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Pelvic Floor Symptoms Improve Similarly After Pessary and Behavioral Treatment for Stress Incontinence

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Abstract

Objective—To determine if differences exist in pelvic symptom distress and impact in women randomized to pessary versus behavioral therapy for treatment of stress urinary incontinence (SUI).

Methods—Change in symptom and condition-specific health related quality of life (HRQOL) measures were compared between pessary and behavioral groups 3-months after randomization in the Ambulatory Treatments for Leakage Associated with Stress Incontinence [ATLAS]) trial. 446 women with symptoms of SUI were randomized to continence pessary, behavioral therapy (pelvic floor muscle training and continence strategies) or combination therapy. Validated measures utilized included urinary (UDI), prolapse (POPDI) and colorectal (CRADI) scales of the Pelvic Floor Distress Inventory; urinary (UIQ), prolapse (POPIQ) and colorectal (CRAIQ) scales of the Pelvic Floor Impact Questionnaire; and stress and urge scale of the Questionnaire for Urinary Incontinence Diagnosis (QUID). Student t- test and ANOVA was used to compare scores within and between groups.

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Results—Mean age of participants was 49.8±11.9 years; 84% were Caucasian and 10% African American. 149 were randomized to pessary and 146 to behavioral therapy. Baseline symptoms and HRQOL scores were significantly reduced within treatment arms at three months post randomization, but there was no statistically significant difference between groups.

Conclusion—There was no difference in pelvic floor symptom bother and HRQOL between the pessary and behavioral therapy arms in women undergoing conservative treatment for SUI. Individualized preference issues should be considered in the approach to the non-surgical treatment of SUI.

Keywords

Pessary; Behavioral Therapy; Stress Urinary Incontinence

Introduction

Stress urinary incontinence (SUI) affects 15% to 35% of women[1], creating a substantial societal and personal burden impacting on health related quality of life (HRQOL), productivity, healthcare utilization, and costs. It is a substantial social problem contributing to embarrassment, negative self-perception[2] , impaired emotional and psychological well-being [2], and impaired sexual relationships [3]. While it is helpful for studies to quantify improvements in objective measures of urinary leakage such as pad weights or voiding diaries before and after an intervention, these clinical outcomes do not fully capture patients' changes in HRQOL with treatment. Validated symptom and HRQOL measures are available to characterize the bother and impact on a woman's daily life from various pelvic floor disorders including urinary incontinence, colorectal symptoms, and pelvic organ prolapse.

In the Ambulatory Treatments for Leakage Associated with Stress Incontinence (ATLAS) trial, compared to the pessary arm, more women in the behavioral arm reported having no bothersome stress incontinence symptoms (49% versus 33%, p=0.006) and treatment satisfaction (75% versus 63%, p=0.02), at 3 months, respectively [4]. In this planned secondary analysis of the ATLAS trial, our objective was to determine whether use of pessary or behavioral therapy for treatment of SUI results in overall improvements in bother and HRQOL from global urinary, prolapse, and colorectal symptoms. Relative differences in symptom improvement between the 2 treatments may help in counseling patients on their options of non-surgical SUI management.

Methods

This is a planned secondary analysis of a multi-center, randomized trial (ATLAS) that assigned 446 women with symptoms of SUI to continence pessary, behavioral therapy (pelvic floor muscle training and continence strategies) or combination therapy [4]. The methods and primary outcome of the ATLAS trial is published [4,5]. Eligible women at least 18 years old with symptoms of pure or predominant SUI were enrolled. Inclusion criteria included at least 2 SUI episodes on 7-day bladder diary and more SUI episodes than other types of incontinence episodes recorded on the diary. Women with continuous urinary leakage, current incontinence drug therapy, stages III or IV pelvic organ prolapse, incomplete bladder emptying or neurologic disorders associated with incontinence were excluded. Institutional review board approval was obtained at each of the 7 clinical sites and the data-coordinating center, and all participants provided written informed consent. Participants were randomly assigned to one of three treatment arms: pessary, behavioral therapy, or a combination of the two treatments. Randomization was stratified by incontinence type (SUI versus mixed) and severity (fewer than 14 versus greater than or equal to 14 incontinence episodes) determined by 7-day bladder diary.

