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CLINICAL ARTICLE

Comparison of the TVT SECUR System "hammock" and "U" tape positions for management of stress urinary incontinence

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ABSTRACT

Objective: To assess the efficacy and complications associated with use of the TVT SECUR System device with placement of the tape in either a "hammock" or "U" position for management of stress urinary incontinence (SUI). *Methods:* A prospective study of patients with SUI allocated into one of two groups: "hammock" or "U" tape placement. Preoperative urodynamic results were compared with results at the 6-month and 1-year follow up. Outcome measures were objective cough test assessment and subjective patient responses to a questionnaire at follow up. *Results:* Of 82 patients included in the study, 43 comprised the "hammock" group and 39 comprised the "U" group. The objective cure rate at 1-year follow up was 62.8% (n = 27) in the "hammock" group and 71.8% (n = 28) in the "U" group. At 1-year follow up, the subjective cure, improvement, and failure rates for the "hammock" group were 60.5%, 13.9%, and 25.7% respectively, and 69.2%, 12.8%, and 17.9% respectively, for the "U" group. *Conclusion:* The efficacy of the TVT SECUR System was lower (<72%) than the cure rates reported for other TVT procedures; further studies are required.

1. Introduction

The introduction of tension-free vaginal tape (TVT) in 1995 [1] was a significant step in the management of stress urinary incontinence (SUI) owing to its low complication rate and ease of performance compared with previous methods of similar efficacy. Two new operative techniques were described, based on the use of TVT, to overcome the necessity for cystoscopy. The first was the outside-in transobturator technique (TOT) in 2001 [2], followed by the inside-out technique (TVT-O) described in 2003 [3].

Use of these two techniques demanded extensive knowledge of the anatomy of the pelvic floor and surgical expertise. A new technique, the TVT SECUR System (Ethicon; Somerville, NJ, USA), has been introduced in recent years with the aim of providing similar efficacy as previous methods, but with greater ease of performance and a lower risk of complications. The TVT SECUR System consists of a polypropylene tape measuring 8 cm long and 1 cm wide; the tape can be placed in either a "U" position, similar to the TVT procedure, or a "hammock" position, similar to the TVT Obturator System (Ethicon), using the same instrument [4].

The aim of the present study was to compare the efficacy and complications associated with placement of the TVT SECUR System device with the tape in either a "hammock" or "U" position for management of SUI.

2. Materials and methods

A prospective study was conducted at the Department of Obstetrics and Gynecology, University of Athens, Greece, between November 1, 2006 and September 15, 2009. The study received approval from the hospital's Ethical Committee and the participants provided written informed consent. Inclusion criteria were patients with SUI who could be managed operatively and were willing to participate in the study. Exclusion criteria were patients with a preoperative maximum urethral closure pressure (MUCP) of less than 20 cm H_2O, urodynamic findings of detrusor overactivity, history of anterior vaginal wall surgery, or prolapse greater than stage I according to the International Continence Society Classification. Diagnosis of SUI and detrusor overactivity was based on cystometric findings.

Patients had a full history taken and a complete gynecological examination at the initial visit. Negative urine analysis and culture results were a prerequisite prior to undergoing urodynamic investigation. Preoperative urodynamic investigations included filling and voiding cystometry, uroflow, and urethral profilometry (Triton; Laborie, Mississaugua, Canada). Preoperative assessment of the severity of urinary incontinence was determined according to the Ingelman-Sundberg scale [5].

Patients meeting the inclusion criteria were allocated alternatively to undergo the TVT SECUR System procedure with the tape placed in either a "hammock" or "U" position.

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The procedure was performed using epidural anesthesia in all patients by the same experienced surgeon. The procedure to place the tape in the "U" position was performed as follows: The patient was placed in the lithotomy position and a urethral Foley catheter was placed to empty the bladder. The vaginal wall was grasped at each side of the urethra with Allis clamps. A sagittal incision measuring 1–1.5 cm was made, starting approximately 1 cm from the external urethral meatus. Using a small pair of blunt scissors, two small paraurethral dissections were made directed at 45° from the sagittal midline. A rigid catheter guide was placed and was moved to the side of the TVT SECUR device placement. The procedure was then repeated on the other side. The tip of the needle holder was placed over the release wire and inside the straight grooved end of the inserter, clamping the two together. Holding the needle holder, the inserter and the device were placed into the dissected paraurethral tissue on the right and left side of the urethra until the device was firmly in the connective tissue. Cystoscopy was performed to exclude damage to the bladder or urethra. Positioning of the tape was assessed by the patient performing a cough stress test. Final adjustments, if needed, were made by reconnecting the needle holder to the inserter. At the end of the operation the inserter was removed from the device by pulling the release wire using a needle holder; the inserter was then removed through the incision. A vaginal pack was placed for a few hours and the catheter was removed the next morning. Residual urine volume was checked before discharge and a residual of less than 100 mL was considered normal.

