ICS 2009 Abstract Form

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Abstract Title:

A Randomized Trial of Pessary vs. Behavioral Therapy vs. Combined Therapy for Treatment of Stress Urinary Incontinence

Abstract Text:

Hypothesis / aims of study

Non-surgical treatment for stress urinary incontinence (SUI) is recommended as first-line therapy [1]. Clinical trials have established that behavioral therapy, consisting of pelvic floor muscle training with learning skills and strategies to prevent urine loss, is effective for reducing SUI. Intravaginal continence pessaries represent another conservative approach to the treatment of SUI and are thought to improve incontinence by stabilization of the proximal urethra and urethrovesical junction. However, there are few prospective studies and no randomized trials examining the effectiveness of pessaries for treating SUI. The primary aim of this study was to compare effectiveness of a continence pessary to standard behavioral therapy on patient perception of improvement and SUI symptoms at 3 months after randomization. A second aim was to determine if combined treatment was more effective than either treatment alone.

Study design, materials and methods

This multi-center randomized clinical trial compared intravaginal continence pessary, behavioral therapy, and a combination of the two treatments for SUI in women ≥ 18 years with predominant SUI. Subjects were stratified with respect to type of incontinence (stress only versus mixed with stress predominant) and frequency of incontinence (<14 total incontinence episodes vs. ≥14 total episodes per 7-day bladder diary) and randomized within site to one of the three treatment groups. All subjects received a one-page handout on general incontinence management tips, including information and suggestions about optimal volume of fluid intake, constipation management, measures to reduce urgency by spreading out fluid intake, avoiding caffeine and other potential bladder irritants, as well as use of pelvic floor muscles to control urgency. Subjects in the pessary alone group were fitted with a continence pessary (ring or dish) in up to 3 clinic visits at 1-2 week intervals. Behavioral therapy consisted of pelvic floor muscle training and exercise, as well as skills and strategies for active use of muscles to prevent stress incontinence, and was implemented in 4 clinic visits at 2-week intervals. Combined therapy included the components of both pessary and behavioral therapy. All subjects completed a daily bladder diary for 6 weeks to control for the potential self-monitoring effect. Outcomes were measured at 3 months (**primary outcome time-point**), with additional assessment at 6 and 12 months post-randomization. Two primary outcome measures were used: the Patient Global Impression of Improvement (PGI-I), where success was defined as a response of “much better” or “very much better;” and the stress incontinence subscale of the Pelvic Floor Distress Inventory (PFDI), where success was defined as an answer of “no” to all of the seven stress subscale questions or “yes” with a bother component of “not at all” or “somewhat.” On the 7-day bladder diary, success was objectively defined as 75% reduction in incontinence episodes. Patient-reported satisfaction was assessed using the validated Patient Satisfaction Question (PSQ). Logistic regression, adjusting for the stratification factors, was used to compare pessary and behavioral treatments. Each of the two individual treatment arms was compared to the combination arm in separate similar logistic regression analyses. The combination arm was considered better than the individual arms only when both tests were significant, so there was no need to adjust for the number of tests being performed. Analyses used an intention-to-treat approach, and dropouts, including subjects in the pessary alone group who could not be fitted with pessaries, were set to failures. Mantel-Haenzel tests and ANCOVA were used to compare baseline characteristics between the three treatment arms, adjusting for the stratification factors.

Results

Subjects had a mean age of 50 years (range, 18-89), were vaginally parous and most were white (85%). There were no significant differences in baseline characteristics across the three treatment groups. Overall, 47% of participants reported that they were “much better” or “very

much better" using the PGI-I at 3 months (combo 53.3%, behavioral 49.3%, pessary 39.6%), and outcomes did not differ between the behavioral and pessary groups (p=0.10). The proportion of women reporting treatment success using the PFDI differed by individual treatment group at 3 months (behavioral 48.6% vs. pessary 32.9%, p < 0.01; Table 1). Combined therapy at 3 months was not considered better than both pessary and behavioral therapy alone on either primary outcome measure (at least one p>0.05 in comparisons of each outcome), although treatment success in combined therapy was higher than in pessary treatment (p=0.02 for PGI-I and p=0.05 for PFDI stress). Approximately 50% of patients in each group showed at least 75% reduction in incontinence episodes at 3 months (p>0.05 for all comparisons). Patient satisfaction was significantly higher in the behavioral group compared to the pessary group at 3 months (75.3% vs. 63.1%, p = 0.02). Treatment success as defined by PGI-I or PFDI stress was attenuated at later time-points, with no statistically significant differences in comparisons of the individual therapies or of combination therapy vs. individual therapy (Table 1).There were no significant group differences in reduction of incontinence episodes or patient satisfaction at the 6 and 12 month time-points across all treatment groups.

Table 1. Intention-to-Treat Analysis of Success Rates Across Groups at 3, 6, and 12 months.

Measure	Combined N=150 N (%)	Behavioral N=146 N (%)	Pessary N=149 N (%)	Behavior vs Combined p-value	Pessary vs Combined p-value	Pessary vs Behavior p-value
PGI-I						
3 mos	80 (53.3%)	72 (49.3%)	59 (39.6%)	0.49	0.02	0.10
6 mos	63 (42.0%)	59 (40.4%)	52 (34.9%)	0.78	0.21	0.33
12 mos	49 (32.7%)	48 (32.9%)	47 (31.5%)	0.97	0.83	0.83
PFDI Stress						
3 mos	66 (44.0%)	71 (48.6%)	49 (32.9%)	0.42	0.05	**<0.01**
12 mos	49 (32.7%)	59 (40.4%)	52 (34.9%)	0.17	0.68	0.33
Satisfaction						
3 mos	118 (78.7%)	110 (75.3%)	94 (63.1%)	0.50	<0.01	**0.02**
6 mos	104 (69.3%)	95 (65.1%)	87 (58.4%)	0.43	0.05	0.25
12 mos	81 (54.0%)	79 (54.1%)	75 (50.3%)	0.96	0.53	0.53

Withdrawals differed by treatment group over time (p=0.02). At 3 months, withdrawal rates were 26% for pessary, 15% for behavioral and 12% for combined therapy. Adverse events were less than 8% across the three groups.

Interpretation of results

There does not appear to be a significant difference between pessary and behavioral therapy for SUI based on global impression of improvement. Improvements in stress-specific PFDI outcomes were seen at 3 months, with behavioral therapy over pessary, however these initial improvements appear to attenuate over time, reaching similar treatment success rates within 6 to 12 months. Combination therapy did not confer additive benefits over single treatment with the continence pessary or behavioral therapy. The proportion of subjects reporting treatment satisfaction was higher than the proportion of women reporting that their symptoms were "much better" or "very much better," however these rates also diminished over time.

Concluding message

This well-powered study did not demonstrate a statistically significant difference in 3-month success based on the PGI-I, but significant differences were observed in SUI symptoms and satisfaction outcome measures. Combining pessary and behavioral therapy as an initial approach does not appear to improve outcomes over that achieved with individual treatment. The impact of these conservative treatments decreased over time, therefore efforts to help maintain short-term outcomes need to be considered. Further research is needed to delineate which patients are more likely to benefit from non-surgical versus surgical therapy.