Behavioral therapy was implemented in four visits at approximately 2-week intervals, and participants were given individualized prescriptions for daily pelvic floor muscle exercise and practice. Pessary treatment included a physician or nurse fitting the participant with a continence ring or dish. Outcomes were measured at baseline and 3, 6 and 12 months after randomization, with primary outcomes assessed at 3 months. All research personnel who collected patient-oriented outcome data were blinded to treatment group assignment.

Urinary incontinence and other pelvic symptoms and condition-specific HRQOL were assessed with validated questionnaires, including the Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ) and Questionnaire for Urinary Incontinence Diagnosis (QUID) [6–8]. The PFDI includes a urinary scale (UDI; score range 0–300) including three subscales (Stress, Irritative and Obstructive; each with score range 0–100), as well as prolapse (POPDI; score range 0–300) and colorectal (CRADI; score range 0–400) scales. Higher PFDI scale and subscale scores reflect increasing symptom bother. The PFIQ includes 3 scales, urinary (UIQ), prolapse (POPIQ) and colorectal (CRAIQ), each with score range of 0–300. Higher PFIQ scores suggest greater daily impact from pelvic symptoms. The QUID includes Stress and Urge scales (each with score range 0–15), assessing the frequency of stress and urgency urinary incontinence symptoms. Higher QUID scores reflect increasing symptom frequency.

As our objective was to study and compare symptom bother and HRQOL outcomes after pessary and behavioral treatment, data from the combined therapy treatment group were not included. Baseline characteristics and measures were compared between the pessary and behavioral treatment groups using chi-squared or two-sample t-tests. Changes from baseline to 3 months in the PFDI, PFIQ and QUID scores were calculated (change score = 3 month score – baseline score). Paired t-tests were conducted to compare the within-treatment changes at 3 months post randomization from baseline, and one-way ANOVA were conducted to compare the 3-month changes between the pessary and behavioral groups, adjusting for the baseline measures.

Results

Between May 2005 and October 2007, 741 women were assessed for eligibility, and 446 participants were randomly assigned to pessary (n=149), behavioral therapy (n=146), or combination therapy (n=151). The 295 participants randomized to pessary or behavioral therapy had a mean age ± SD of 49 ± 11.9 and a median vaginal parity of 2 (range 1–3). Eighty-five percent of the participants were Caucasian, and 10% were African American. Participants in the pessary and behavioral groups had similar baseline demographic characteristics and urinary incontinence and other pelvic floor symptom frequency, bother and quality of life impact (Table 1). Ninety-five percent of subjects completed the symptom and HRQOL measures at baseline and 71% at 3 months. In the following analysis, we assume that this missingness is completely at random and does not lead to any selection bias.

Both the pessary and behavioral groups had significant within group improvement on each of the symptom and HRQOL measures at 3-months (Table 2); however, score improvement did not differ significantly between groups. Table 2 shows mean score improvement on each of the measures in both groups. Similarly, QUID stress and urge scores improved within each group, although these improvements did not significantly differ between the pessary and behavioral groups.

Conclusion

Pelvic floor symptom frequency, bother and impact (HRQOL) improve similarly 3-months after both pessary and behavioral therapy in women undergoing non-surgical treatment for SUI. Barber et al [9] recently described the minimum important differences (MID) or minimal change that is considered to have a clinically significant impact for the UDI, UDI stress subscale and UIQ of 11, 8 and 16 points, respectively. The improvements seen at 3-months in women in the ATLAS study receiving pessary and behavioral therapy were in excess of these estimates, suggesting that both forms of treatment result in clinically significant improvements in urinary incontinence. The MID for the QUID, also assessing urinary incontinence symptoms, has not been determined, although the changes seen in QUID scores in this trial exceeded 0.5 SD change, proposed as a conservative measure of clinical difference in patient reported questionnaires [7,10]. The MID for the POPDI has been estimated to be 37 points, while those for the colorectal subscales (CRADI, CRAIQ) have not been determined [11]. It is unlikely that the changes in the prolapse or colorectal scales represent clinically important differences using either existing estimates or a 0.5 SD change. These findings are not unexpected, as treatments were aimed at urinary incontinence symptoms and because eligibility criteria for the ATLAS trial included bothersome stress predominant urinary incontinence rather than prolapse or bowel symptoms; in fact, patients were excluded for greater than stage II prolapse. However, it is important to note that both the pessary and behavioral therapy groups experienced improvement, rather than deterioration, in bowel and prolapse symptoms. These findings of improvements in urinary, prolapse and bowel symptoms have important implications for the counseling of women considering non-surgical treatment for stress incontinence.

