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A randomized clinical trial of how to best position retropubic slings for stress urinary incontinence: Development of a study protocol for the mid-urethral sling tensioning (MUST) trial

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ABSTRACT

The goal of this trial is to compare two techniques for tensioning retropubic midurethral slings: a Mayo scissor between the tape and urethra vs. a Babcock clamp creating a measured loop underneath the urethra. The primary outcome is a composite of abnormal bladder function at 12 months post surgery. Abnormal bladder function is defined as bothersome stress incontinence or worsening over active bladder symptoms, a positive cough stress test, re-treatment of stress urinary incontinence, post-operative urinary retention requiring either catheterization beyond 6 weeks or surgical intervention. Secondary outcomes include the duration of post operative urinary retention, quality of life scores, and physical examination. This article describes the rationale and design of this clinical trial, which will be of interest to those who care for patient with pelvic floor disorders such as stress urinary incontinence.

1. Introduction

In 1996, Ulmsten described the tension-free vaginal tape for stress urinary incontinence (SUI). The technique for placement was specified as having the sling "loosely placed – without elevation – around the urethra", and it was intended for intra-operative cough stress testing (CST) to be performed to determine the tension of the tape [1]. Since that introduction, a number of techniques have been described as CST can not always be performed in the operating theatre. Reasons for this include the tape being placed with the patient under general anesthetic or a deep sedative that does not allow the patient to follow commands. As such, others have advocated for intra-operative suprapubic pressure (Credé's maneuver) [2], the use of an instrument as a spacer between the urethra and tape [3], and a standardized way of measuring the amount of tape left in the suburethral space by using a Babcock clamp to create a loop of free tape [4].

Few studies on how retropubic tapes should be tensioned exist [5–9]. These papers have mixed results and are limited to evaluation of provocative cough stress testing in the operating room. Some studies have found that women with intra-operative cough stress test did not have different outcomes compared to those who had the tension of their tapes determined by placement of surgical scissors as a spacer [5,7]. In contrast, others found superior improvement in SUI symptoms when an intra-operative cough stress test was used rather than no provocative testing [6].

Given the minimal body of data on the best practice of intra-operative retropubic sling tensioning, a well designed trial of two standardized techniques is required. The impact of such a study would be far reaching. If a preferred technique could be determined by such a study, it could facilitate training, thus improving patient outcomes, decreasing complication rates, and setting a standard that provides medico-legal reference in the future.

2. Materials and methods

2.1. Rationale for tensioning methods used in this protocol

To determine which techniques were currently used by surgeons in Canada, an anonymous questionnaire was administered at an interdisciplinary Female Pelvic Medicine & Reconstructive Surgery (FPMRS) conference in Calgary, Alberta, Canada. This conference was attended by the majority of FPMRS surgeons in Western Canada, as well as a small proportion of surgeons from Eastern Canada. Of the 21 surgeons in attendance, 19 responded that they routinely performed retropubic midurethral slings. Respondents

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were asked "What is your practice for establishing the tension/tightness of a retropubic midurethral sling?" and given the opportunity to provide one or more responses. All answered the question with one to three answers. The most frequently reported technique was to place curved Mayo scissors between the sling and urethra (57.9%, n = 11). Other reported techniques included applied pressure on the bladder by the surgeon, "Credé's maneuver" (15.8%, n = 3), "eye balling" or visual inspection of tension without an instrument (15.8%, n = 3), the use of a Babcock clamp over a measured portion of the mesh (10.5%, n = 2), urethroscopy (5.3%, n = 1), placement of Metzenbaum narrow scissors between the sling and urethra (5.3%, n = 1), a dilator between the sling and urethra (5.3%, n = 1), a dilator in the urethra (5.3%, n = 1), and intra-operative cough testing (5.3%, n = 1).

In deciding which techniques to compare, it was decided that one arm of the study should evaluate the most frequently reported method and the technique used most often by the surgeons designing the study, use of Mayo scissors as a spacer. In choosing a second arm of the study, we wanted a highly reproducible technique that could be standardized between surgeons. Provocative techniques, such as intra-operative cough tests and Credé's maneuvers were decided against as level of sedation for coughing, and force used during Credé's, can not be standardized between patients and surgeons. Additionally, provocative measures can not be performed under general anesthetic (GA). In our experience, a significant portion of women opt for GA during their procedure. Visual inspection without an instrument was decided against, as there would be no way to objectively measure the amount of tension for each case. Dilators were decided against, as there was no consensus on what size of dilator should be used. While not a frequently reported technique, the use of a Babcock clamp over a measured portion of the mesh [4] was felt to be the most reproducible. This is because the distance in the "loop" held by the Babcock could be measured with a surgical ruler to an exact length for all cases.

