

A Retrospective Study Comparing Tension-free Vaginal Tape and Transobturator Suburethral Tape for Surgical Treatment of Female Stress Urinary Incontinence — A Preliminary Report

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Background: The aim of this study was to assess the efficacy and complications of tension-free vaginal tape (TVT) versus tension-free transobturator vaginal tape (TVT-O) from inside to outside for the surgical treatment of stress urinary incontinence (SUI) in women.

Methods: Retrospectively, 35 patients with SUI were recruited into this study; 18 patients were assigned to the TVT procedure and 17 patients to the TVT-O operation. Preoperative evaluation included subjective symptoms according to the SEAPI incontinence score (IC score), objective assessment by urodynamic study (including cystometry, electromyography, urethral pressure profile, uroflow), and bead chain voiding cystourethrogram. Patients with cystocele greater than grade II were excluded. The mean operative time, hospital stay, perioperative complications, and 1-year outcome including SEAPI IC score and late complications were compared.

Results: Patient characteristics and preoperative IC score were similar in the 2 groups. Mean operative time was significantly shorter in the TVT-O group (31.9 ± 10 minutes vs. 55 ± 12 minutes; $p < 0.001$). No bladder injury occurred in the TVT-O group versus 5.0% ($n = 1$) in the TVT group ($p > 0.05$). The rate of postoperative temporary dysuria was 28% ($n = 5$) in the TVT group versus 24% ($n = 4$) in the TVT-O group. The cure rate for SUI was 88%, similar for the TVT and TVT-O groups. As for late complications, no vaginal erosion was noted in the TVT-O group, but 1 bladder erosion with stone formation was found in the TVT group. In terms of bladder outlet obstruction, none developed in the TVT-O group, but 1 patient developed persistent dysuria in the TVT group.

Conclusion: There appears to be equal efficacy between TVT and TVT-O for the surgical treatment of female SUI, but operative time was significantly shorter in the TVT-O group because intraoperative cystoscopic check-up is not required. [*J Chin Med Assoc* 2007;70(12):541–544]

Key Words: female stress urinary incontinence (SUI), tension-free vaginal tape (TVT), transobturator suburethral tape (TVT-O)

Introduction

Stress urinary incontinence (SUI) is a common functional pathologic condition in women. There are many transvaginal surgical procedures for the treatment of female SUI. The tension-free vaginal tape procedure (TVT; Gynecare, ETHICON Women's Health and Urology, Somerville, NJ, USA) has been used in the

treatment of female SUI since 1995,¹ and it is now considered by many surgeons to be the gold standard procedure for female SUI with its simplicity and excellent long-term efficacy.² Although TVT has a high success rate, ranging from 84% to 95%,³ there are concerns regarding its perioperative complications, such as bowel, bladder and urethral perforation, major blood vessel injuries,⁴ and postoperative voiding difficulties,

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such as transient urine retention in 8–17%, and urgency in 5–15%.^{4,5} A method of suburethral suspension by the transobturator route, inside-out, was developed recently by de Leval,⁶ with the aim of avoiding the risk of urethra and bladder injuries. The clinical results⁷ and anatomical studies⁸ suggested that the approach could be safer. Furthermore, positioning the tape in a plane at an angle of 45° with the horizontal might limit the risk of excess strain of the urethra that is responsible for possible postoperative voiding difficulties. Therefore, the aim of this study was to retrospectively compare TVT with TVT-O regarding clinical outcome and complications.

Methods

Between March 2004 and January 2006, 35 women with SUI were enrolled in the study. Eighteen women underwent TVT and 17 underwent TVT-O. Preoperative evaluation included detailed history, physical examination with a stress test, urinalysis and urodynamic study (including cystometry, electromyography, urethral pressure profile, uroflowmetry). All patients were evaluated by the SEAPI (stress incontinence, emptying ability, anatomy, protection, and instability) incontinence score (IC score),⁹ with grading from 0 to 3. Patients with urodynamically proven detrusor overactivity or acontractility, post-voiding residual urine more than 100 mL, cystocele more than grade II, or active urinary or vaginal infection were excluded from the study.