The improvements in the UDI and UIQ are less than those experienced after surgical management [11,12], however do represent clinically important reductions without the attendant morbidity of a surgical intervention. While both women receiving pessary and behavioral therapy demonstrated clinically meaningful improvements in symptom bother and HRQOL, there were no differences in those scores between the groups. Women in the behavioral therapy group experienced greater overall satisfaction with their therapy and a smaller proportion had bothersome stress incontinence as assessed by the PFDI (33% vs 49%, p= 0.006) at 3 months [4]. However, when change in the mean bother or HRQOL scores are compared, these between group differences were not found. These data suggest that both behavioral and pessary treatment have a clinically important role in the treatment of stress incontinence. Women can be reassured of symptom improvement with either treatment modality, and individual patient characteristics and preferences can determine which non-surgical therapy to use.

The present study was not designed to evaluate which patient factors or preferences inform patient satisfaction or improvement with conservative treatment with either pessary or behavioral therapy. Women's perception of their goals for treatment and the attainment of these goals are related to their compliance with pessary management and likely impact their satisfaction with behavioral management as well. Given the lifestyle and treatment differences associated with pessary and behavioral therapy, it is likely that patients will self select between these forms of treatment. Based on the challenges in recruiting patients to a randomized trial comparing medical versus surgical management for mixed incontinence [13], it is unlikely that these therapies can directly be compared to surgical management. Therefore, data on symptom and quality of life improvement becomes of paramount importance in the discussion of non-surgical management with patients. Further investigation is warranted to determine which specific clinical and other patient factors may be associated with successful conservative management with either pessary or behavioral therapy.

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References

1. Shamliyan TA, Kane RL, Wyman J, et al. Systematic review. randomized, controlled trials of nonsurgical treatments for urinary incontinence in women. Ann Intern Med. 2008; 148:459. [PubMed: 18268288]
2. Berghmans LC, Hendriks HJ, Bo K, et al. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. Br J Urol. 1998; 82:181. [PubMed: 9722751]
3. Burns PA, Pranikoff K, Nochajski TH, et al. A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community-dwelling women. J Gerontol. 1993; 48:M167. [PubMed: 8315230]
4. Richter HE, Burgio KL, Brubaker L, et al. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: a randomized controlled trial. Obstet Gynecol. 2010; 115:609. [PubMed: 20177294]
5. Richter HE, Burgio KL, Goode PS, et al. Non-Surgical Management of Stress Urinary Incontinence: Ambulatory Treatments for Leakage Associated with Stress Incontinence (ATLAS) Trial. Clinical Trials. 2007; 4
6. Barber MD, Spino C, Janz NK, et al. The minimum important differences for the urinary scales of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. Am J Obstet Gynecol. 2009; 200:580.e1. [PubMed: 19375574]
7. Bradley CS, Rahn DD, Nygaard IE, et al. The questionnaire for urinary incontinence diagnosis (QUID): validity and responsiveness to change in women undergoing non-surgical therapies for treatment of stress predominant urinary incontinence. Neurourol Urodyn. 2010; 29:727. [PubMed: 19787711]
8. Barber MD, Kuchibhatla MN, Pieper CF, et al. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. Am J Obstet Gynecol. 2001; 185:1388. [PubMed: 11744914]
9. Barber MD, Brubaker L, Nygaard I, et al. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol. 2009; 114:600. [PubMed: 19701041]
10. Sloan JA, Cella D, Hays RD. Clinical significance of patient-reported questionnaire data: another step toward consensus. J Clin Epidemiol. 2005; 58:1217. [PubMed: 16291464]
11. Barber MD, Walters MD, Cundiff GW. Responsiveness of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) in women undergoing vaginal surgery and pessary treatment for pelvic organ prolapse. Am J Obstet Gynecol. 2006; 194:1492. [PubMed: 16647933]
12. Wadie BS, Mansour A, El-Hefnawy AS, et al. Minimum 2-year follow-up of mid-urethral slings, effect on quality of life, incontinence impact and sexual function. Int Urogynecol J Pelvic Floor Dysfunct. 2010; 21:1485.
13. Brubaker L, Moalli P, Richter H, et al. Design of the Mixed Incontinence - Medical or Surgical Approach (MIMOSA) Trial: A Randomized Trial of Surgical vs. Non-Surgical Treatment for Mixed Urinary Incontinence. Clin Trials. 2009; 6:355. [PubMed: 19625327]

