# **ORIGINAL ARTICLE**



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# Outcomes of transobturator tape surgery in the treatment of stress urinary incontinence: 24-month results

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#### **ABSTRACT**

**Objective:** Urinary incontinence is a symptom defined as objectively demonstrable involuntary urinary leakage causing a social or hygienic problem. The prevalence is twice as high in women as in men. It affects the individual's entire daily life, restricting social activities and also increasing healthcare costs. This study investigates the results and complication rates of the transobturator tape (TOT) procedures used for stress urinary incontinence (SUI) treatment in a tertiary center in central Türkiye.

**Materials and Methods:** Forty-four patients undergoing TOT procedures for SUI were prospectively evaluated. Their sociodemographic and clinical characteristics and operative outcome parameters were analyzed.

**Results:** The mean age of the patients was  $51.22\pm8.63$  years, their body mass index was  $28.45\pm4.32$  kg/m², 128 (63.7%) patients were menopausal, and the mean duration of menopausal period was  $9.56\pm5.34$  years. Surgery was successful in 40 (90.9%) cases, the mean operative time was  $24.26\pm4.82$  minutes, mean pre- and post-operative hemoglobin values were  $11.80\pm1.06$  g/L and  $10.75\pm1.03$  g/L, respectively, and the mean length of hospital stay was  $1.06\pm0.22$  days. Groin pain and dyspareunia were present in one (2.8%) patient, urinary tract infections and urine retention in one (2.8%), and mesh erosion two (4.6%). The successful and unsuccessful surgery groups were comparable in terms of age, numbers of pregnancies and parities, duration of symptoms, numbers of patients who delivered via the vaginal route, numbers who underwent episiotomies, numbers of menopausal patients, and the mean duration of the menopause.

**Conclusion:** This study shows that the TOT procedure, a minimally invasive and easily performed technique with a very low complication rate, has a very high success rate in appropriate and correct SUI indications.

**Keywords:** Stress urinary incontinence; surgery success; transobturator tape

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# INTRODUCTION

Urinary continence refers to the ability to retain urine outside periods of voluntary voiding, its mechanism depending on the anatomical and functional urethral length, urethral closure pressure and anatomical support, and pelvic floor muscle activity during stress.<sup>1</sup> Urinary incontinence is defined by the International Continence Society as an objectively demonstrable involuntary leakage of urine that causes a social or hygiene problem.<sup>2</sup> Urinary incontinence is a symptom and a condition that affects the individual's entire daily life, restricts social activities, and also increases healthcare costs. Its frequency in women varies between 14% and 49%, and it is twice as common in women.<sup>3-5</sup>

Stress urinary incontinence (SUI) is defined as involuntary leakage of urine from the urethra without detrusor contraction, due to increased intra-abdominal pressure during activities such as exercise, sneezing, coughing, or laughing.<sup>6</sup> The two basic mechanisms involved in the etiopathogenesis of SUI are urethral hypermobility and intrinsic sphincter deficiency. Weakness of the pelvic floor muscles and connective tissue causes hypermobility in the urethra due to inadequate support for the bladder neck in anatomical terms, while neuromuscular damage to the urethral sphincter also causes intrinsic sphincter deficiency.<sup>7</sup> Advanced age, obesity, vaginal delivery, family history, smoking, diabetes, stroke, menopause, urogenital surgery, cognitive disorders, and dementia constitute known risk factors for SUI.<sup>8</sup>

Previous medical treatment and surgery should be investigated during the evaluation of SUI. Urodynamic evaluation should be performed in the presence of significant urge incontinence and SUI that does not improve despite surgical treatment.<sup>2</sup>

The aim of treatment in SUI is to improve the individual's quality of life by relieving the symptoms. It includes conservative and medical smoking cessation, Kegel exercises including pelvic floor training, pessary use, pharmacological treatment, and surgical procedures such as the Marshall-Marschetti, Burch, transvaginal tape, and transobturator tape (TOT) procedures.<sup>9,10</sup>

Suburethral sling procedures, which generally involve the placement of midurethral slings or bladder neck slings, form the basis of surgical treatment of SUI in modern medical practice. However, slings cannot always correct SUI and may rarely cause bladder hyperactivity, obstruction, or difficulty in emptying the bladder.<sup>2,11</sup> The TOT procedure was first introduced by Delorme in 2001 to avoid complications (bladder perforations, vascular, and bowel injuries) associated with other retropubic placement operations, and is today widely employed in the surgical treatment of SUI.<sup>2,5</sup>

This study aimed to compare the therapeutic success, intraand postoperative results, and complication rates of the TOT procedure used in the surgical treatment of SUI in a tertiary center.

