Comparison of Tension-free Vaginal Tape Versus Transobturator Tape in Women with Stress Urinary Incontinence

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Abstract

Objective: This study compared the Tension-free vaginal tape (TVT) and Transobturator tape (TOT) procedures for surgical treatment of stress urinary incontinence in women.

Materials and methods: This prospective non randomized clinical trial was conducted in Vali-e-asr hospital from March 2001 to March 2005. A total of 71 patients with clinical and urodynamic diagnosis of Stress urinary incontinence (SUI) were enrolled in the study. Patients were divided into two groups and underwent TVT or TOT procedures. Mean operation time, cure rate, post operative urinary retention, bleeding and infection were compared between two groups. SPSS software was used for statistical analysis. Chi square and fisher exact test calculated the effects of the nominal variables. Mean difference of quantitative variables were compared by student's T- test. P ≤0.05 was considered statistically significant.

Results: There was no significant difference in mean time of operation and peri-operative complications among groups. Urinary retention was 13.8% (n=5) in the TVT group versus 2.8% (n=1) in TOT group (NS). The rates of cure (91.6% vs 91.4%), improvement (5.6% vs 8.6%) and failure (2.8% vs 0) were similar for the TVT and TOT groups. The rate of hemorrhagic complications was 5.5% in TVT and 2.8% in TOT group (NS).

Conclusion: TOT appears to be equally efficient to TVT for surgical treatment of stress urinary incontinence after 30 months follow-up.

Keywords: Tension- free vaginal tape, Transobturator tape, Stress urinary incontinence, Women

Introduction

The most commonly used surgical treatment for urinary incontinence is Tension-free vaginal tape (TVT) method, which applies a poly-propylene mono-filament mesh with a core size of 500mm. It was first described by Ulmsten in 1995 and is currently used as a standard minimally invasive procedure (1). De-lorme (2) first described suburethral placement of a tape or the Transobturator tape (TOT), a method less likely to injure the bladder or urethra.

De tayrac et al (3) performed a randomized trial for comparison of TVT and TOT in females with SUI. TOT appeared to be equally efficient to TVT for surgical treatment of SUI in women, with no reducetion of bladder out let obstruction at 1 year follow-up. The aim of this study was to compare the TVT and TOT procedures for the surgical treatment of stress

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urinary incontinence (SUI) in women.

Materials and methods

This study was a prospective non randomized clinical trial which was approved by ethical committee of Vali-e-Asr Reproductive Health Research Center. From March 2001 to March 2005, 71 consecutive patients with proven SUI were recruited.

Preoperative work up included clinical examination, stress test and urodynamic assessment. Pelvic floor defects were determined with standardized system of the international continence society (4). All patients underwent a stress test in the supine position at bladder volumes of 150 ml and 300 mL. The test was considered positive if leakage occurred concurrent with cough or valsalva maneuver. Multichannel urodynamic evaluation that included uroflowmetry, provocative twin-channel subtracted cystometry at a filling rate of 100 mL/min, and urethral profilometry were performed. The urethral pressure profile was taken with the patient in the supine position, at a bladder volume of 300 ml.

Patients presenting any criterion in following list were excluded from study: type III involuntary detrusor contractions during bladder filling, maximum flow (Q max) less than 15 ml/s and / or positive residual urine of more than 20% of the volume voided. Patients with irritative symptoms without urodynamically proven contractions were included.

Thirty six women with SUI were assigned to TVT (group 1) and thirty five patients underwent TOT (group 2). Urinary catheter was inserted for a duration of 12-24 hrs postoperatively for each patient. The catheter was removed on the first postoperative day, and post void residual urine was measured before patients` discharge from the hospital.

Follow up was performed at first month and every 6 months there after. At these recalls, the patients were questioned by simple standardized test about persistent urinary stress incontinence, difficulties in micturation i.e. voiding dysfunction and urgency. The subjective results were classified according to Blavias and Jacobs (5) in to three categories: (a) cured: absence of incontinence, (b) improved: frequency of incontinence episodes less than once every 2 weeks, and (c) failure: frequency of incontinence episodes more than once a week. Patients were also asked to show their overall satisfaction with the surgical outcome, with the four possible choices being very satisfied, moderately satisfied, not very satisfied, not at all satisfied (unsatisfied).

Qualitative variable frequencies were compared by fisher exact test and chi-square tests between two groups. Mean differences of quantitative variables were compared by Student's T-test. Results were considered statistically significant at $p \leq 0.05$. Binary regretssion was used for confirming the results.

Results

The basic characteristics, demographic data and preoperative clinical parameters of all patients are presented in table 1.There were no significant differences between two groups. Mean follow up was 30 months (24- 48). Mean operative time was 36 (20-45) minutes in TVT and 20 (12-25) minutes in TOT groups. There was not any significant difference between two groups. Perioperative complications are shown in table 2. The rate of post operative urinary retention was 13.8% (n=5) in the TVT group versus 2.8% (n=1) in the TOT group (NS). No subpubic hematoma occurred in TOT group versus 5.5% (n=2) in the TVT group.

