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# Non-surgical management of stress urinary incontinence: ambulatory treatments for leakage associated with stress (ATLAS) trial

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**Background** 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.

**Purpose** 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 six 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), seven-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).

**Limitations** 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. *Clinical Trials* 2007; 4: 92–101. <http://ctj.sagepub.com>

## Brief summary

The rationale, methods and key design features of the ongoing Ambulatory Treatments for Leakage Associated with Stress (ATLAS) trial are presented and

discussed, emphasizing challenges in trial design and subsequent resolutions. This trial will help practitioners to counsel patients about the efficacy of pessary, behavioral therapy and both combined for the control of stress urinary incontinence.

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## Background

Stress urinary incontinence (SUI) is the complaint of involuntary urine leakage with physical effort or exertion, such as sneezing or coughing [1]. Non-surgical treatment is generally recommended as first-line therapy, with minimal risks and lower costs compared with surgery. One of the most commonly used non-surgical treatment for SUI is behavioral therapy consisting of pelvic floor muscle training (PFMT) and exercise, as well as skills and strategies for active use of muscles to prevent stress incontinence. Several clinical trials have demonstrated that behavioral therapy is effective for SUI, as well as for mixed stress and urge incontinence [2–7], with a reported reduction in the frequency of incontinence ranging from 57% to 86%. However, the short-term results of clinical trials may not be replicated in clinical practice. In addition, initial and sustained improvement with behavioral therapy depends, in part, on patient motivation and adherence to the exercise regimen and practice in the use of pelvic floor muscles to prevent incontinence episodes.

Continence pessaries represent an alternative or complementary approach to the treatment of SUI. Although not well understood, pessaries are thought to restore or improve continence by stabilization of the proximal urethra and urethrovesical junction, facilitating pressure transmission to the proximal urethra independent of pelvic floor muscle function [8]. Pessaries have been shown to improve functional urethral length, urethral closure pressures, and cough profiles [8,9]. Nygaard [10] demonstrated that a Hodge pessary prevented exercise-induced SUI in a one-time clinic testing session in 36% of subjects randomized to pessary versus tampon or no mechanical device. However, the literature contains only a few studies describing their effectiveness in treating SUI [11].

To address this knowledge gap, investigators in the Pelvic Floor Disorders Network designed the ambulatory treatments for leakage associated with stress (ATLAS) trial, a randomized clinical trial comparing three nonsurgical interventions for the treatment of predominant SUI in women: intravaginal continence pessary, behavioral therapy, and a combination of the two. The purpose of this paper is to describe the design of the trial, focusing on several key design features of interest to researchers in the field of female pelvic floor disorders, as well as other fields where similar design issues arise.

## Methods

### Design overview

Figure 1 depicts the overall ATLAS trial design. The primary aim of the study is to determine whether

treatment with a continence pessary is as effective as behavioral therapy for reducing SUI 12 weeks after randomization. We will also determine whether treatment with pessary plus behavioral therapy is more effective than either treatment alone. Secondary aims include identifying variables associated with successful therapy; and comparing treatment groups with regard to treatment adherence, irritative bladder symptoms, quality of life outcomes, patient satisfaction and medium-term efficacy and satisfaction.

