



# The Efficacy of Mid-Urethral Sling Procedures, Transobturator Tape and Tension-Free Vaginal Tape in the Treatment of Female Stress Urinary Incontinence: A Comparative Study of Twelve Months Follow-Up After Surgery

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## Abstract

**Objective:** The aim of the study is to compare the efficacy and safety of tension-free vaginal tape (TVT) and transobturator tape (TOT) procedures in the treatment of female stress urinary incontinence (SUI) in a two-arm study with a 1-year follow-up.

**Methods:** The single-center retrospective study included 73 patients who underwent TVT or TOT between January 2006 and October 2012. Patients who had neurological disease or required surgical repair of cystocele or rectocele were excluded from the study. The primary outcome was treatment efficacy and safety at 12 months, defined by overactive bladder (OAB) scores and self-reported absence of symptoms. For comparisons between the groups, chi-square and Student-t tests were used.

**Results:** Among the women included in the analysis, 52 patients underwent TVT and 21 underwent TOT. The mean age of the patients was 48.9 years in the TOT group and 46.2 years in the TVT group ( $p=0.713$ ). The patient satisfaction rate was found to be 82.5% in the TOT group and 84.6% in the TVT group ( $p=0.917$ ); complete dryness rates were similar in both groups (57.5% vs. 58.3%,  $p=0.817$ ). There was a significant decrease in using pads in both groups, and OAB scores also showed a statistically significant decrease.

**Conclusion:** Tension-free vaginal tape and TOT have similar efficacy as a minimally invasive technique for the treatment of female SUI. The symptoms of urgency urinary incontinence can also be reduced in parallel with OAB scores.

**Keywords:** Stress urinary incontinence, mid-urethral sling, tension-free vaginal tape, transobturator tape, follow-up, treatment outcome

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## Introduction

Although urinary incontinence (UI) is not a life-threatening problem, it is a public health condition that affects approximately 35%-50% of women worldwide with physical, psychological, social, and economic implications (1, 2). UI is also a major factor contributing to nursing home admission and hospital readmission among older women with comorbid conditions such as diabetes mellitus and hypertension (3, 4). Moreover, the total economic cost of urinary incontinence annually is estimated to be \$19.5 billion in the United States (5) and £740 million in the United Kingdom (6).

Stress UI (SUI) is defined as a condition of involuntary leakage of urine upon effort, exertion, sneezing, or coughing or as the inability to hold urine within the bladder at times other than during voluntary micturition (7). SUI is the most common type of UI, and its prevalence ranges between 8% and 33% (8). The most common risk factors for SUI are female gender, parity, obstetric history, chronic cough, advanced age, estrogen levels, obesity, and pelvic surgery history (9). The treatment options of SUI include lifestyle changes such as weight loss, pharmacotherapy, pelvic floor muscle training, electrical stimulation, and urethral bulking agent injection. Surgical therapy is often offered to women who do not benefit from conservative treatment option (10). Mid-urethral sling [transobturator tape (TOT) and tension-free vaginal tape (TVT)] procedures are a gold standard in the treatment of female SUI (11, 12).

The objective of this study was to evaluate patient-reported outcome at 12 months after TOT and TVT for SUI in a retrospective manner and compare complication rates of both procedures.

## Methods

A retrospective analysis was performed in 73 patients who underwent mid-urethral sling procedure in Şişli Etfal Training and Research Hospital between January 2006 and October 2012. We included a total of 52 TOT and 21 TVT cases in the study, and patients with neurological disease that might affect bladder function and those who required surgical repair of cystocele or rectocele were excluded from the study. The study was conducted in compliance with recognized inter-

national standards, including the principles of the Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013) for research involving human subjects, and each patient's written, undersigned informed consent was obtained for the use of their information.

The study compared surgical treatment of SUI with either TOT (Boston Scientific; Natick, MA, USA) or TVT (Gynecare, Ethicon Inc.; Johnson & Johnson, Somerville, NJ, USA). Preoperative evaluation of the patients included a detailed urological and gynecological history and a physical examination. Data on age, body mass index (BMI), parity, gravidity, mode of delivery, complications during delivery, menopausal status, postmenopausal hormone therapy and anticholinergic medication usage preoperatively, pad usage, intraoperative complications, and follow-up duration were collected. All patients were examined in the lithotomy and standing positions at maximal bladder capacity, including a standardized cough test to assessment of the type UI. An ultrasonography was performed to determine the fullness of the bladder before the cough test and possible urinary retention. The primary efficacy end point was evaluated with an eight-item overactive bladder (OAB) questionnaire (OAB-V8). OAB-V8 is a self-administered form of OAB questionnaire, containing eight questions related to irritating symptoms such as frequency, urgency, urgency UI, or nocturia (13). A score of 8 indicates a positive diagnosis. A score <8 suggests that the OAB diagnosis may be either questionable or absent. The terms used in this questionnaire are given in detail: frequency (eight or more micturitions per day), nocturia (waking at night with the need to void two or more times), urgency (a sudden urge to pass urine), and urgency UI (involuntary loss of urine with urgency).

