Curr Bladder Dysfunct Rep (2010) 5:163–167
DOI 10.1007/s11884-010-0054-7

Nonsurgical Interventions for Incontinence: Where Is the Evidence?

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Published online: 12 May 2010

Abstract Urinary incontinence is a remarkably common urologic condition that results in significant clinical and economic sequelae. Although it is likely underestimated, the overall prevalence of urinary incontinence is projected to be between 15% and 38%. Evaluation frequently can be completed without invasive testing. Conservative therapy for incontinence often employs a multimodal approach that can include behavioral therapy, pelvic floor muscle training, external stimulation, medical devices, and pharmacologic treatment. Herein we present an overview of several conservative treatment options for stress and mixed urinary incontinence and review the available literature regarding these therapies. Despite substantial research into conservative incontinence treatment, few robust studies exist to guide practitioner interventions, and great opportunity exists for future evaluation to advance our knowledge regarding nonsurgical incontinence therapy.

Keywords Stress urinary incontinence · Mixed urinary incontinence · Conservative management · Pelvic floor muscle training · Behavioral therapy · Duloxetine · Topical hormone therapy

Introduction

Stress urinary incontinence (SUI), defined by the International Continence Society as the involuntary loss of urine on effort or exertion, is an astonishingly common urologic condition associated with dramatic clinical and economic sequelae. Despite increasing public recognition as well as appreciation by the medical community of the impact of SUI, the projected prevalence is most likely substantially underestimated secondary to social factors, such as embarrassment and fear, that preclude open discussion of incontinence symptoms. Several population-based studies based on data accumulated from the National Health and Nutrition Examination Survey and the Medical, Epidemiologic, and Social Aspects of Aging study indicate an overall prevalence for urinary incontinence (UI) in the United States of 15.7% to 38% [1–3]. Although representative of the best available effort, these population studies remain limited because they fail to account for patients they cannot measure, namely those affected by UI who have not sought medical attention. The burden of incontinence on the health care structure is of notable consequence; recent estimates suggest expenditures of more than 19.5 billion dollars per year for treatment [4].

The management costs of UI often fall disproportionately on the patient when compared with other diseases. In the Stress Incontinence Surgical Treatment Efficacy Trial, Subak et al. [5•] reported that women enrolled in this randomized surgical trial spent on average about $750 per year out of pocket for incontinence management. Stothers et al. [6] reported an estimated 17% prevalence of UI in men older than 60 years of age, with annual expenditures of $7702, compared with $3204 for men without UI. Aside from the financial burden, significant social costs are associated with UI, with tremendous impact on quality of life.

A treatment continuum exists for patients with UI, from conservative/noninvasive treatments to surgical therapy. Conservative treatment for UI is often preferred by patients in that it is often safe and well-tolerated, even without comparable efficacy to invasive modalities [7]. Historically,

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there have been different definitions of what constitutes "conservative" therapy. Treatments that are completely reversible often have been considered conservative, with pharmacologic therapies often included in this category [7]. Although this review spotlights primarily conservative therapies for SUI, mixed incontinence is frequently present in this population, and several appropriate conservative treatment modalities for the urge component are also discussed. However, most studies reviewed herein do not address incontinence resulting from neurologic compromise or outlet obstruction. It is additionally imperative to recognize the concomitant issues regarding complex pelvic organ prolapse and pelvic floor dysfunction that may contribute to incontinence symptoms.

The approach of the physician to the patient with UI must start with a full medical assessment as well as an ascertainment of the effect of SUI symptoms on the patient's quality of life. For history taking and patient report of status, the basic element of outcomes assessment has been the patient-reported validated questionnaire. In the context of evaluation of SUI, questionnaires are useful in assessing the impact the condition has on the patient's activities and well-being. Ideally, a questionnaire might be able to elucidate the cause of a patient's condition, limiting the need for more costly and/or invasive studies. Although often considered a more "subjective" measure of outcome reporting, questionnaires may in actuality endow a more realistic snapshot of an individual patient's comprehensive surgical outcome as compared with an individual "objective" measure, such as a pad test.

In many cases, conservative treatment measures can be initiated without the need to perform extensive or invasive diagnostic studies. A detailed history and physical examination along with patient-reported outcome measures are often sufficient to allow the physician to begin empiric therapy for stress, urgency, or mixed incontinence.

Conservative treatments for UI include behavioral therapy, pelvic floor muscle training (PFMT) and biofeedback, peripheral electrical and magnetic stimulation, use of occlusive devices, and pharmacologic therapy. The following reviews these conservative treatment modalities and their supporting data and highlights the most recent significant studies.

Behavioral Therapy

Behavioral therapy focuses on education of the patient regarding his or her condition and the factors that affect it, then using this education to help change the behavior to ameliorate or resolve the symptoms. There is no optimal protocol for behavioral therapy, but it often consists of a multimodal approach recommending pelvic floor education, bladder training, smoking cessation, caffeine/fluid restriction, and weight reduction.