2.2. Study design

We developed a randomized clinical trial (RCT) with superiority study design to be carried out at two Urogynecology centers in western Canada (Calgary and Edmonton, Alberta). Outcomes of retropubic mid urethral slings (Boston Scientific Advantage Fit) tensioned by two standardized non-provocative techniques: surgical scissor as a spacer vs. creation of a tape-loop with babcock clamp [3–5] will be compared. Study flow and design are shown in Fig. 1.

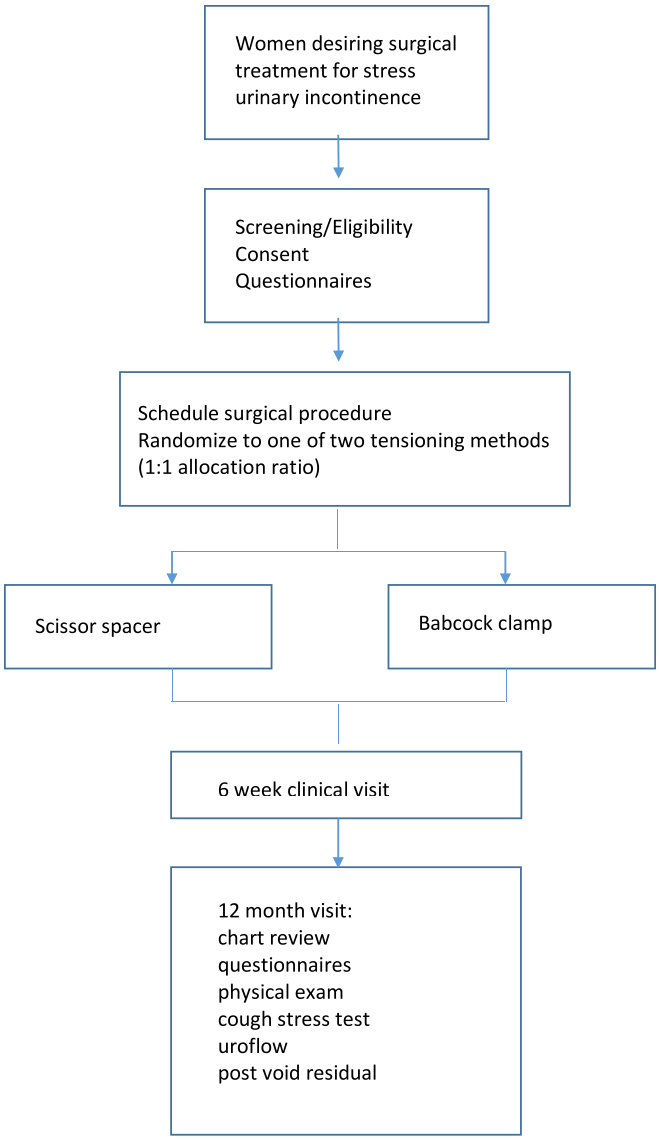

Fig. 1. Study design flow diagram.

2.3. Participant selection

2.3.1. Inclusion criteria

Women aged 18 or older who have elected for surgical management of symptomatic stress urinary incontinence. They must have the ability to read and write in English for completing informed consent and quality of life forms. Patient must consent to participation in the RCT. Prolapse surgery at time of TVT placement is allowed within the study parameters.

2.3.2. Exclusion criteria

Women who elect for non-surgical management of their symptomatic stress urinary incontinence, or who decline participation in this RCT. Those who have had a prior incontinence procedure, or who have pre-existing urinary retention defined as post-void residual >100 mL are not eligible. Women who are clinically felt to have overactive bladder as the predominant cause of their urinary incontinence are excluded. Women who have asymptomatic stress urinary incontinence (latent SUI) are not included, as the lack of symptoms means the condition should have minimal impact on their quality of life and therefore, we would be unable to detect any positive difference in these parameters as a result of the surgical procedure.

2.4. Recruitment

Women referred to any of the collaborating clinicians, who fulfill the inclusion and exclusion criteria will be offered the opportunity to join the trial. The woman's clinician will briefly introduce the study, then the woman will be referred to the study nurse who is not involved in the woman's routine clinical care. The study nurse will explain the trial in full and provide detailed information. Women may have further discussion with their surgeon if they wish, and women who decide to participate will sign a consent form. Recruitment began in September 2015. During the first 7 months, 99 women enrolled in the study. Using a projected recruitment rate of 8–10 participants per month, enrollment is expected to finish in September 2018.