### MATERIALS AND METHODS

This retrospective cohort study involved 44 TOT procedures at the Obstetrics and Gynecology Clinic of University of Health Sciences Türkiye, Antalya Training and Research Hospital, Türkiye, which serves as the largest reference center in Central Anatolia. The institution's Local Ethics Committee of University of Health Sciences Türkiye, Ankara Training and Research Hospital approved the study (reference date: 3/13) and written consent was obtained from the patients during hospitalization for all surgical procedures. The study was performed in compliance with the ethical principles for medical research involving human subjects as set out in the 18<sup>th</sup> World Medical Association Declaration of Helsinki.

Surgical procedures were performed by a gynecologist specializing in the field (BSI). Patients with symptomatic SUI and urge urinary incontinence, and urinary tract infection, and pregnant women were included in the study, while patients receiving chronic anticoagulant therapy were excluded.

# **Preparation Before Surgery**

The day before surgery, the patient scheduled for TOT underwent blood tests, coagulation tests, and electrocardiography, and was evaluated by the anesthesiologist. The patient was administered prophylactic intravenous antibiotics (1 g cefazolin) approximately 30 minutes before surgery, and a bladder catheter was also inserted.

#### **Operative Procedure**

The patient was placed in the supine lithotomy position under spinal anesthesia, and the surgical site was covered to maintain a sterile field following disinfection. Local anesthetic containing epinephrine was injected into the paraurethral area and into the lower parts of the vaginal wall. The polypropylene mesh band (Safyre™, Autofixation Systems) covered with the plastic sheath used for the sling in the TOT procedure was installed from outside to inside with the help of helical trocars, as described by Delorme. The time elapsing from local anesthetic application to the closure of the incision site was measured and recorded as the operative time. The bladder catheter was removed after mobilization on the sixth to eighth hours postoperatively. Patients who were able to urinate spontaneously were discharged on the first postoperative day.

# Statistical Analysis

Data were analyzed on SPSS version 15.0 for Windows software (SPSS, Chicago, IL, USA). The Kolmogorov-Smirnov test was used to determine the normality of distribution of all continuous variables. Normally distributed variables were compared between the groups using the paired t-test, while the Wilcoxon test was applied in case of non-normally distributed variables. Categorical data were analyzed using Pearson's chi-square or Fisher's exact test, as appropriate, and were expressed as numbers and percentages. A *p*-value lower than 0.05 was regarded as statistically significant.

# **RESULTS**

Thirteen of the 57 patients initially accepted for the study were excluded due to unsuitability (urinary incontinence, urinary tract infection, and anticoagulant therapy). The remaining 44 patients were subjected to analysis. All cases were evaluated from hospital admission to discharge.

Table 1 shows the participants' demographic and clinical characteristics. The patients' mean age was 51.22±8.63 years, and their mean body mass index (BMI) was 28.45±4.32 kg/m². The mean number of pregnancies was 4.28±1.34, mean number of parities 3.82±1.61, and the mean duration of symptoms 6.20±2.72 years. Forty-three (97.2%) patients delivered via the vaginal route was and one (2.8%) by cesarean section. Twenty-seven (61.4%) underwent episiotomies, 128 (63.7%) were experiencing the menopause, and the mean length of menopause was 9.56±5.34 years.

Operative outcome parameters are given in Table 2. The success of surgery was 40 (90.9%), the mean operative time was 24.26±4.82 minutes, pre- and post-operative hemoglobin levels were 11.80±1.06 g/L and 10.75±1.03 g/L, respectively, and the mean length of hospital stay was 1.06±0.22 days. No bladder injuries, urethral injuries, vaginal lacerations, bowel injuries, vascular injuries, or pelvic hematomas occurred during the surgical procedures, although groin pain and

Features (n=44)	Mean ± SD	Median (min-max)	Number	%
Mean age (years)	51.22±8.63	44.0 (24.0-71.0)		
BMI (kg/m²)	28.45±4.32	26.32 (23.28-37.14)		
Gravity	4.28±1.34	4.0 (2.0-11.0)		
Parity	3.82±1.61	3.0 (1.0-9.0)		
Duration of symptoms (years)	6.20±2.72	6.00 (2.0-15.0)		
Number of patients delivered via vaginal			43	97.2%
Number of patients perform episiotomy			27	61.4%
Number of patients delivered via cesarean section			1	2.8%
Number of patients in menopausal period of life			28	63.7%
Menopausal period (year)	9.56±5.34	7.00 (2.0-18.0)		
Systemic diseases n (%)				
Hypertension			12	27.3%
Diabetes			10	22.7%
Goiter			9	20.5%
Chronic obstructive pumonary disease			8	18.2%
Hypertension + diabetes			5	11.4%
Hypertension + goiter			4	9.1%
Hypertension + chronic obstructive pumonary disease			3	6.8%
Diabetes + goiter			3	6.8%
Smoking status (%)			18	41.0%
Alcohol consumption (%)			4	9.1%
Caffein consumption (%)			9	20.5%
Cell phone usage (%)			40	90.1%
Drug abuse (%)			4	9.1%
SD: Standard deviation, BMI: Body mass index				