Bladder training and timed voiding have long been implemented as standard behavioral therapies for mixed and urge UI. Bladder training consists of instructing the patient to void at mandatory or self-adjusted intervals with the expectation that voiding will then precede bladder volumes that provoke incontinence. This voiding interval is then gradually increased as the patient experiences clinical improvement [7]. Bladder training is focused on restoration of continence, whereas other methods, such as prompted voiding, habit retraining, and timed voiding, focus on the avoidance of incontinence [8]. For patients with mixed UI, anticholinergic therapy is often used in conjunction with bladder training. Elder and Stephenson [9] demonstrated improvement in or cure of symptoms in 86% of patients at 3 months after they underwent outpatient bladder training. In a randomized controlled trial of 123 noninstitutionalized women with UI, bladder training reduced the number of incontinent episodes by 57% [10]. Timed voiding consists of patients voiding at a given frequency (eg, every 2 h to 3 h), with hopes that bladder volumes will stay relatively low and decrease leakage when stress occurs [7]. This method is often used for patients who cannot participate in bladder training and independent toileting. In a systematic review, Ostaszkiewicz et al. [11] reported that the data are too few and of insufficient quality to provide support for or against timed voiding.

In a prospective cohort study of 6,424 women, Dallosso et al. [12] reported significant increased risk of overactive bladder and SUI associated with smoking, obesity, and carbonated beverage intake. However, in a separate longitudinal study of 4,887 men, Dallosso et al. [13] demonstrated no significant association between smoking, obesity, or physical activity and overactive bladder. The International Consultation on Incontinence (ICI) committee could make no evidence-based recommendation with regard to the effect of smoking cessation on UI symptoms [14].

Evaluation of fluid and caffeine intake in older adult women showed fewer episodes of incontinence with decreased caffeine intake and increased fluid intake, although it was not significant [15]. High caffeine intake also has been shown to be associated with detrusor overactivity on urodynamics [16]. Despite the availability of data from small studies such as these, the ICI committee stated that "there is scant level 1 evidence that decreasing caffeine improves continence" [14]. Conflicting data exist with regard to fluid intake, with some studies demonstrating improvement with regard to incontinence with fluid restriction and others showing improvement with increased fluid intake [17, 18].

In a systematic review, Subak et al. [19] reported a 20% to 70% increase in UI risk with each five-unit increase in

body mass index and that weight loss via surgical and nonsurgical means resulted in significant improvements in UI symptoms.

Pelvic Floor Muscle Training and Biofeedback

PFMT, now the accepted term for what is also known as Kegel or pelvic exercises, is defined as any health care professional–taught program of repeated voluntary pelvic floor muscle contractions [14]. The difficulty in analyzing studies involving PFMT is multifactorial, including substantial variations in treatment regimens, patient selection, and outcomes recorded, and the fact that PFMT is often combined with other treatment modalities [7]. In a systematic review, Shamliyan et al. [20•] evaluated four randomized controlled trials comparing PFMT with regular care in treatment of SUI. In two of these studies, biofeedback was combined with the PFMT. In their analysis, pooled RRs for continence after PFMT (7.1 [95% CI, 2.8–18.4]) and PFMT with biofeedback (11.2 [95% CI, 2.2–56.4]) were significant and consistent across the studies, but pooled absolute risk differences of resolved or improved UI were inconsistent across the studies, leading the authors to conclude that the available data did not demonstrate that PFMT with or without biofeedback provided consistent valid benefit for UI [20•]. Conversely, the ICI committee reviewed 15 randomized controlled trials comparing PFMT with essentially no intervention and gave a grade A recommendation that PFMT should be offered as a first-line therapy to all women with UI [14]. In a recent Cochrane review, 672 women among 12 trials were compared to assess the effect of PFMT versus no treatment or placebo on UI. Women who performed PFMT experienced fewer episodes of incontinence per day and less leakage on short, office-based pad test and reported better continence-specific quality of life compared with controls [21•]. Trials focusing on SUI recommended a longer training period and concluded that support exists for the widespread recommendation that PFMT be included in first-line conservative management programs for women with UI [21•].

Biofeedback consists of methods used to help the patient strengthen the muscles of the pelvic floor. Methods include palpation of a pelvic floor muscle contraction during digital examination, use of vaginal cones, and use of more modern computer systems that monitor pressures or electromyogram activity. In a review of randomized controlled trials and systematic reviews regarding use of biofeedback, Weatherall [22] concluded that evidence is lacking to support firm recommendations for the inclusion of biofeedback in conservative treatment of UI.

Peripheral Electrical and Magnetic Stimulation

Peripheral electrical stimulation and magnetic stimulation are additional modalities used to impact UI. The attractiveness of these techniques lies in the fact that they are passive treatments, and their success does not depend on patient effort, as in PFMT [7]. Shamliyan et al. [20•] reviewed 12 randomized controlled trials and found inconsistent low-level evidence demonstrating that magnetic or electrical stimulation did not cure or improve UI in women better than sham stimulation or PFMT. The effectiveness of stimulation varied with type administered and type of incontinence; the improvement seen with magnetic stimulation increased from 23% in women with urge UI to 74% in women with SUI [23, 24]. Of those randomized controlled trials, the greatest improvement, 85% in urge UI, was seen in women who underwent intravaginal electrical stimulation [25].

