

A RANDOMIZED TRIAL OF PESSARY VERSUS BEHAVIORAL THERAPY VERSUS COMBINED THERAPY FOR TREATMENT OF STRESS URINARY INCONTINENCE (SUI)

Objective: To compare effectiveness of a continence pessary to behavioral therapy on patient perception of improvement and SUI symptoms at 3 months and determine if combined treatment was more effective than either treatment alone.

Methods: Subjects were stratified by type of incontinence (stress only versus mixed with stress predominant) and frequency of incontinence (<14 total vs. ≥14 total episodes per 7-day bladder diary). Outcomes were measured at 3, 6, and 12 months post-randomization. Two primary outcome measures were used: the Patient Global Impression of Improvement (PGI-I), and the stress incontinence subscale of the Pelvic Floor Distress Inventory (PFDI). Patient-reported satisfaction was assessed using the validated Patient Satisfaction Question. Analyses used an intention-to-treat approach. Logistic regression, was used to compare pessary and behavioral treatments. The combination arm was considered better than the individual arms only when both tests were significant. Mantel-Haenzel tests and ANCOVA were used to compare baseline characteristics among the three treatment arms. All tests adjusted for stratification factors.

Results: 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%). PGI-I outcomes did not differ between the behavioral and pessary groups (p=0.10), but stress symptoms and satisfaction were significantly better in the behavioral group at 3 months. This benefit was not observed at 6 and 12 months.

. 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

Conclusions: 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 symptom 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.