### Study population

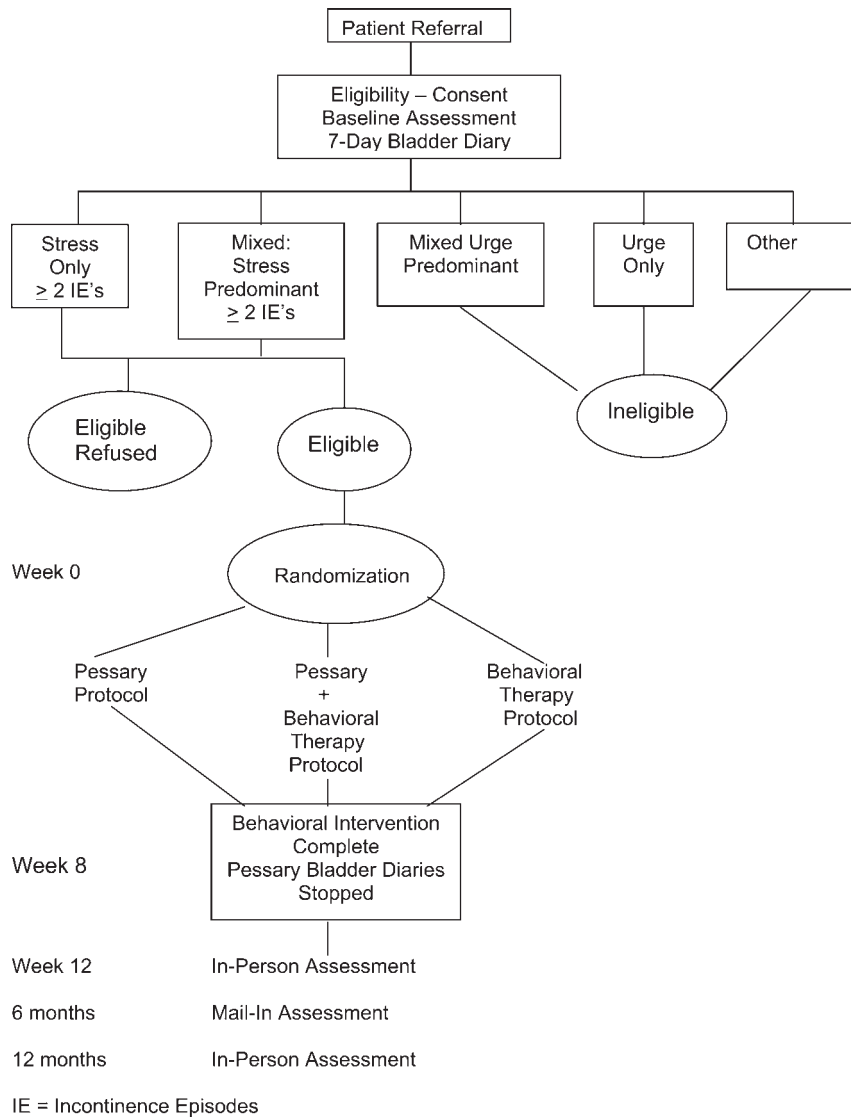
Participants are women aged 18 or older with symptoms of SUI or predominant SUI who desire non-surgical treatment. The design purposefully includes women with mixed incontinence to increase the generalizability of the results because, as demonstrated in a recent population-based, ethnically diverse epidemiologic study, the number of women with mixed stress predominant incontinence is about the same as the number who have pure stress incontinence [12].

### Baseline clinical evaluation

Inclusion and exclusion criteria are listed in Table 1. In addition to medical history and physical examination, assessment of pelvic floor muscle strength was conducted using the Brinks standardized grading system [13]. Post void residual volume is measured by catheterization or ultrasound. The Pelvic Organ Prolapse Quantification (POP-Q) is performed according to the guidelines established by the International Continence Society [14]. If the vaginal epithelium is severely atrophic by clinical judgment, the participant may be treated with vaginal or other forms of estrogen until the atrophy resolves, after which she is re-examined to ascertain eligibility.

### Primary outcomes

Two primary outcomes are evaluated at the 12-week postrandomization visit. The first primary outcome is the Patient Global Impression of Improvement (PGI-I) rating [15–17]. The PGI-I consists of a single item that asks the participant to rate improvement of her continence status using a seven-point Likert scale with the following anchors: very much better, much better, a little bit better, no change, a little bit worse, much worse, very much worse. Participants are considered “successfully” treated if they respond that they are “very much better” or “much better”. All other response options or receipt of any other treatment outside the ATLAS protocol for stress or urge incontinence symptoms defines treatment failure.



**Figure 1** ATLAS trial design

The second primary outcome measure is the Pelvic Floor Distress Inventory (PFDI), a symptom inventory that includes a measure of bother for each symptom, quantified as not at all, somewhat, moderately or quite a bit [18]. Women who answer the PFDI Stress Subscale questions with “no” or with “yes” but also “none” or “somewhat” on the bother component will be considered successfully treated.

**Secondary outcome measures**

*Bladder diary*

Reduction of incontinence episodes is measured using a seven-day bladder diary completed

preintervention and at 12 weeks and six and 12 months postrandomization. A successful outcome is defined as  $\geq 75\%$  reduction in the frequency of incontinence episodes compared to the baseline frequency.

*Treatment side effects*

A physical examination is performed at each intervention visit and at 12 weeks and 12 months postrandomization to document vaginal erosions, bleeding or other adverse findings. Discomfort, incomplete bladder emptying and other symptoms possibly associated with either pessary use or pelvic floor muscle exercise are also ascertained.

