

Tension-Free Vaginal Tape Versus Transobturator Tape for Treatment of Female Stress Urinary Incontinence: A 2-Year Follow-Up Investigation

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Submitted August 18, 2010 - Accepted for Publication September 24, 2010

ABSTRACT

INTRODUCTION: The purpose of the study was to compare intraoperative, perioperative, and long-term (2-year) safety and efficacy of procedures using tension-free vaginal tape (TVT) versus transobturator tape (TOT) for the treatment of female stress urinary incontinence (SUI).

METHODS: Participants were 120 female patients with SUI. They were randomly assigned to 2 equal groups, receiving either TVT or TOT. All patients were evaluated by history, physical examination, urine culture, pelviabdominal ultrasound, and urodynamics; they also completed the International Consultation of Incontinence Questionnaire-Short Form (ICIQ-SF). Patients were followed for 2 years. The groups were compared for operative outcomes, complications, maximum flow rates (Qmax) before surgery and at 3-month follow-up intervals, cure rates, and ICIQ-SF scores.

RESULTS: Patients receiving TVT had significantly higher intraoperative blood loss ($P < .001$) and longer operative times ($P < .001$). There was no significant group difference in length of hospital stay. Qmax levels decreased after surgery, with no group differences at any follow-up evaluation. Minor complications occurred in $< 10\%$ of all patients, with no significant group differences. The success rate was 93.3% (cure 83.3%; improved 10%) following use of TVT and 96.6% (cure 86.6%; improved 10%) following use of TOT; group differences were not significant. All patients with failed procedures had VLPP < 60 cmH₂O and grade III SUI. Mean preoperative ICIQ-SF scores, a quality of life measure, were significantly lowered for all patients following surgery with no significant group differences.

CONCLUSIONS: Use of TVT and TOT in surgery result in similar outcomes, including cure rates. Based on the results of this 2-year study, both procedures have similar morbidity and should be considered safe and effective.

KEYWORDS: Stress urinary incontinence; Transobturator tape (TOT); Tension-free vaginal tape (TVT)

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CITATION: *UroToday Int J.* 2010 Oct;3(5). doi:10.3834/uij.1944-5784.2010.10.13

Abbreviations and Acronyms

ICIQ-SF = International Consultation of Incontinence Questionnaire-Short Form

ISD = intrinsic sphincteric dysfunction

PVR = postvoid residual

Qmax = maximum flow rate

SUI = stress urinary incontinence

TOT = transobturator tape

TVT = tension-free vaginal tape

VLPP = Valsalva leak point pressure

INTRODUCTION

Urinary incontinence is a common pelvic floor disorder in women. The reported prevalence rates range from 4.5% to 53%, with an early prevalence peak of 30% to 40% in midlife [1]. Urinary incontinence has a significant psychosocial impact on individuals and families. It can result in a loss of self-esteem and decreased ability to maintain an independent lifestyle. As a consequence, excursions outside home, social events, and sexual activity may be restricted or entirely avoided [2].

More than 150 different surgical procedures for treatment of female stress urinary incontinence have been described in the literature. Before the mid-1990s, the Burch retropubic colposuspension was considered the primary technique for management of patients complaining of stress urinary incontinence [3].

Procedures using tension-free vaginal tape (TVT) quickly became one of the most common treatments for female stress incontinence after its introduction by Ulmsten and Petros in 1995 and its reported cure rate of 84% [4,5]. Unfortunately, the use of TVT is associated with a variety of intraoperative complications such as bladder, bowel, and pelvic blood vessel injury. Serious complications such as massive hemorrhage and even death are well documented [6]. TVT has also been associated with various perioperative complications including bladder perforation, injuries to retropubic organs, pain, urinary infection, urinary retention, and de novo detrusor overactivity [7]. These complications led to development of other minimally invasive surgical techniques such as procedures using transobturator tape (TOT). The TOT procedure was originally described by Delorme in 2001 [8]. Theoretically, the advantage of the transobturator technique is that the trocar does not pass through the retropubic space, resulting in less risk of bladder, bowel, major blood vessel, or pelvic organ injury.

Several noncomparative studies have reported good short-term [9,10] to medium-term [11] success rates with TOT or TVT. The purpose of the present study was to compare intraoperative, perioperative, and long-term (2-year) safety and efficacy of procedures using TOT versus TVT for the treatment of female stress urinary incontinence (SUI).

