Randomized Clinical Trial Comparing TVT SECUR System (TVT S) and Trans Vaginal Obturator Tape (TVT-O) for Surgical Management of Stress Urinary Incontinence

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Study Protocol

January 6, 2007
Revised Feb 23, 2007
Revised Aug 5, 2007
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Objective

To compare the efficacy and complications of the TVT SECUR system (TVT S) and trans-vaginal obturator tape (TVT-O) procedures for the surgical management of female stress urinary incontinence.

Introduction

Stress urinary incontinence continues to be a common problem significantly impacting the quality of life of women. After conservative measures are unsuccessful, surgical management is usually pursued. There have been many surgical techniques devised for treating this condition. However, there is still no consensus about the best surgical procedure.

The new minimally invasive mid urethral tape procedures have revolutionized the treatment of stress urinary incontinence. Ulmsten introduced the first of these, the TVT in 1996. Although long term results have been good to date, concerns regarding complications of bladder injury, retropubic hematoma, large vessel injury, and gastrointestinal tract injury have emerged. To avoid the retropubic space Delorme introduced the trans obturator tape (TOT) procedure in 2001. Since then many studies have randomly compared the retropubic and obturator approaches. Efficacy was similar between the two approaches in all studies. All found increase OR time for the TVT procedure. Bladder injury was more common with the TVT procedure. Vaginal injury was found to be more common with the TOT in one study. Otherwise the procedures were comparable.

The TOT can be performed either from an outside in or inside out surgical approach. Concern with either approach is injury to the obturator nerve and vessels as the device is past through the obturator foramen. In addition the incidence of post operative groin and thigh pain has arisen as the device does pass through the adductor tendons and skin. The TVT SECUR (TVT S) is a new surgical device for the treatment of stress incontinence. The device does not pass through the obturator foramen of adductor tendons and skin. Therefore it is hypothesized that it will lead to less surgical
complications, less post operative pain and be less complicated to perform. To our knowledge there have been no human studies with the TVT S system. Our objective is to compare in randomized fashion the new TVT S to the TOT approach.

Patient Selection

Inclusion Criteria

Female patients with symptoms of stress urinary incontinence and a positive cough test who require surgical management. Cough test is positive when leakage of urine is seen from the urethra synchronously with the patient performing a cough or valsalva manuver with a comfortably full bladder in the lying or standing position.

Exclusion Criteria

- Women with predominantly symptoms of urge urinary incontinence
- Presence of prolapse greater than Pelvic organ prolapse quantification (POPQ) Stage 1 or prolapse requiring surgery
- Detrusor overactivity on cystometrogram at urodynamic testing
- Previous surgery for incontinence
- Intrinsic sphincter deficiency (MUCP<20 cm H₂O or Q –tip <30º)
- Voiding dysfunction with postvoid residual >100 cc

Study Design

If patients satisfy these criteria, consent will then be obtained for entry into the study. Pre-operative assessment will include:

- History and general assessment
- Urogynecologic examination (included prolapse assessment by POPQ exam)
- Urine dipstick and catheter urine for culture
- Complete multichannel urodynamics (performed in accordance with criteria established by the ICS\textsuperscript{11}).
  - Cystometrogram
  - Urethral presser profilometry (MUCP measurement)
  - Uroflow and post void residual
- Cough test performed at capacity in lying or standing position
- Q-tip test: Q tip inserted into urethra to level of bladder neck – Patient then performs a valsalva and the angle the end of the Q-tip makes with the horizontal plane is measured.
- Patient Questionnaire (Completed preop, at 8 weeks post op, and at 1 year)
  - Urinary Distress Impact Questionnaire (UDI-6)\textsuperscript{12} – for severity of incontinence
  - Incontinence Impact Questionnaire (IIQ-7)\textsuperscript{12} – for social/emotional impact of incontinence.

Once the pre-operative assessment is complete patients will then be booked for surgery. In the operating room the patient will be randomized by opaque sealed envelopes to the TVT S or TVT-O procedure.

All surgery will be carried out under local anesthetic with sedation. Patients will be pre-medicated with one tablet percocet and naprosyn 250 mg one hour preoperative. The amount of anesthetic required will be recorded. Standard local anesthetic mixture will be 1% xylocaine 20 mL combined with 1% xylocaine with epinephrine 20 mL. The TVT-O procedure will be carried out as described by Delorme\textsuperscript{8}. The TVT S procedure will be carried out as described by Gynecare utilizing the “hammock position” technique for the tape. After the procedure 240 cc of fluid will be placed into the patient’s bladder through the foley, then it will be removed. In the recovery room the patients voided volume and post void residual will be recorded. If the residual is >150 cc or the patient voids <2/3 of the total bladder volume the patient will either be taught intermittent self catheterization or have a foley inserted. She will then be discharged home. The duration the patient requires the use of a catheter for voiding dysfunction will be recorded by the physician when the catheter is discontinued.
The patient will be assessed in 8 weeks. At that time history and examination will be conducted. Subjective questionnaires will be filled out. The patient will then be seen one year from surgery and undergo history, exam, cough test (bladder filled to capacity of 300cc), uroflow and post void residual. Assessments will not be done by the operating surgeon. A blinded physician will conduct the examinations. Adverse events as defined as any clinical outcome which has a negative impact on the patient will be recorded in the intra operative or post operative data collection forms. Examples would be intraoperative injury, bleeding requiring transfusion, post operative infection, vaginal mesh erosion, etc.

**Primary outcome**

Objective cure as defined by the cough test at one year from surgery

**Secondary outcomes**

Subjective cure as defined as the absence of symptoms of stress urinary incontinence one year from surgery. In addition quality of life scores from the questionnaires will be included.

Other outcomes

- Perioperative complications: bleeding, injury, anesthetic required, operating time
- Post operative complications: pain (Visual analogue scale: VAS Scale 0-10), infection, voiding dysfunction, groin discomfort

**Statistical Analysis**

Power Calculation: Literature supports an objective cure of stress incontinence with TOT at one year of 90%. It was decided that a 15% difference in the success rate between the two procedures would be clinically significant. Therefore to detect a 15% difference with an \( \alpha \) of 0.05 and power of 80%, 68 subjects would be required in each group. Therefore a total of 136 patients will be required.

Data will be analyzed by EXCELL software. Student t-test and ANOVA will be used for continuous variables. Chi square and Fisher exact tests will be used for proportions.
Data Collection Forms

Data collection forms will be made up to record patient demographic, history, and examination variables. Forms will also be drafted for use to collect intra-operative information. Post operative follow up data will also be collected either form the physicians chart or data sheet. All data will be entered into a computer database software program (EXCELL).

Informed Consent

This will be done by the nurse research coordinator. Patient confidentiality will be maintained at all times. Records and data base to be stored on secured computer. Patients will be recruited through the practices of Dr. Maslow and Dr. Gupta.

Data Disclosure/Publication

Data will be published in summarized fashion. All data published will be anonymous to the patients involved.

Project Flowchart
Patient meets entry criteria

Patient Consented

Patient demographics & pre op info collected

Patient randomized to TVT-O vs TVT S

TVT-O Group
  F/U 8 weeks
  F/U 1 year

TVT S Group
  F/U 8 weeks
  F/U 1 year
References