**Table 1** Protocol inclusion and exclusion criteria

## 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
- Seven-day baseline bladder diary, the subject completed the bladder diary in an adequate manner on at least five out of seven 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 eight 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 six months postpartum
- 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
- Postvoid residual volume  $\geq 150$  mL
- Strongly desires surgery for stress urinary incontinence within 12 months
- Within three 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 two weeks)
- Previously participated in a behavioral therapy research trial or formalized clinical behavioral therapy program for urinary and/or fecal incontinence
- Vaginal foreign body (eg, exposed mesh or suture)
- Currently using a pessary or used one within the past two months (the participant may stop using the pessary for two months and be re-evaluated for participation at that time)
- Neurologic conditions that may impact on bladder symptoms, eg, Parkinson's, multiple sclerosis, or stroke

*Quality of life assessment*

Several validated measures are used to assess the effects of treatment on urinary incontinence, other pelvic floor symptoms and quality of life. The effects of treatment on activities of daily living are assessed using the Pelvic Floor Impact Questionnaire (PFIQ) [18]. The Medical Outcomes Study Short Form Health survey (SF-36) [19] is used to assess changes in overall health related quality of life. The Health Utility Item (HUI) [20], a single validated self-assessment question, is used to measure how a patient feels about her overall health status. The Questionnaire for Urinary Incontinence Diagnosis (QUID) [21] is used to assess frequencies of stress and urge incontinence symptoms. Severity of urinary symptoms is assessed by the two-item Hunskar Severity Index [22]. Changes in sexual function are characterized using the Pelvic Organ Prolapse-Urinary Incontinence Sexual function Questionnaire (PISQ-12) [23] and the Short Form Personal Experience Questionnaire (SPEQ) [24].

**Assessment schedule**

The primary outcome is determined at 12 weeks postrandomization. Data are collected in person at baseline prior to randomization, and at 12 weeks and 12 months postrandomization. At six months, an assessment is conducted by mail.

**Randomization**

Prior to randomization, patients are stratified with respect to type of incontinence (stress only versus mixed with stress predominant) and severity of incontinence (<14 total incontinence episodes versus  $\geq 14$  total episodes) per seven-day bladder diary. Participants are randomized using a permuted block randomization schedule to pessary alone, behavioral therapy alone, or combined pessary plus behavioral therapy. Any research staff involved in outcome data collection are blinded to the subject's randomization group.

## Interventionists

The interventionists are physical therapists (four), registered nurses (four), and certified registered nurse practitioners (two). Interventionists attended a two-day program of centralized training to prepare them to implement the ATLAS protocol. Training included didactic lectures, hands-on training and certification in pelvic floor muscle examination, training with live models and certification in the conduct of patient visits by direct observation of structured role play interactions.

## Intervention

Women in all treatment groups receive 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.

### *Intravaginal pessary*

At the first treatment visit, each participant randomized to pessary or combined treatment is fitted with a continence ring or dish pessary. Proper size is assured and, if the pessary is not retained, an attempt is made to improve the pessary fit. The participant is taught how to insert and remove the pessary and encouraged to do so at least once a week. After the initial fitting, the participant returns in one to two weeks to assess fit and troubleshoot any difficulties associated with pessary use. A speculum examination is done to ensure that there are no vaginal erosions or infection. To be consistent with the behavioral therapy group, participants in the pessary group complete a bladder diary daily for six weeks to control for the self-monitoring effect. If no pessary can be successfully fit after a minimum of three visits, the participants in the pessary alone group are considered treatment failures and referred to clinical care and follow-up per protocol.

### *Behavioral therapy*

Behavioral therapy consists of PFMT and exercise as well as skills and strategies for active use of muscles to prevent stress incontinence. Treatment consists of four clinic visits at two-week intervals. Participants complete a daily bladder diary throughout treatment. During visits two to four participants complete questionnaires to assess exercise performance, barriers to adherence and use of behavioral strategies.

### *Combined behavioral training and intravaginal pessary*

Treatment consists of four clinic visits at two-week intervals and includes the components of both behavioral therapy and pessary.

## Twelve-week post-treatment assessment

Twelve weeks after randomization, participants return to the Interventionist to receive an exercise maintenance plan after a physical evaluation of their exercise technique and adherence (for those participants in the behavioral therapy groups), and for preparation for the physical exam with an evaluator who is blinded to their treatment assignment. All treatment groups receive an individualized treatment maintenance plan.