METHODS

The present was a cross sectional (descriptive) study. It was conducted with patients attending the Urology Department in Benha University Hospital between May 2007 and May 2008, with a follow-up period of 2 years. The study protocol was approved by the research ethics committee of Benha Faculty of Medicine. Written informed consent was provided by all

participants.

Participants

The participants were 120 female patients with stress urinary incontinence. Exclusion criteria included patients with detrusor overactivity, low bladder volume (< 200 cc), and patients with grade III and IV cystocele.

Procedures

All patients provided a complete medical history and received a physical examination that included a cough stress test while the bladder was partially filled. Other investigations included urine analysis, culture, and sensitivity, abdominopelvic ultrasonography (to exclude other bladder pathologies), and urodynamic study in the form of free flowmetry and cystometry with measurement of Valsalva leak point pressure (VLPP). Patients also completed the International Consultation of Incontinence Questionnaire-Short Form (ICIQ-SF) in the validated Arabic version [12]. The severity of SUI was evaluated clinically by using Stamey's grading system [13].

The patients were randomly assembled into 2 groups:

Group 1 (n = 60). Patients in group 1 underwent the TVT procedure using the traditional technique as described by Ulmsten [4], where the tape was placed loosely under the midurethra and the 2 ends of the tape were pulled out through 2 small suprapubic incisions.

Group 2 (n = 60). Patients in group 2 underwent the TOT procedure as described by Delorme [8], using the outside-in technique. The tape was placed under the midurethra and pulled through the obturator foramen through 2 small skin incisions.

Patients were followed biweekly for 1 month, every 3 months in the first year, and every 6 months in the second year. Follow-up examinations included full history, physical examination, and pelvic ultrasonography with estimation of postvoid residual urine (PVR).

Data Analysis

The 2 groups were compared regarding baseline characteristics (age, incontinence types, VLPP), operative outcomes (blood loss, operative time, length of hospital stay), complications, maximum flow rates (Qmax) before surgery and at 3-month follow-up intervals after surgery, ICIQ-SF scores, and cure rates. The data were tabulated and analyzed using the Statistical Package of Social Science (SPSS) version 11 (Chicago, IL, USA). Descriptive statistics of frequencies, mean, and standard deviation (SD) were calculated. Groups were compared using

Table 1. Baseline Information About Types of Incontinence for Both Patient Groups.

doi: 10.3834/uij.1944-5784.2010.10.13t1

Characteristic	Group 1 (n = 60)		Group 2 (n = 60)		Total (N = 120)	
	n	%n	n	%n	n	%N
Stress urinary incontinence						
Grade 1	28	46.7	26	43.3	54	45.0
Grade 2	26	43.3	30	50.0	56	46.6
Grade 3	6	10.0	4	6.7	10	8.3
Incontinence type						
Pure stress incontinence	48	80.0	50	83.3	98	81.6
Mixed incontinence	12	20.0	10	16.7	22	18.3

the *t* test. The Microstat program was used to calculate the *Z* test. The probability value of .05 was used to indicate statistical significance. A power test was not performed; sample size was estimated from a review of the literature. Therefore, the possibility of type 2 error exists.

RESULTS

Baseline Patient Characteristics

The mean (SD) age of group 1 (receiving TVT) was 42.1 (15.2) years; the mean age of group 2 (receiving TOT) was 36.4 (12.3) years. A total of 24 (40%) in group 1 and 14 (23.3%) in group 2 were menopausal. There were no statistically significant group differences in the age or menopause baseline variables.

Table 1 contains baseline information about types of incontinence for both patient groups. The majority of patients in both groups had grade I or grade II SUI, according to Stamey's grading system. The 5 patients with grade III SUI had VLLP <60 cm H₂O. There were approximately equal numbers of patients in each group with pure stress incontinence or mixed incontinence. There were no statistically significant group differences in any of the baseline incontinence variables.

The history of previous anti-incontinence surgery was provided

by all patients. There were 4 patients in group 1 with past history of anti-incontinence surgery; 3 of them underwent failed colposuspension and the 4th patient underwent failed fascial sling procedure. Two cases in group 2 underwent failed colposuspension. The duration of SUI per years was calculated; the mean was 3.1 (1.4) years in group 1 and 4 (4.3) years in group 2.

