Title Abstract: Non-Surgical Management of Stress Urinary Incontinence: Ambulatory Treatments for Leakage Associated with Stress (ATLAS) Trial

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Introduction: Non-surgical treatment for stress urinary incontinence (SUI) is recommended as first-line therapy, yet few prospective studies and no randomized trials compare the most common non-surgical treatments for SUI.
Objective: To present the design and methodology of the Ambulatory Treatments for Leakage Associated with Stress (ATLAS) trial, a randomized clinical trial comparing three interventions for predominant SUI in women: intravaginal continence pessary; behavioral therapy (including pelvic floor muscle training and exercise and bladder control strategies), and a combination of the two treatments.
Methods: Treatment outcome measures, collected at 12 weeks and 6 and 12 months post-randomization, include the Patient Global Impression of Improvement (PGI-I), the Stress Incontinence Scale of the Pelvic Floor Distress Inventory (PFDI), 7-day bladder diaries, Pelvic Floor Impact Questionnaire (PFIQ), Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire (PISQ-12), Patient Satisfaction Questionnaire (PSQ), and the Medical Outcomes Study Short Form Health Survey (SF-36).

Inclusion Criteria

- At least 18 years of age.
- Ambulatory.
- Able to come to the clinic for study visits.
- Reports symptoms of stress incontinence (by interview and on bladder diary).
- Reports incontinence persisting for at least three months.
- 7-day baseline bladder diary, the subject completed the bladder diary in an adequate manner on at least 5 out of 7 days and documented at least two stress incontinence episodes. In addition, the number of stress incontinence episodes must exceed the number of other types of incontinence episodes.
- If oral and/or vaginal estrogen is used, usage is stable for at least the past 8 weeks.
- Ability to complete bladder diary, questionnaires and quality of life forms in English.
- Stage 0, 1 or 2 prolapse as assessed by the POP-Q.

Exclusion Criteria

- Continual leakage. Participants who describe continual leakage or always being damp or wet.
- Urinary tract infection (defined as a positive dip with 1+leukocytes and/or nitrates and/or growth of greater than 10,000 colonies per ml of a urinary pathogen on urine culture). Participants will be treated with antibiotics and may be enrolled if incontinence persists after the urinary tract infection is resolved
- Pregnant or planning pregnancy within the next year.
- Within 6 months post partum.
- Severe atrophic vaginitis (defined as thin, friable vaginal epithelium that bleeds easily on speculum examination). Participants may be treated with estrogen and reevaluated for eligibility.
- Post-void residual volume ≥150 mL.
- Strongly desires surgery for stress urinary incontinence within 12 months.
- Within 3 months of failed surgery for stress incontinence.
- Current medication for incontinence (includes imipramine and antimuscarinics, and does not include other antidepressants or stable estrogen therapy. If a participant is on a medication for incontinence, she may discontinue the medication and be re-evaluated after 2 weeks.)
- Previously participated in a behavioral therapy research trial or formalized clinical behavioral therapy program for urinary and/or fecal incontinence
- Vaginal foreign body (e.g., exposed mesh or suture)
- Currently using a pessary or used one within the past 2 months. (The participant may stop using the pessary for 2 months and be re-evaluated for participation at that time.)
- Neurologic conditions that may impact on bladder symptoms, e.g., Parkinson's, multiple sclerosis, or stroke.

Results and Limitations: The study has finished recruitment and is awaiting the final 1-year outcome results. The study design reduces most common biases, but some degree of selection bias may remain.
Conclusion: This trial will provide useful information to help counsel women with stress and mixed incontinence about the relative efficacy and satisfaction with pessary, behavioral therapy, and both treatments combined.

Key Words: pessary, behavioral therapy, pelvic floor muscle training, stress urinary incontinence, physical therapy

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