The seven-day post-treatment bladder diary and the questionnaires are returned and reviewed for completeness by the evaluator. A urine dipstick is obtained to screen for urinary infection, and a physical examination performed, consisting of pelvic floor muscle strength assessment (Brinks) and visual inspection of the vaginal epithelium via speculum. All participants in pessary group will have removed the pessary prior to the examination.

## Sample size

The primary endpoint of this study is whether the participant responds that she is improved ("very much better" or "much better") on the PGI-I. The sample size calculation is based on previous trials where the endpoint was reduction in incontinence episodes, with the assumption that a woman who reduces the number of incontinence episodes by 75% will respond that she is improved [7,25–27]. This trial is powered (80%) to detect a 15% difference in the success rates of pessary and behavioral therapy. To assess whether combined therapy is more effective than either treatment alone, we assumed 60% as the upper bound for the success rate for either of the individual therapies and at least a 75% success rate for the combination therapy. With 150 subjects per group, there will be 80% power to identify a difference between 60% and 75% using a 5% level of significance.

## Interim analysis

An interim analysis is planned. Using East 3<sup>®</sup> (Cytel Software Corp., Cambridge, 2003), the necessary sample size with two interim looks is 150 subjects per group to achieve 80% power when there is a 15% difference (60% versus 75%) in the success rates. Using the O'Brien-Fleming (1979) stopping

rule, the  $\alpha$ -levels will be 0.00305 after 50% of the observations are obtained, 0.0183 after 75%, and 0.044 after all data have been collected. If the true difference is 15% as predicted, the powers at these three looks will be 16%, 53% and 79%. If the true difference is 20%, ie, 55% versus 75%, the powers at these three looks will be 37%, 80% and 95%.

### Statistical analysis

The primary analysis will be an intent-to-treat analysis. A secondary per protocol analysis will be conducted to examine efficacy of intervention only among participants who completed the treatment interventions and provided final results at the 12-week postrandomization visit. Logistic regression, adjusting for baseline frequency of incontinence, the two stratification variables, and other factors as covariates, will be used to determine whether the two treatment arms have different "success" rates. Similarly, each of the two individual treatment arms will be compared to the combination arm in separate analyses. The combination arm will only be considered better than the individual arms when both tests are significant at the 5% level of significance. Therefore, there is no need to adjust for the number of tests being performed.

Similar analyses will be performed for other dichotomized outcome measures. General linear models with similar covariates will be fitted to continuous outcome measures, such as quality of life summary scores. To identify predictors of successful treatment outcome, success based on the PGI-I will also be modeled by logistic regression after including these potential predictors.

### Results

The ATLAS trial is currently underway. Recruitment goals are on target to date and the trial is projected to be completed in 2007. The trial is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### Comment

There were several issues that arose during the design and implementation of the trial that ultimately resulted in protocol changes.

### Choice of study design

This trial compares two non-surgical treatments, each implemented alone, and a combination of the two treatments. There is no untreated or placebo control group, primarily because this would not be

considered ethical in light of the known efficacy of behavioral intervention. Therefore, it is not possible to test whether there is an interaction between the two primary treatments (behavioral treatment and pessary). The combined therapy group may be more efficacious due to one of two reasons: either 1) the combination of the two therapies is better than either therapy individually, or 2) the subject is able to select the therapy that fits her life style better and then will adhere to that therapy more successfully. At each intervention visit and at the three-month visit, every subject is asked about adherence to treatment. This may enable the analysis to differentiate between the two reasons.

### Inclusion criteria for defining stress incontinence

The population of interest in this trial is adult women with symptoms of stress urinary incontinence and without concomitant conditions that could cause or contribute to urinary dysfunction. That deceptively simple statement represents one of the chief challenges in designing studies of urinary incontinence and in interpreting published studies. While urinary incontinence itself can be defined concisely, defining it in terms specific enough for clinical research is more complicated. There is no consensus in the clinical or research community as to a definition of clinically significant incontinence by frequency of incontinence episodes, amount of urine lost, or type of incontinence. This is further complicated by the highly individual experience of the life impact of urinary incontinence. Characteristics describing incontinence can be measured in a variety of ways requiring the investigators to make choices about degree of severity and homogeneity of the study population.