Table 2 contains the preoperative VLPP for both patient groups. The majority of patients in both groups had pressures between 60 and 89 cmH₂O. There were no significant group differences in any of the VLPP measures.

Operative and Perioperative Outcome Measures

Table 3 contains operative outcome measures for the patients in both groups. There were significant group differences in intraoperative blood loss (*P* < .001) and operative time (*P* < .001). Patients receiving TVT had higher blood loss and longer operative times. There was no significant group difference in the length of hospital stay.

The number of patients with perioperative complications in both patient groups are presented in Table 4. No major complications occurred and there were no significant group differences.

Table 2. Baseline Valsalva Leak Point Pressures for Both Patient Groups.

doi: 10.3834/uij.1944-5784.2010.10.13t2

Valsalva Leak Point Pressure	Group 1 (n = 60)		Group 2 (n = 60)		Total (N = 120)		<i>Z</i>	<i>P</i>
	n	%n	n	%n	n	%N		
≥ 90 cmH ₂ O	8	13.4	6	10.0	14	11.6	.57	>.05
≥ 60 and < 90 cmH ₂ O	46	76.0	50	83.3	96	80.0	.91	>.05
< 60 cm H ₂ O	6	10.0	4	6.7	10	8.4	.66	>.05

Table 3. Operative Outcome Measures for Both Patient Groups (N = 120).

doi: 10.3834/uj.1944-5784.2010.10.13t3

Outcome Measure	Mean	SD	Range	t	P
Intraoperative blood loss (mL)					
Group 1	77.5	15.3	50-100	11.46	<.001
Group 2	49.3	11.4	40-65		
Operative time (minutes)					
Group 1	30.1	1.9	20-40	41.4	<.001
Group 2	15.2	2.3	10-20		
Hospital stay (days)					
Group 1	1.3	0.9	1-3	1.64	>.05
Group 2	1.1	0.3	1-2		

Maximum Urinary Flow Rate

Table 5 contains the preoperative and postoperative Qmax at 3-month follow-up intervals for both patient groups. Patients in both groups had lower Qmax values after surgery. There were no significant group differences in Qmax outcome measures at any of the follow-up examinations.

Cure Rates and ICIQ-SF Outcome

Patients were considered *cured* when there was no leakage, as measured subjectively or objectively. Patients were considered *improved* when they stated that there was marked decrease in the amount of urine that leaked during effort. Table 6 contains the number of patients in each category, subdivided according to VLPP levels. The majority of patients in both groups (83.3% receiving TVT; 86.6% receiving TOT) were categorized as cured. Of the patients that improved, 4 patients in each group had VLPP ≥ 60 cmH₂O; 2 patients in each group had VLPP < 60 cm H₂O. All patients with failed procedures had VLPP < 60 cmH₂O

and grade III SUI. Failed procedures were detected immediately after surgery and the patient did not improve during the follow-up period. There were no significant group differences in any of the cure rate outcomes.

Mean preoperative ICIQ-SF scores were 14.11 (6.8) in group 1 and 14.51 (3.62) in group 2. Postoperative scores significantly lowered to 3.1 (1.6) in group 1 and 3.6 (2.4) in group 2. The differences in the mean preoperative and postoperative scores for the combined groups were statistically significant ($P < .05$).

DISCUSSION

Genuine SUI is involuntary release of urine without the detrusor muscle being contracted when pressure inside the urinary bladder exceeds a maximum closing pressure of the urethra [14]. There are numerous methods of treating SUI surgically. The early gold standard of traditional Burch colposuspension [14] has been supplemented by other procedures. The present study compares outcomes of surgery using TVT and TOT.