Table 1

Baseline characteristics and pelvic symptom frequency, bother and impact in the pessary and behavioral therapy treatment groups.

Characteristic or Questionnaire(score range)	Pessary N=149	Behavioral Therapy N=146	P-Value*
Age [years]	50.18±10.96	49.63±13.01	0.69
Race			
Caucasian	125 (84.46%)	132 (90.4%)	0.29
African American	15 (10.14%)	10 (6.8%)	
Other	8 (5.41%)	4 (2.7%)	
UDI (0–300)	83.54±40.6	77.8±35.7	0.21
UDI Stress (0–100)	48.8±22.0	47.0±17.7	0.43
UDI Obstructive (0–100)	14.8±15.7	12.8±14.4	0.28
UDI Irritative (0–100)	19.9±15.5	18.0±14.5	0.29
POPDI (0–300)	54.5±47.6	45.8±48.7	0.13
CRADI (0–400)	66.0±57.5	56.5±60.3	0.17
UIQ (0–400)	70.6±60.1	67.1±53.4	0.61
POPIQ (0–400)	19.1±44.3	10.9±27.7	0.06
CRAIQ (0–400)	23.4±48.5	18.5±38.4	0.30
QUID Stress (0–15)	8.1±4.5	8.5±3.2	0.35
QUID Urge (0–15)	4.2±4.2	4.3±3.3	0.80

Date presented as mean±SD unless otherwise indicated.

* p-values calculated using chi-squared or 2-sample t tests.

UDI=Urinary Distress Inventory, POPDI=Pelvic Organ Prolapse Distress Inventory, CRADI=Colorectal-Anal Distress Inventory, UIQ=Urinary Impact Questionnaire, POPIQ=Pelvic Organ Prolapse Impact Questionnaire, CRAIQ=Colorectal-Anal Impact Questionnaire, QUID=Questionnaire for Urinary Incontinence Diagnosis,

Table 2

Change in symptom frequency, bother and impact 3-months after starting therapy

Questionnaire (score range)	Pessary N=149	Behavior N=146	P-value within treatment arm*	P-Value between treatment arms**
UDI	− 33.9±38.5	− 30.7±33.4	<0.0001	0.88
UDI Stress	− 19.9±23.6	− 18.2±20.5	<0.0001	0.78
UDI Obstructive	− 5.4±12.3	− 5.1±10.2	<0.0001	0.48
UDI Irritative	− 8.6±13.4	− 7.3±12.2	<0.0001	0.67
POPDI	− 13.5±30.1	− 14.7±34.1	<0.0001	0.24
CRADI	− 16.4±39.2	− 15.4±41.0	<0.0001	0.83
UIQ	− 31.4±50.0	− 32.1±38.4	<0.0001	0.61
POPIQ	−7.2±42.5	−5.25±28.99	0.0003	0.26
CRAIQ	− 12.9±37.8	− 10.7±28.7	<0.0001	0.66
QUID Stress	− 4.2±6.2	− 4.0±3.6	<0.0001	0.20
QUID Urge	− 2.0±5.4	− 2.3±2.8	<0.0001	0.36

Change in scores (3 months – baseline) presented as mean±SD.

* Paired t-tests.

** One-way ANOVA, adjusted for the baseline score.

UDI=Urinary Distress Inventory, POPDI=Pelvic Organ Prolapse Distress Inventory, CRADI=Colorectal-Anal Distress Inventory, UIQ=Urinary Impact Questionnaire, POPIQ=Pelvic Organ Prolapse Impact Questionnaire, CRAIQ=Colorectal-Anal Impact Questionnaire, QUID=Questionnaire for Urinary Incontinence Diagnosis,