For the ATLAS trial, several parameters defining and describing women with incontinence were chosen, guided by evidence when possible or by the investigators' experience when necessary. To capture incontinence as a chronic rather than transient condition, the duration of symptoms was set at a minimum of three months. Incontinence frequency was chosen to define a minimum level of symptoms so the interventions would have a measurable effect, while still representing a "typical" level of severity at which many women seek non-surgical treatment. The investigators chose at least two episodes of stress incontinence documented on the seven-day bladder diary.

Type of incontinence is problematic for a number of reasons. While textbooks define stress incontinence as distinctly different from urge incontinence, women do not necessarily experience their symptoms in such a clear-cut way. In addition, only a minority of women have "pure" stress incontinence

symptoms. For the ATLAS trial, the investigators determined that it was most appropriate to include women with stress or "stress-predominant" incontinence, defined as more stress incontinent episodes than other types of incontinent episodes (urge or unspecified) on the bladder diary.

### Exclusion criteria

As we considered issues of inclusion and exclusion criteria, concern arose about the comparability of the treatment groups. On a practical level, we recognized that some participants randomized to the pessary alone condition would fail if they could not be fitted successfully with a pessary. In reviewing how many participants might not be fitted successfully, we entertained the possibility that the pessary alone group could be disadvantaged by this fact.

To overcome this potential disadvantage, we considered the possibility of attempting a pessary fitting in all eligible participants, excluding those who could not be fit, and then randomizing those participants who demonstrated potential to benefit from a pessary by virtue of a successful fitting. The down side of this approach was that we would be unnecessarily fitting pessaries for many participants who would not use them. The other disadvantage is that the results would be generalizable only to patients who had a successful fitting.

Eventually we decided to accept the potential failure of pessary fitting as part of clinical practice and adopted an intent-to-treat approach. In doing so, we also recognize that there will be a group of participants assigned to pelvic floor muscle training who will not be able to identify or exercise their muscles initially, which in the opinion of some clinicians would make this treatment futile.

### Duration of interventions

One of the main challenges in designing this trial was deciding how to compare two treatments that, in usual clinical practice, have a different number of visits and duration of active intervention. Ordinarily, a pessary fitting can be accomplished in one or two visits and takes effect immediately. Because behavioral treatment is based on learning new skills and building muscle strength, it generally takes effect more gradually and patients are seen in more than two visits over a period of weeks and sometimes months. In designing a clinical trial one ordinarily attempts to make treatments of equal duration and intensity, so that differences in outcomes are attributed not to these factors, but to the essential differences in the nature of the interventions.

In the case of this trial, adopting a short timeframe for intervention would undermine the

effectiveness of the behavioral intervention. Yet adopting a longer timeframe would have been unnatural for implementing the pessary treatment. After considerable discussion, we decided to design a pragmatic trial that adopted the time frames used for these interventions in usual clinical practice, yet limited the duration of behavioral treatment to eight weeks, which is adequate for most patients.

### Use of the bladder diary

One component of the behavioral treatment protocol is a daily bladder diary. The purpose of the diary is to increase patients' awareness of their bladder habits and the situation in which they will need to use their continence skills. In addition, it helps the behavioral interventionist identify patterns in the patient's incontinence, and use them to help the patient implement behaviors to prevent incontinence episodes that occur in specific circumstances as well as reinforcement of progress over the course of treatment. However, it seemed apparent that simply keeping the diary could have a self-monitoring effect and influence improvement.

While some investigators believed that the self-monitoring effect is intrinsic to behavioral intervention, others were concerned that it was an added advantage for the behavioral groups. Therefore, it was decided that all three groups would complete six weeks of bladder diaries during intervention to control for this potential self-monitoring effect. The advantage of controlling for the bladder diary in this way is that any differences between the treatment groups will not be attributable to the independent effects of the diary.

### Primary outcome measure

Non-surgical therapy does not usually result in perfect continence. Thus, it is important to determine how much improvement should define an outcome as successful. Since incontinence is inherently a subjective experience, having a subject determine what level of improvement constitutes success for her is a logical choice in study design, provided appropriate tools are available to measure this. Validated condition-specific measures are now available for urinary incontinence. Thus, the primary outcome was defined using the Patient Global Impression of Improvement (PGI-I) rating scale [15]. The PGI-I consists of a single item that asks the participant to rate her continence status using a seven-point scale: very much better, much better, a little bit better, no change, a little bit worse, much worse, very much worse. However, defining "success" as a dichotomy requires dividing

these responses into two groups; based on the instrument's validation studies. The investigators defined "successful" treatment for responses of "very much better" or "much better." In addition, any incontinence treatment outside the ATLAS protocol also determines treatment failure.