Table 1: Patient's characteristics and preoperative clinical parameters

	TVT (n=36)	TOT (n=35)	P-value
Age: mean (range)	48 (32-63)	50 (26-74)	N.S
Weight	all<100 kg	all<100 kg	N.S
Parity: mean (range)	5 (1-11)	6 (1-14)	N.S
Menopause	6	7	N.S
Previous surgery for prolapse	-	2	N.S
Previous surgery for SUI	-	-	N.S
Previous hysterectomy	-	1	N.S
Duration of SUI: mean(range)	5 (2-10) years	6 (1-13) years	N.S
Frequency (>8/day)	16	13	N.S
Nocturia (>2/night)	4	5	N.S
Urgency	16	15	N.S

Table 2: Duration of procedures and complications

	TVT (n=36)	TOT (n=35)	P-value
Duration: mean (range)	36 (20-45) min	20 (15-25) min	N.S
Bladder perforation	-	-	N.S
Hemorrhage >300 ml	-	-	N.S
Retzius hematoma	-	-	N.S
Subpubic hematoma	2 (5.5%)	-	N.S
Obturator hematoma	-	-	N.S
Urinary retention	5 (13.8%)	1 (2.8%)	N.S
Vaginal erosion	1 (2.7%)	1 (2.8%)	N.S
Urinary infection	-	-	N.S

Table 3 showed length of hos-pitalization. The majority of patients in both groups were able to leave the hospital on post operative day. At the time of most post operative visits, the vast majority of patients in both groups reported being cured of their incontinence. The rates of cure (91.6% vs. 91.4%), improvement (5.6% vs. 8.6%) and failure (6.5% vs. 6.7%) were similar for TVT and TOT groups, respectively. The 6 months outcome data were collected in all patients. No vaginal erosion occurred in either groups and 6% of TVT group and 8% of TOT group reported persistent urgency.

From 31 patients with complaint of preoperative urgency, after mean follow up of 30 months, 78% vs. 71% become symptom free after TVT and TOT procedures respectively. Based on telephone interview, patient satisfaction was as following: very satisfied: 32 (91.4%) in TOT and 32 (88.8%) in TVT, moderately satisfied: 2 (5.7%) in TOT and 2 (5.6%) in TVT , not very satisfied: 1 (2.9%) in TOT and 1 (2.8%) in TVT and unsatisfied: none in TOT and 1 (2.8%) in TVT.

Discussion

The aim of this study was to compare the TOT and TVT methods. The two series were similar in most aspects. There were no statistically significant differences in patients` age, history of incontinence and/or prolapse surgery or severity of preoperative SUI symptoms.

The literature (6, 7, 8, 9) reports 6-15% of bladder perforations in TVT procedures, though there was no bladder perforation during this study in both groups. Although bladder perforations do not typically represent serious complications and they usually heal without difficulty, a decreased incidence with TOT may constitute an improvement of the technique.

Although the main risk of TOT procedure is possible urethral injury as the needle enters the dissection space between the vagina and the urethra but there was not any urethral and bladder injury in two groups of this study.

Regarding the literature (10-11), the risk of hemorrhage is particularly high in TVT procedure, with reports of retzius space hematoma, (making secondary evacuations necessary), as well as sometimes fatal injuries of the large retroperitoneal vessels. In TOT procedure hemorrhagic complications can occur due to periurethral bleeding from the adjacent venous plexus. In this study no hemorrhagic complication occurred in TOT group versus 5.5% in the TVT group (NS).

A multi center study by Abouassaly et al evaluated the safety of TVT surgery in 241 patients (13). Some immediate complications included bladder perforation in 5.8% of patients, blood loss greater than 500 ml in 2.5%, pelvic hematoma in 1.9%. In 65 patients that underwent TOT in Domingo et al study (14) vaginal mesh erosion was noted in 13.8%. This complication was attributed to the characteristics of

Table 3: Length of hospitalization

Post operative discharge day	TOT (n=35) (%)	TVT (n=36) (%)	P-value
1	34 (97.1)	31 (86.1)	N.S
2-3	1 (2.9)	3 (8.3)	N.S
≥3	-	2 (5.6)	N.S

the tape. Eight patients required complete removal of the tape and only two had recurrence.In this study a vaginal erosion occurred in each group. But no patient required complete removal of the tape.

According to mean follow up of 30 months, TOT appears to be equally efficient as TVT for surgical treatment of SUI. As mentioned in the literature (15), because of the nature of the procedure, major hemorrhage and bowel perforation do not occur in the TOT procedure. Although small number of cases and non randomized methodology are limitations of this study, but simplicity, safety and continence results reveal that the obturator approach represents an excellent method of suburethral tape insertion for the treatment of SUI.

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