The procedure to place the tape in the "hammock" position was performed as follows: Using the needle holder, the inserter and device were inserted into the previously dissected paraurethral incision as described above, on the patient's right side. The inserter tip was oriented at an angle of 45° from the midline, toward the ischiopubic ramus, while holding the needle holder and inserter parallel to the floor. The inserter tip was approximately in the 9 o'clock position or parallel to the floor (patient's right side). The inserter was advanced until it contacted the inferior edge of the pubic ramus; while light constant contact was maintained with the bone, the device was advanced until it was firmly into the obturator internus muscle. The same process was followed for insertion of the second inserter and adjustment of the tape was the same as that described above. Removal of the inserters and skin closure was performed as described above.

During both tape-positioning procedures, adjustment of the tape was made intraoperatively; the bladder was filled with 350–400 mL of normal saline or up to maximum cystometric capacity. The patient then performed the cough stress test (forceful coughing performed 6–7 times) and the tension applied to the tape was the minimal tension required to achieve no leakage of urine during the test.

Postoperatively, patients underwent clinical examination at 4 to 6 weeks. Follow-up assessment occurred at 6 months and 1 year and included examination of urine and urine culture, clinical examination, filling and voiding cystometry, and uroflow. Objective assessment was based on the findings of a cough stress test at 1-year follow up. Objective cure was defined as the absence of urine leakage during the cough test performed in the lithotomy or upright position. Improvement was defined as the loss of a few drops of urine after repeated coughing, whereas failure was defined as the loss of a greater amount of urine. Subjective cure, improvement, and failure were assessed using a simple questionnaire at the follow-up examination at 6 months and 1 year to examine whether patients felt cured, improved, about the same, or worse after the operation.

To detect a statistically significant difference between the cure rates of the "hammock" and "U" procedures, the required sample size, calculated retrospectively, was 567 patients in each group (α level of 0.05 and β level of 0.10).

Statistical analysis was performed with MedCalc version 7.6.0.0 (MedCalc Software, Mariakerke, Belgium) using the *t* test for paired samples and the Wilcoxon signed rank test. $P<0.05$ was considered statistically significant.

Table 1
Patient's characteristics (n = 82).[a]

Characteristics	"Hammock" position (n = 43)	"U" position (n = 39)	*P* value
Age, y	58.8 ± 10.2	57.6 ± 11.0	>0.05
Parity	2.0 ± 0.91	1.90 ± 0.9	>0.05
BMI	26.7 ± 1.64	26.4 ± 1.55	>0.05
Menopausal	34 (79.1)	30 (76.9)	

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).
[a] Values are given as mean ± SD or number (percentage).

3. Results

A total of 87 eligible patients with SUI were included in the study: 45 allocated to the "hammock" group and 42 to the "U" group. Five patients did not attend for follow up and were excluded (2 from the "hammock" group and 3 from the "U" group), leaving 82 women included in the study. Patient's characteristics were similar between the groups (Table 1).

Preoperative urodynamic findings and at 6-month and 1-year follow up are shown in Tables 2 and 3 for patients in the "hammock" and "U" groups, respectively. No differences between the preoperative findings and follow-up results were observed in either group ($P>0.05$). However, it should be noted that study was underpowered to detect a difference because more than 500 patients in each group were necessary.

The objective cure rate based on the cough test at 1-year follow up was 62.8% (n = 27) in the "hammock" group compared with 71.8% (n = 28) in the "U" group. Overall, the efficacy of the TVT SECUR System was 67.1% (n = 55). Subjective cure, improvement, and failure rates based on the responses to the questionnaire at the 6-month and 1-year follow up are presented in Table 4. The subjective cure rate at 1-year follow up was 60.5% (n = 26) in the "hammock" group compared with 69.2% (n = 27) in the "U" group. De novo detrusor overactivity and de novo urgency were seen in 7.0% (n = 3) and 9.3% (n = 4), respectively, of patients in the "hammock" group, and in 7.7% (n = 3) and 10.2% (n = 4), respectively, of patients in the "U" group.

There were no cases of significant intraoperative bleeding or hematoma formation and the incidence of postoperative lower urinary tract infection was 4.6% (n = 2) for patients in the "hammock" group and in 5.1% (n = 2) for patients in the "U" group. Rejection of the tape did not occur in any patient.

4. Discussion

The TVT procedure consists of application of a prolene mesh tape without tension around the mid-urethra, and without fixation in the pelvis [1]. The tape provokes changes in the paraurethral connective tissue metabolism and improves tissue properties, which may lead to reinforcement of the pubo-urethral ligament and the suburethral vaginal hammock, and provide a long-term cure for SUI [6]. Recent studies indicate that the TVT procedure does not affect proximal urethral mobility and conclude that cure of SUI does not require the

Table 2
Urodynamic findings preoperatively and at the 6-month and 1-year follow up for patients undergoing the "hammock" procedure (n = 43).[a]

Urodynamic results	Preoperative	6 months	1 year	*P* value
First desire, mL	110.1 ± 20.5	112.3 ± 16.5	109.07 ± 15.08	>0.05
Maximum cystometric capacity, mL	397.6 ± 58.0	401.6 ± 53.6	397.9 ± 48.13	>0.05
Maximum flow rate, mL/s	25.6 ± 5.5	24.9 ± 4.7	24.0 ± 4.39	>0.05
Postvoid residual volume, mL	13.02 ± 15.04	15.8 ± 12.19	14.4 ± 13.8	>0.05

[a] Values are given as mean ± SD.