Occlusive Devices

Various supportive and occlusive devices are available for the management of UI. Pessaries, generally used for vaginal support and treatment of prolapse, are also used to treat SUI. The Hodge pessary was demonstrated to reduce incontinence in a randomized controlled trial studying SUI associated with aerobic exercise [26]. The only device approved specifically for SUI, the Introl bladder neck support prosthesis (UroMed, Suwanee, GA), demonstrated good effectiveness—up to 81% in one study—but it was later withdrawn from the market [27]. Several urethral meatal occlusive devices have been developed and approved for treatment of female SUI, although despite good effectiveness for mild to moderate SUI, all of these have been withdrawn from the market [7]. Urethral inserts are used to treat SUI and work by occluding the urethra. A multicenter controlled study of 150 women studying the effect of the FemSoft urethral insert (Rochester Medical Corp., Stewartville, MN) demonstrated significant reduction in daily incontinence episodes and volume of urine loss, with 93% of women having a negative pad weight test at 12 months [28].

Pharmacologic and Hormone Therapy

Particularly with regard to urge and mixed UI, pharmacologic agents have played a significant role in the treatment of UI during the past several decades. Anticholinergics have been a mainstay of medical therapy. A systematic Cochrane review studying use of various anticholinergics versus placebo or no treatment demonstrated cure or improvement (RR, 1.39; 95% CI, 1.28–1.51), difference in number of leakage episodes per

24-hour period (weighted mean difference, −0.54; 95% CI −0.67 to −0.41), and difference in number of voids per 24-hour period (weighted mean difference, −0.69; 95% CI, −0.84 to −0.54) that were statistically significant in favor of medication [29]. In their systematic Cochrane review of randomized trials using adrenergic agonists in women versus placebo, Alhasso et al. [30] found weak evidence to suggest that the use of adrenergic agonists was superior to that of placebo in the treatment of UI. In a systematic Cochrane review of nine randomized controlled trials in which 3327 patients with predominantly SUI symptoms were randomly assigned to receive duloxetine or placebo, duloxetine was found to be significantly better than placebo in terms of improving patients' quality of life and perception of improvement, although this same benefit in objective data, such as 24-hour pad weight, failed to demonstrate significant improvement with duloxetine [31]. The duration of treatment with duloxetine in these studies ranged from 3 weeks to 12 weeks, which led the authors to question whether such quality-of-life improvements would be sustainable. About one in three patients in a duloxetine treatment arm reported adverse effects with treatment, usually nausea, and about one in eight patients stopped treatment due to adverse effects [31].

Hormone therapy in the form of estrogen often has been prescribed for treatment of UI in women. The Women's Health Initiative conducted a multicenter, double-blind, randomized controlled trial studying menopausal hormone therapy versus placebo in 27,347 postmenopausal women—23,296 of whom were known to have UI symptoms—at baseline and 1 year [32]. Patients were randomly assigned to receive placebo, estrogen, or estrogen plus progestin. This large-scale study demonstrated that systemic hormone therapy increased the incidence of all types of UI at 1 year among women who were continent at baseline, and that the frequency of incontinence worsened in both treatment arms for women who had UI at baseline [32]. The authors therefore concluded that estrogen with or without progestin should not be administered for the prevention or relief of UI. In a randomized trial of 88 symptomatic menopausal women comparing oral hormone therapy, percutaneous gel, and transdermal patch, the best rates of continence were reported in patients who received the estrogen patch (100%) and the percutaneous estrogen gel (90%) [33]. Local hormone therapy (ie, intravaginal creams or tablets) has demonstrated benefit for improvement in incontinence with an acceptable side effect profile [34].

Conclusions

A growing body of evidence is accumulating to assist practitioners in the formulation of treatment plans involving nonsurgical conservative therapies for the management of UI, although there are few guidelines for such approaches. Given the prevalence and burden of disease of UI, additional studies are warranted, particularly with regard to the standardization of methods of PFMT with and without adjunctive treatments. The data regarding PFMT for the treatment of UI are conflicting, but they do suggest that no evidence-based role exists for biofeedback. The instruction of PFMT or other conservative UI treatments by a health care professional in the setting of a busy clinical practice may preclude adequate training. Therefore, future research may focus on novel delivery models for patient education. A new model for treatment of UI whereby patients self-refer themselves to a specialty care team composed of nurses and a continence educator without physician consultation was studied and compared with a more traditional pyramidal model whereby patients are referred to see subspecialists. Farrell et al. [35•] compared the results among 232 women in these two arms of treatment delivery and demonstrated that both groups showed significant improvement in all measures of UI after treatment. Interestingly, patients in the self-referral model experienced significantly better resolution of SUI and irritative voiding symptoms [35•]. Although various medical devices in the past have been developed and demonstrated efficacy in the treatment of UI, many of these have suffered limited market durability secondary to patient noncompliance, discomfort, or cost. Anticholinergic medical therapy should continue to be the mainstay of medical therapy for select types of mixed and urge UI based on the data reviewed.

Disclosures Dr. Kaufman has served as a consultant for American Medical Systems. No other potential conflicts of interest relevant to this article were reported.

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