dyspareunia were present in one (2.8%) patient, urinary tract infections and urine retention in one (2.8%) patient, and mesh erosion in two (4.6%), all of which were observed in the early stage. Medical treatments were administered to the patients for the groin pain, urinary tract infections, and dyspareunia, and the vaginal lacerations were primarily repaired. The mesh erosions were asymptomatic and were followed-up. Bladder catheterizations were applied for urine retention over an average of one week, after which the catheters were withdrawn. The surgical success rate was determined as 90.9% at six months. No complications occurred during long-term follow-up.

The data results for the patients with successful and unsuccessful operative outcomes are compared in Table 3. The two groups were comparable in terms of mean age  $(50.73\pm3.60 \text{ vs.} 54.50\pm9.53)$ , respectively, p=0.102, BMI  $(29.25\pm3.59 \text{ vs.} 31.50\pm3.18)$ , p=0.176, numbers of pregnancies [3.5 (2.25-6.25) vs. 4.0 (3.0-5.0), p=0.508], parities [2.0 (1.25-3.5) vs. 3 (2.0-4.0), p=0.119], duration of symptoms  $(6.85\pm2.96 \text{ vs.} 8.75\pm3.30)$ , p=0.233, numbers of patients who delivered via the vaginal route [39 (97.5%) vs. 4 (100.0%), p=0.660], numbers of patients who underwent episiotomies [26 (65.0%) vs. 2 (50.0%), p=0.552], numbers of menopausal patients [25 (62.5%) vs. 4 (100.0%), p=0.282], and length of menopause  $(8.52\pm4.18 \text{ vs.} 10.75\pm2.98)$ , p=0.214).

# DISCUSSION

This study assessed the operative outcomes of the TOT procedures used for SUI treatment in our hospital. We compared the data results for successful and unsuccessful patients postoperatively. No significant differences were observed in terms of mean age, numbers of pregnancies, numbers of parities, or duration of symptoms, numbers of patients who delivered via the vaginal route, who underwent episiotomies, or who were experiencing the menopause, or mean length of the menopausal period.

SUI has become an important health problem as average life expectancy has increased, especially in middle-aged and older menopausal women. Since estrogen levels in the reproductive period decrease rapidly with the menopausal process, SUI is observed more frequently in this time of life. The average age of women undergoing the TOT procedure, the leading surgical treatment method for SUI, in studies varies between 45 and 60.<sup>2,12</sup> In the present study, and consistent with the previous literature, the mean age of the patients who underwent TOT was 51.22±8.63 years, and 63.7% were in the postmenopausal period. In addition, no significant difference was determined between the successful and unsuccessful treatment groups in terms of either age (50.73±3.60 vs. 54.50±9.53, respectively) or duration of menopause (8.52±4.18 vs. 10.75±2.98).

The operative time in TOT surgery, which entails a shorter surgical time and hospital stay compared to other sling procedures,

Table 2. Operative outcome parameters						
	Mean ± SD	Median (min-max)	Number (%)			
Success of surgery			40 (90.9%)			
Duration of operation (minutes)	24.26 <u>+</u> 4.82	19.00 (15.0-29.0)				
Preoperative Hb (gr/L)	11.80 <u>+</u> 1.06	12.7 (10.4-13.4)				
Postoperative Hb (gr/L)	10.75 <u>+</u> 1.03	10.12 (9.6-13.2)				
Hospital stay (days)	1.06 <u>+</u> 0.22	1.00 (1.0-2.0)				
Complications			4 (9.1%)			
Bladder injury			-			
Uretral injury			-			
Bowel injury			-			
Vascular injury			-			
Pelvic hematoma			-			
Vaginal injury			-			
Groin pain + dyspareunia			1 (2.8%)			
Urinary tract infection + urine retention			1 (2.8%)			
Mesh erosion			2 (4.6%)			