The success of procedures, defined as having no postoperative SUI at 12 months, was assessed subjectively and objectively. Objective success was determined by a cough stress test with a naturally filled bladder during pelvic examination in the outpatient clinic. Subjective success was determined by patient-reported outcome as the absence of any leakage with coughing, laughing, sneezing, or exertion. At 12 months postoperatively, the patients were questioned about their satisfaction with the operation. The patients were also asked whether they leak urine. In the study, the primary outcome measure was cure of SUI. Secondary outcome measures included perioperative and postoperative complications.

### Statistical Analysis

The statistical analyses were performed using Statistical Package for Social Sciences version 20.0 (IBM Corp.; Armonk, NY, USA) software. The Student-*t* test was used for testing the relationship between continuous variables and the chi-square test was used for testing nominal variables. Wilcoxon sum rank test was used to

compare statistical significance between preoperative and postoperative OAB scores and daily pad usage. A  $p < 0.05$  was considered significant.

### Results

The mean age of the patients was 48.9 years in the TOT group and 46.2 years in the TVT group, with their age ranging from 26 to 72 years ( $p = 0.713$ ; Table 1). There was no statistically significant difference in terms of BMI between the two groups ( $p = 0.468$ ). Baseline data for parity, gravidity, mode of delivery, complicated delivery, menopausal status, preoperative use of postmenopausal hormone therapy, and anticholinergic medications were similar in both groups.

We achieved a cure rate of 57.5% in the TOT group and 58.3% in the TVT group, whereas patient satisfaction rates were 82.5% in the TOT group and 84.6% in the TVT group at the end of the first year postoperatively. Moreover, there were no statistically significant differences in either cure or satisfaction rates between the two groups ( $p = 0.817$  and  $p = 0.917$ ). There was a statistically significant decrease in the number of pads used daily in the TOT and TVT groups ( $p < 0.05$ ). Moreover, there was a statistically significant decrease in OAB scores in both groups ( $p < 0.05$ ). Secondary outcomes are summarized in Table 2.

Regarding complications, we observed only bladder perforation as an intraoperative complication in one case during control cystoscopy, whereas no intraoperative complication was observed in the TOT group. This case was managed by urethral catheterization for a while without requiring any surgical repair. In the early postoperative period, mesh erosions were seen in three patients. These patients underwent a second-look surgery for mesh revision. Meanwhile, urinary retention observed in one case in the TOT group and in one case in the TVT group on postoperative day two (Table 3). These two patients were sufficiently treated with anti-inflammatory drugs and urethral catheterization for a while.

### Discussion

Following introduction of TVT in 1996, minimally invasive sling procedures have become a choice of treatment for female UI (12). Thereafter, in 2001, another minimally invasive procedure, TOT, was developed because of increased bladder perforation complications associated with TVT (14). However, the success and complication rates of TVT and TOT procedures have been a subject of debate in several studies. Enzelsberger et al. (15) reported that success rates for TVT and TOT were 86% and 84%, respectively, as compared with the objective cure that was defined as the absence of UI in a negative stress test and urodynamic studies at the end of a follow-up of 15 months. In another comparative study, Porena et al. (16) reported that objective cure rates for TVT and TOT were 70.2% and 78.6%, respectively, at the end of 13.4-month follow-up; however, the objective cure rate was not defined in their study.