All operations were performed under epidural anesthesia. After the vagina was prepared with aqueous iodine, a 20 mm incision was made on the anterior vaginal wall and the mid-urethra was identified. In the TVT procedure,¹ the trocar and tape was placed

through the urogenital diaphragm into the retropubic space close to the back of the pubic bone and up to the skin incision. In the TVT-O procedure,⁶ the trocar and tape was carried transobturator foramen, inside-out, with a curved tunneling to the internal surface of the thigh. Cystoscopy was subsequently routinely performed to verify the absence of bladder injury in the TVT group, but no cystoscopy was required in the TVT-O group except in the initial 5 cases. The tape was adjusted to a tension that was just enough to maintain continence according to the cough stress test. A Foley catheter and suprapubic Cystofix[®] were placed at the end of the procedure. The Foley catheter was removed the next day following the procedure. The Cystofix[®] was kept to check residual urine, and was removed if residual urine volume was less than 60 mL.

All patients were followed up for at least 1 year, and recorded their SEAPI IC score and postoperative complications, including dysuria, *de novo* frequency, vaginal or urethral erosions, and thigh pain. Cure of SUI was defined as the disappearance of subjective and objective SUI, as assessed by the SEAPI IC score and physical examination (negative cough test).

Statistical analysis

Comparisons between the TVT and TVT-O groups were performed with nonparametric analysis. Mann-Whitney and Fisher's exact tests were used to evaluate variables including patient characteristics, pre- and postoperative IC scores, and postoperative complications; $p < 0.05$ was considered statistically significant.

Results

Patient characteristics and preoperative data are summarized in Table 1. There was no significant difference

Table 1. Patient characteristics and preoperative evaluation*

	TVT (n = 18)	TVT-O (n = 17)	p
Age (yr)	62.5 ± 9.6	63.2 ± 11.2	NS [†]
Stress UI	2.4 ± 0.5	2.7 ± 0.5	NS [†]
Urge UI			
Case number	10 (55)	13 (73)	NS [‡]
Average score	0.7 ± 0.8	1.2 ± 0.9	NS [†]
Protection	2.5 ± 0.5	2.4 ± 0.5	NS [†]
Emptying (score > 0)	0 (0)	0 (0)	NS [†]

*Data are presented as mean ± standard deviation or n (%); [†]Mann-Whitney test; [‡]Fisher's exact test. TVT = tension-free vaginal tape; TVT-O = tension-free transobturator vaginal tape; NS = not significant; UI = urinary incontinence.

between the groups for age, previous medical history, and preoperative IC data. Mean operative time was significantly shorter in the TVT-O group (Table 2). None of these patients had heavy intraoperative bleeding (estimated blood loss >100 mL), postoperative obturator or perineal hematoma, or neurologic complications. There was 1 bladder perforation in the TVT group and none in the TVT-O group. The rate of postoperative temporary voiding difficulty (emptying IC score = 1 or 2) was 28% ($n=5$) in the TVT group versus 24% ($n=4$) in the TVT-O group (Table 3). Unilateral thigh pain occurred in 2 patients in the TVT-O group; it subsided spontaneously and there was no need for opioid analgesia.

The 1-year follow-up data were collected in the 2 groups. The cure rate (SUI IC score = 0) was 88%,

similar for the TVT and TVT-O groups (Table 4). The rate of urge urinary incontinence was 33% ($n=6$) in the TVT group and 41% ($n=7$) in the TVT-O group, with mild urge urinary incontinence (IC score = 1 or 2); both groups showed improvement compared with the preoperative data (Table 1). After 1 year of follow-up, there was 1 patient in the TVT group and 2 patients in the TVT-O group with persistent urge urinary incontinence (IC score = 1 or 2). Protection with pads was required for 2 patients in the TVT group (IC score = 1) and 2 patients in the TVT-O group (1 had IC score = 1, the other had IC score = 3, because she had severe arthritis with disability of movement).

Among the late complications, there were 3 cases of *de novo* frequency in the TVT group versus 1 case

Table 2. Perioperative details*

	TVT ($n=18$)	TVT-O ($n=17$)	p
Operation time (min)	55.0 ± 7.0	31.9 ± 7.2	<0.0001 [†]
Blood loss (>100 mL)	0 (0)	0 (0)	NS [‡]
Hospital stay (d)	4.5 ± 1.2	4.8 ± 2.2	NS [‡]
Immediate complications			
Bladder perforation	1 (5.5)	0 (0)	NS [‡]
Hematoma	0 (0)	0 (0)	NS [‡]

*Data are presented as mean ± standard deviation or n (%); [†]Mann-Whitney test; [‡]Fisher's exact test. TVT = tension-free vaginal tape; TVT-O = tension-free transobturator vaginal tape; NS = not significant.