Table 3. A comparison of data for successful and unsuccessful patients after surgery							
	Group 1 Successful treatment (n=40)	Group 2 Unsuccessful treatment (n=4)	<i>p</i> -value				
Mean age (years)	50.73 <u>+</u> 3.60	54.50 <u>+</u> 9.53	0.102				
BMI (kg/m²)	29.25 <u>+</u> 3.59	31.50 <u>+</u> 3.18	0.176				
Gravity	3.5 (2.25-6.25)	4.0 (3.0-5.0)	0.508				
Parity	2.0 (1.25-3.5)	3 (2.0-4.0)	0.119				
Duration of symptoms (years)	6.85 <u>+</u> 2.96	8.75 <u>+</u> 3.30	0.233				
Number of patients delivered via vaginal	39 (97.5%)	4 (100.0%)	0.660				
Number of patients perform episiotomy	26 (65.0%)	2 (50.0%)	0.552				
Number of patients in menopausal period of life	25 (62.5%)	4 (100.0%)	0.282				
Menopausal period (year)	8.52 <u>+</u> 4.18	10.75 <u>+</u> 2.98	0.214				
BMI: Body mass index							

varies between 15 and 30 minutes. $^{13,14}$  In the present study, the operative time was  $24.26\pm4.82$  minutes and the length of hospital stay was  $1.06\pm0.22$  days. These results were also compatible with the current literature.

Previous research has determined that the factors affecting the success of TOT are urethral mobility, mixed type urinary incontinence, and the type of mesh used. <sup>15</sup> The presence of mixed type urinary incontinence and lack of mobility of the urethra reduce the success of treatment. Success also varies depending on the type of mesh used. Age is not a factor in success, although the failure rate increases in procedures performed on women over 70. Body weight is also not a factor related to success, although morbid obesity (over 35 years of age) has been described as a risk factor for failure. <sup>2,16</sup> Similar results emerged from the present study, consistent with the previous literature.

A study involving the type of mesh used compared the autologous pubovaginal sling with the synthetic TOT Safyre sling and concluded that the success rate of the autologous pubovaginal sling was much higher.<sup>6</sup>

A woman with normal bladder functions can empty at least 85% of her post-voiding bladder volume, and the post-voiding residual bladder volume should be less than 50 cc. It should be remembered that postoperative edema, infection, and dysuria may cause urinary retention in sling procedures. If this urinary retention persists longer than a week to 10 days, the sling band should be loosened immediately by reopening the same vaginal incision line.<sup>2,17</sup> In the present study, temporary urinary retention was observed in only one (2.8%) patient after TOT surgery, and this disappeared following temporary bladder catheterization performed for approximately one week.

The TOT procedure has a very low complication rate compared to other sling operations. While urination difficulty is the most

prominent complication in the Burch procedure, those that may be seen in sling procedures include groin pain, urinary tract infections, vaginal injuries, dyspareunia, urinary retention, and mesh erosion.<sup>18</sup> Such erosion refers to the emergence of the mesh placed through the vagina by destroying the underlying vaginal tissue and mucosa, instead of the fibroblastic activity that the mesh placed in TOT should normally create. 19 While bladder perforation and inability to urinate or difficulty urinating are the most common and important complications of the midurethral region retropubic sling placement procedure, the reason why these complications are less common in TOT surgery is that the mesh does not form folds in the suburethral region and runs horizontally.<sup>20</sup> The fact that the surgical maneuvers applied in TOT surgery are far distant from the retropubic region is another reason why complications are observed less frequently compared to other sling surgeries.<sup>21</sup> No serious complications were involved in any case in the present study. The most common complication was mesh erosion (5.6%).

#### **Study Limitations**

The potential limitations of this study include the lack of comparison with other sling operations and the absence of long-term results. Particular strengths are that a single experienced urogynecologist performed the TOT surgery and evaluated the results, and that the findings can be adapted to the whole of Türkiye since the clinic where the study was conducted represents the center of the country.

# CONLUSION

In conclusion, this study shows that the TOT procedure, a minimally invasive and easily applied technique with a very low complication rate, has a very high success rate in appropriate and correct SUI indications. However, further studies with larger

cohorts are needed to confirm the results of the current study and to determine long-term outcomes.

### **ETHICS**

**Ethics Committee Approval:** Ethics committee approval was obtained from the University of Health Sciences Türkiye, Antalya Training and Research Hospital Clinical Research Ethics Committee before starting the study (decision no: 3/13, date: 2024.03.21).

**Informed Consent:** Consent was obtained from the patients during hospitalization for all surgical procedures.

#### **FOOTNOTES**

## **Contributions**

Surginal and Medical Practies: B.S.İ., B.Ç.K., A.F.Y., O.H., Concept: B.S.İ., B.Ç.K., H.A.İ., Design: B.S.İ., A.F.Y., Data Collection or Processing: B.S.İ., B.Ç.K., O.H Analysis or Interpretation: B.S.İ, Literature Search: B.S.İ., B.Ç.K., O.H., H.A.İ., Writing: B.S.İ., O.H., H.A.İ.

### **DISCLOSURES**

**Conflict of Interest**: No conflict of interest was declared by the authors.

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