increased with larger doses. Dry mouth (10 to 35 percent of patients), constipation (1 to 8 percent), blurred vision, and dry eye were the most common. One-half of women discontinued medication for UI during the first year.¹

Some off-label pharmacotherapies for stress UI were evaluated. Vaginal estrogen preparations were found to be effective for stress UI, whereas transdermal estrogen preparations worsened symptoms. Duloxetine (Cymbalta) was effective in only 7.5 percent of patients, and almost 13 percent of patients discontinued the treatment because of adverse effects.¹

Limited evidence suggests that nonpharmacologic interventions have similar effectiveness and significantly lower the risk of adverse events.¹

These findings indicate that nonpharmacologic therapy should be the initial treatment of choice for all forms of UI. Vaginal estrogens are a good option for stress UI. When opting for pharmacologic intervention for urgency UI, the choice of drug should be guided by adverse effect profile because effectiveness is similar between the drugs.

The views expressed in this article are those of the author and do not reflect the policy or position of the U.S. Army Medical Department, Department of the Army, Department of Defense, or the U.S. Government.

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