Table 4. Number of Patients with Perioperative Complications in Both Patient Groups (N = 120). doi: 10.3834/uj.1944-5784.2010.10.13t4

Complication	Group 1 (n = 60)		Group 2 (n = 60)		Total (N = 120)		Z	P
	n	%n	n	%n	n	%N		
Bladder perforation	2	3.3	0	0	2	1.7	1.43	>.05
Urine retention	2	3.3	0	0	2	1.7	1.43	>.05
Urinary tract infection	4	6.6	4	6.6	8	6.7	0	
Vaginal erosion	2	3.3	0	0	2	2.7	1.43	>.05
Urethral erosion	1	1.6	0	0	1	0.8	1.004	>.05
Dyspareunia	1	1.6	1	1.6	2	1.7	0	

Table 5. Preoperative and Postoperative Maximum Flow Rates (Qmax) at Baseline and 3-Month Follow-up Intervals for Both Patient Groups (N = 120)..

doi: 10.3834/uij.1944-5784.2010.10.13t5

Time of Assessment	Maximum Flow Rate (mL/s)				t	P
	Group 1 (n = 60)		Group 2 (n = 60)			
	mean	SD	mean	SD		
Preoperative	27.7	3.2	27.2	4.1	.53	>.05
Postoperative						
3 month	19.1	2.3	18.8	2.5	.68	>.05
6 month	21.8	2.7	21.9	2.1	.16	>.05
9 month	21.6	2.6	20.9	2.2	1.59	>.05
12 month	20.8	2.2	20.2	1.9	1.13	>.05
24 month	21.2	1.8	20.8	2.1	1.12	>.05

Operative Outcomes

In the present study, there was a statistically significant group difference in the mean operative times of 30.1 minutes (SD, 1.9; range, 20-40 minutes) for the group receiving TVT and 15.2 minutes (SD, 2.3; range, 10-20 minutes) for the group receiving TOT. These results agreed with those reported by Porena et al [15] in which the mean operative times were 30 minutes for patients receiving TVT and 20 minutes for patients receiving TOT. The findings are also consistent with Falkert and Seelbach-Göbel [16] who reported mean operative times of 37 minutes and 17 minutes for patients receiving TVT and TOT, respectively. Sola et al [17] reported a mean operative time of 7 minutes when using TOT. The present study also showed a significant group difference in the amount of blood lost during surgery, in favor of the TOT procedure. These results were similar to those obtained by Neuman [18]. Finally, there was no significant group difference in the length of hospital stay. This result was

different from that found by Aniuliene [19], who reported a significantly shorter hospital stay in the group receiving TOT (1.5 ± 0.5 days) than in the group receiving TVT (4.0 ± 1.6 days).

The differences in operative time may be explained by the time lost during cystoscopy done during the TVT procedure. However, a professional group of the American Urology Association and other researchers recommend cystoscopy for all patients needing surgery for SUI in order to avoid injury to the lower urinary tract. This increase in patient safety is considered more important than shorter operative times.

Complications

In the present study, complications occurred in less than 10% of all patients. No major complications occurred, and there were no significant group differences. Therefore, morbidity was essentially the same across groups.

Table 6. Number of Patients Considered Cured, Improved, or Failed, Subdivided According to Valsalva Leak Point Pressure Levels (N = 120).

doi: 10.3834/uij.1944-5784.2010.10.13t6

Outcome Measure	Valsalva Leak Point Pressure	Group 1 (n = 60)		Group 2 (n = 60)		Total (N = 120)		P
		n	%n	n	%n	n	%N	
Cured	≥ 60 cmH ₂ O	50	83.3	52	86.6	102	85	>.05
	< 60 cmH ₂ O	0	0	0	0	0	0	
Improved	≥ 60 cmH ₂ O	4	6.7	4	6.7	8	6.6	
	< 60 cmH ₂ O	2	3.3	2	3.3	4	3.3	
Failed	≥ 60 cmH ₂ O	0	0	0	0	0	0	
	< 60 cmH ₂ O	4	6.7	2	3.3	6	5	>.05

Bladder injury. Iatrogenic bladder perforation occurred in 2 patients (3.3%) receiving TVT. The perforation was discovered intraoperatively. The needle was removed and reinserted again in the proper pathway, and Foley's catheter was left in place for 5 days. There was no bladder perforation in the group receiving TOT. These results are consistent with those obtained by Neuman [18], who had 6 (8%) cases of bladder perforation with the TVT procedure and no cases with the TOT procedure. deTayrac et al [20] also reported 3 (10%) cases of bladder perforation with the TVT procedure and no cases with the TOT procedure. Finally, George et al [21] reported that bladder perforation was 1.3% in patients receiving TVT but did not occur in patients receiving TOT. Krofta et al [22] reported bladder perforation with 0.7% and 0% of TVT and TOT procedures, respectively.