Table 3. Early postoperative complications*

	TVT ($n=18$)	TVT-O ($n=17$)	p
Dysuria (emptying 1C score = 1 or 2)	5 (28)	4 (24)	NS [‡]
Thigh pain (<7 d)	0 (0)	2 (12)	NS [‡]

*Data are presented as n (%); [‡]Fisher's exact test. TVT = tension-free vaginal tape; TVT-O = tension-free transobturator vaginal tape; NS = not significant.

Table 4. Results

	SCORE	TVT ($n=18$)	TVT-O ($n=17$)	p
Stress UI score (0–3) at 1 yr	0	16 (88)	15 (88)	NS [‡] ($p=1$)
	1–2	2 (11)	2 (11)	
Urge UI score (0–3)				
	At 1 mo			
	0	12 (67)	10 (57)	$p=0.733$ [‡]
	1–2	6 (33)	7 (41)	
At 1 yr				
0	17 (95)	15 (88)	$p=0.602$ [‡]	
1–2	1 (5)	2 (12)		
Protection at 1 yr	1–3	2 (11)	2 (12)	NS [‡] ($p=1$)

*Data are presented as n (%); [‡]Fisher's exact test. TVT = tension-free vaginal tape; TVT-O = tension-free transobturator vaginal tape; UI = urinary incontinence; NS = not significant.

in the TVT-O group. There was prolonged dysuria in 1 case and tape erosion to bladder in 1 case in the TVT group versus none in the TVT-O group. The patient who developed persistent dysuria in the TVT group showed low pressure-low uroflow pattern in the pressure-flow study. Resection of vaginal tape was done and the patient experienced subjective improvement. There was no statistically significant difference in any of the late complications between the 2 groups.

Discussion

This was a retrospective analysis to compare TVT with TVT-O in the surgical treatment of SUI in women. In our study, the mean operative time was shorter in the TVT-O group (31.9 minutes *vs.* 55 minutes). That difference is due to cystoscopy not being required during TVT-O. The reported incidence of bladder perforation occurring during TVT ranges from 0.8% to 21%.^{1,3,4,7} Recent cadaver dissection studies demonstrated that the TVT-O procedure drastically reduces the risk of delivering a direct wound to the bladder or urethra and also curves away from the dorsal nerve to the clitoris, obturator nerve and vessels, and saphenous and femoral vessels, with the conclusion that the technique is very safe, reliable and reproducible and does not call for perioperative cystoscopy.^{8,10}

We demonstrated that the TVT and TVT-O procedures are equally efficacious in the treatment of female SUI over a follow-up period of 12 months. The 88% cure rate in the 2 groups is similar to those reported by other authors, which range from 84% to 95%.^{1-3,6-8}

Despite a high cure rate, the suburethral suspension procedure can be complicated by bladder outlet obstruction with various presenting forms, such as urinary voiding difficulties and *de novo* urgency or frequency.^{3,4,6} The urinary retention is usually partial and transient, and is a consequence of an increased urethral resistance created by the suburethral compression of the tape. Intermittent catheterization and adjustment of the tape by urethral sounding can aid in getting patients through this difficult phase. In our study, mild to moderate dysuria occurred in 28% versus 24% in the TVT and TVT-O groups, respectively, and could be resolved in 1 week. In another prospective randomized study comparing TVT and transobturator suburethral sling, the incidence of dysuria was 38% versus 30%.¹¹ As for this complication, most of the users stopped using the cough test as it led to postoperative

urinary retention or voiding difficulty.⁵ We modified the cough test preoperatively to keep tension just enough to maintain little leakage. The postoperative dysuria was temporary, and excess tension of the vaginal tape could be reduced by urethral sounding. Refractory voiding dysfunction after TVT or TVT-O is a relatively uncommon situation and can be successfully managed with a simple release procedure.¹¹

In conclusion, the number of patients in our study was too small to show any significant difference between TVT and TVT-O. Nevertheless, both procedures appear to be equally efficacious and safe for the surgical treatment of female SUI.

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