The other primary outcome measure, the PFDI, more fully characterizes the symptom of SUI with a "bother" component, which has been found to be sensitive to change and is also a reflection of the impact of this symptom on quality of life. These primary outcomes are supplemented with a more objective condition-specific outcome metric, the seven-day bladder diary, which has been shown to be a reliable measurement method for evaluating the frequency of incontinence episodes and micturition [28].

### Timing of outcome assessment

Related to the issue of treatment duration was the decision about when to measure outcomes. One could potentially evaluate the effects of pessary quite soon after it is placed, whereas behavioral treatment typically requires several weeks at minimum for efficacy. The 12-week postrandomization time point was selected to ensure that participants in all three treatment conditions had adequate opportunity to benefit.

In many trials, the timing of the outcome assessment is based on when patients are expected to complete treatment. However, with the different durations of the pessary and behavioral treatments, this approach would result in very different time points for evaluation of outcomes. Therefore it was necessary to establish a time point for outcome assessment that was anchored to the time of randomization, rather than treatment completion, to equalize the time between treatment initiation and outcome assessment.

With this decision to anchor the assessment to randomization, it seemed only reasonable to anchor the duration of the interventions to randomization as well. The disadvantage of this, however, is that the "clock starts ticking" at randomization. Therefore, it is important to initiate treatment immediately to ensure that the participant has the full benefit of the eight-week intervention period. Any delay in treatment initiation reduces the participant's exposure, and significant delays could disadvantage the behavioral treatment arms and threaten the internal validity of the study. Research staff learned to prepare for treatment initiation at the time of randomization and to delay randomization for patients who had planned absences that would interfere with receiving the complete treatment.

### The challenge of combined treatment

At some sites, the interventionists were able to implement both the pessary and behavioral protocols. At other sites, however, a single interventionist did not have both skill sets and patients in combined therapy had to visit two separate providers. In some cases this required an additional visit or a separate visit to a different site. For example, a physical therapist might be trained in the behavioral protocol but not have the skills needed for fitting pessaries. This sometimes created a logistical issue, as both interventionists would theoretically need to be available at the time of randomization. Careful planning was necessary at each individual site and a "randomization" and "outcomes" visit plan was required by the DCC prior to trial initiation at each site, in order to ensure that evaluators remained blinded and participant burden was minimized.

### Breadth of treatment

Because stress incontinence so often presents with concomitant urge incontinence [12], it was decided very early in the design process that women with mixed incontinence (both stress and urge) would be included. This decision was very important for ensuring generalizability of the results. However, it created the issue of how to respond to women with urge incontinence. In behavioral treatment, urge incontinence is typically treated along with stress incontinence by teaching patients how to use their muscles to control urgency. In contrast, the pessary is thought to improve stress incontinence specifically, and its effect on urge incontinence is unknown. Therefore including urge strategies in the behavioral arms would disadvantage the pessary group.

The study investigators and interventionists had varied opinions on whether to exclude specific instructions for managing urgency from all three interventions, allow them in the behavioral arms as a part of usual behavioral treatment, or to provide them to participants in all three groups. If provided to all groups, then the effect of this treatment component would be controlled. However, patients in the pessary only group would then be somewhat "contaminated" with behavioral therapy and we would not be able to determine the effect of pessary alone.

As a compromise, it was decided that all subjects would receive a handout with general incontinence management instructions, which contains information about controlling urgency, as well as fluid and constipation management. No direct vaginal palpation or additional instructions are provided to the pessary alone group beyond what is on the

instruction sheet. The consensus was that providing this basic information reflects good clinical practice and should be provided to all women undergoing any incontinence treatment. This pragmatic approach was intended to maximize the external validity of the trial.

## Conclusion

The results obtained from this trial will impact significantly on our ability to counsel women interested in pursuing non-surgical treatment for SUI. We will determine if one treatment is more effective than the other for the treatment of SUI, and whether combining these treatments will result in better outcomes than either treatment alone. We hope that the findings will provide insight into the type of patient who is most successful and satisfied with one or both of these non-surgical treatment modalities and identify predictors for failure. The trial will also provide information with respect to the effects of treatment on condition-specific and general quality of life outcomes. Behavioral therapy and continence pessaries (alone or in combination) have not been directly compared in a large randomized trial. The findings of the ATLAS study will have immediate clinical impact, particularly if the findings identify cohorts of women who respond differently to these forms of therapy.

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