Urine retention. Two patients receiving TVT (3.3%) developed transient urinary retention following catheter removal (classified as PVR urine > 100), but recovered after intermittent catheterization for 2 weeks. There were no cases of urinary retention in the group receiving TOT. These results were similar to those mentioned by Sola et al [17] who reported 2 cases (2.6%) of transient urinary retention with TVT and no cases with TOT. Falkert et al [16] reported a 13 cases (23%) of urinary retention in patients treated with TVT and 1 case (2%) in a patient treated with TOT.

Urinary tract infection. Postoperative infections of the urinary tract occurred in 6.6% of patients in both groups. Aniliene [19] reported UTI in 4.4% of the patients following use of TVT and 0.7% following use of TOT.

Mesh erosions. The present 3.3% incidence of vaginal erosion in the group receiving TVT is one of the lowest in the literature, because the reported incidence ranges from 3.8% to 15% [15,23,24]. Vaginal erosion was managed by debridement and simple closure of mucosal defects with local antiseptics and systemic antibiotics. Erosion rates vary with different types of synthetic mesh, operative experience, mesh tension, infection, poor healing, and local ischemia [24]. In the present study, there was 1 case of urethral erosion following use of TVT (1.6%). This case was discovered after 6 months by urethral mobilization and tape extraction. Then, the fascial patch sling procedure was done and the patient became continent. There were no cases of urethral erosion following the TOT procedure. These results agreed with those from deTayrac et al [20], who also had 1 case (3.2%) complicated by urethral erosion in patients treated with TVT and no cases following use of TOT.

Sexual disorders. In the present study, dyspareunia occurred equally in the groups (1.6%). Porena et al [15] reported a higher

percentage of dyspareunia after sling operations; reports of sexual disorders occurred in 16.4% and 21.3% of the patients following use of TVT and TOT, respectively.

Qmax and VLPP

There were no statistically significant group differences in Qmax at the 3, 6, 9, 12, or 24-month evaluations. The PVR urine was insignificant (< 100 mL). Zullo et al [25] also found no clinically significant increase in PVR 1 year after using TVT and TOT procedures.

In the current study, the relationship between the preoperative VLPP and the postoperative cases that were cured, improved, or failed was evaluated. There were 6 cases (10%) with VLPP < 60 cm H₂O in patients receiving TVT and 4 cases (6.7%) in patients receiving TOT, with no significant group differences. Four of the 6 patients in group 1 and 2 of the 4 cases in group 2 improved; the others failed. The failure may be explained by the fact that intrinsic sphincteric dysfunction (ISD) incontinence is the most severe form of SUI. It is difficult to cure. The TVT and TOT procedures were designed to correct hypermobility, and their position away from the bladder neck may be the cause of failure in patients with ISD [26].

Cure Rate

In the current study, the cure rate was 83.3% following use of TVT and 86.6% following use of TOT. An additional 10% of the patients in both groups improved. The procedure failed in 6.7% of the patients following TVT and 3.3% of the patients following TOT, respectively. There were no significant group differences in any of the cure rates.

These results agreed with Porena et al [15], who had a cure rate of 71.4% and 77.3% following treatment with TVT and TOT, respectively. When the patients who improved were added, the rates increased to 90% following use of TVT and 90.6% following use of TOT. The results also agreed with deTayrac et al [20], who found a cure rate of 83.9% following use of TVT and 90% following use of TOT, with 30 patients in each group. They also found improvement in 9.7% and 3.3% of patients and failure in 6.7% and 6.7% of patients following TVT and TOT, respectively. Finally, these results are in agreement with Zugor et al [27], who had a cure rate of 81% for patients who received TVT and 77.7 for patients who received TOT.

The present study revealed significant improvements in the ICIQ-SF following both TVT and TOT treatments, with no significant group differences. These data suggest an improvement in quality of life for all patients. Similar results have been demonstrated in other studies such as Krofta et al [22].

CONCLUSION

Use of TVT and TOT in surgery result in similar outcomes, including cure rates. Based on the results of this 2-year study and those of other investigations, both procedures have similar morbidity and should be considered safe and effective.

ACKNOWLEDGEMENTS

The authors are grateful to the residents in the Urology Department, Benha University Hospital, Benha, Egypt for help in patient recruitment and follow-up.

Conflict of Interest: none declared.

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