Although complications, such as necrotizing fasciitis, ischioanal abscess, bowel injury, and urethrovaginal fistula, have been reported, they were thought to be in a very limited number when the randomized controlled trials were evaluated (17). Herein, we highlight that we have also observed no major complications such as those mentioned above. However, we observed a case of blad-

**Table 1. Demographic characteristics and primary outcomes of the patients**

	TVT (n: 21)	TOT (n: 52)	p
Age (years)	46.2±7.8	48.9±8.2	0.713
BMI (kg/m <sup>2</sup> )	29.2±5.1	28.9±4.6	0.468
Complete dryness rate (%)	58.3	57.5	0.817
Satisfaction rate (%)	84.6	82.5	0.917

BMI: body mass index; TVT: tension-free vaginal tape; TOT: transobturator tape

**Table 2. Secondary outcomes of the study**

	Pre-op OAB score	Post-op OAB score*	p	Pre-op daily pad usage	Post-op daily pad usage*	p
TVT	27.3±7.9	9.8±6.1	p<0.05	4.9±4.2	0.7±1.2	p<0.05
TOT	25±8.9	11.4±7.9	p<0.05	4.1±2.9	0.95±1.5	p<0.05
All patients	25.6±8.7	11±7.5	p<0.05	4.3±3.3	0.9±1.4	p<0.05

\*at the end of first year TVT: tension-free vaginal tape; TOT: transobturator tape; OAB: overactive bladder

**Table 3. Complications rates of groups**

	TOT	TVT	p
Urinary retention (n)	1	2	0.197
Bladder perforation (n)	-	1	0.288
Mesh erosion (n)	3	-	0.355

TVT: tension-free vaginal tape; TOT: transobturator tape

der perforation without requiring surgical repair in the TVT group, whereas no intraoperative complication was observed in the TOT group. Mesh erosion occurred in three patients in the early postoperative period, and these patients underwent mesh revision.

Regarding the meta-analysis of randomized controlled trials, complication rates were reported to be lower in TOT with regard to bladder perforation and hematoma in two systematic reviews (17, 18). However, no significant differences with respect to erosion rate and OAB scores were found in these meta-analyses. These meta-analyses presented the result of a short-term follow-up because of the heterogeneity of outcome measures and the lack of the randomized controlled studies with long-term follow-up. Furthermore, it was also highlighted that many studies had limited methodological and clinical qualities in these trials. Therefore, good quality and adequately powered trials with long-term follow-up are required. In a meta-analysis, Novara et al. (19) reported that mid-urethral and pubovaginal slings had similar efficiency in the treatment of SUI, although pubovaginal slings were associated with storage lower urinary tract symptoms. Moreover, they emphasized that bladder perforations were less common in pubovaginal sling procedures. The Cochrane Review also demonstrated that minimally invasive suburethral sling procedures were as effective as traditional surgical approaches in short-term, and there was no clear evidence to suggest that either of the procedures was preferable to the other (16). Although the maximum follow-up time was 36 months up to the present, one of the common points of this meta-analysis was the lack of long-term follow-up studies (19). A recently published meta-analysis involving the long-term ( $\geq 5$  years) results of TVT and TOT demonstrated that objective and subjective cumulative cure rates for TVT and TOT were 61.6% and 76.5% and 64.4% (95% CI: 61.4-67.4) and 81.3% (95% CI: 78.9-83.7), respectively, and both TVT and TOT are associated with similar long-term objectives ( $p=0.62$ ) and subjective ( $p=0.58$ ) cure rates. In addition, this study also shows that there was no significant difference in the complication rates for all comparisons: TVT versus TOT ( $p=0.40$ ) (20).

Despite the nonavailability of long-term follow-up studies comparing the cost-effectiveness of sling procedures till date, TOT was found to be a better alternative to TVT in terms of cost-effectiveness at the end of a 12-month follow-up period (21). Although our present study does not include a comparison of economic evaluation, TVT might be costlier if a routine control cystoscopy is performed in all TVT procedures (22). Therefore, TOT is an economic

alternative to TVT, because of the lack of a routine cystoscopy after the operation to check the bladder injuries.

The retrospective nature and the small sample size are the principal limitations of the present study. Moreover, the evaluation of patients with OAB-V8 is another limitation of the study. The evaluation of severity of SUI with a validated questionnaire such as the modified Incontinence Impact Questionnaire and the Urogenital Distress Inventory may be helpful in clinical assessment. Despite these facts, we believe that we have contributed to the literature on female SUI in terms of achieving a decrease in OAB scores in both TOT and TVT procedures.

## Conclusion

Our clinical outcomes demonstrate that TOT and TVT have similar success rates. Although the present study was not a comparison with traditional colposuspension methods, either TOT or TVT can be performed safely for the treatment of female SUI as a minimally invasive approach. In addition, the symptoms of urgency UI can be relieved by these surgical interventions along with decreasing OAB scores.

**Ethics Committee Approval:** Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

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