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# **Transobturator tape surgery experience: urodynamic evaluation of** 220 patients in a single tertiary center in Turkey

Iskustvo u hirurškom lečenju primenom transopturatorne trake: urodinamska procena 220 bolesnika u tercijarnom centru u Turskoj

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## Abstract

Background/Aim. Stress urinary incontinence (SUI) is the involuntary leakage of urine after increased intraabdominal pressure, and it causes a significant public health problem by reducing the quality of life, causing sexual dysfunction, and increasing the cost of care due to increased morbidity. The aim of the study was to investigate the intra- and postoperative results and complication rates of the transobturator tape (TOT) procedures used for SUI treatments in a tertiary center located in central Turkey. Methods. This prospective study analyzed a total of 220 patients undergoing TOT procedures for SUI. The demographic and clinical characteristics, preoperative and postoperative cystometry values, and operative outcome parameters of the study participants were analyzed. Results. While no significant difference was noted between the preoperative and postoperative periods with respect to residual volume (27.09  $\pm$  8.51 mL vs. 26.01  $\pm$  3.51 mL, p =0.125), there were significant differences in terms of the first urinary urge (142.61 ± 20.25 mL vs. 145.64 ± 20.91 mL, p < 0.001), maximum bladder capacity (423.70 ±  $38.43 \text{ mL vs. } 402.32 \pm 39.46 \text{ mL}, p < 0.001$ ), the Q-tip angle (45.54  $\pm$  5.33° vs. 43.81  $\pm$  6.15°, p = 0.001), the maximum flow rate (37.65  $\pm$  11.54 mL/s vs. 24.38  $\pm$  9.26 mL/s, p < 0.001), average flow rate (19.92 ± 9.64 mL/s vs. 14.77  $\pm$  8.71 mL/s, p < 0.001), the number of urinations in the daytime (7.29  $\pm$  1.35 vs. 6.58  $\pm$  1.29, p < 0.001), and the number of urinations at nighttime (1.48  $\pm$  1.01 vs. 0.92  $\pm$  0.83, p < 0.001). **Conclusion.** The TOT procedure improves the quality of life of SUI patients and can reduce morbidity. Nevertheless, additional studies are needed to corroborate our findings and determine the long-term effects.

## Key words:

female; suburethral slings; surgical procedures, operative; urinary incontinence, stress.

## Apstrakt

Uvod/Cilj. Urinarna stres inkontinencija (USI) je ispuštanje nevoljno urina posle povećanja intraabdominalnog pritiska što predstavlja značajan zdravstveni problem, smanjuje kvalitet života, uzrokuje seksualnu disfunkciju i povećava troškove nege zbog povećanog morbiditeta. Cilj rada bio je da se ispitaju intra- i postoperativni rezultati i stopa komplikacija u procedurama u kojima se primenjuje transopturatorna traka (TOT) u lečenju USI, u tercijarnom zdravstvenom centru u centralnoj Turskoj. Metode. Prospektivnom studijom ispitana su 22 bolesnika podvrgnuta proceduri u kojoj se primenjuje TOT u lečenju USI. Analizirane su demografske i kliničke karakteristike, preoperativne i postoperativne vrednosti cistometrije i parametri ishoda operativnog lečenja. Rezultati. Nije utvrđena značajna razlika između preoperativnog i postoperativnog perioda u odnosu na rezidualni volumen (27,09  $\pm$  8,51 mL vs. 26,01  $\pm$  3,51 mL, p = 0,125), a nađena je značajna razlika u pogledu prvog poziva na mokrenje (142,61  $\pm$  20,25 mL vs. 145,64  $\pm$  20,91 mL, p < 0,001), maksimalnog kapaciteta mokraćne bešike (423,70  $\pm$  38,43 mL vs. 402,32  $\pm$  39,46 mL, p < 0,001), Q-tip ugla (45,54  $\pm$  5,33° vs. 43,81  $\pm$ 6,15°, p = 0,001), maksimalnog protoka urina (37,65 ± 11,54 mL/s vs. 24,38  $\pm$  9,26 mL/s, p < 0,001), prosečnog protoka urina (19,92  $\pm$  9,64 mL/s vs. 14,77  $\pm$  8,71 mL/s, p < 0,001), broja mokrenja (BM) u toku dana (7,29 ± 1,35 vs. 6,58 ± 1,29, p < 0,001) i BM u toku noći (1,48 ± 1,01 vs.  $0,92 \pm 0,83, p < 0,001$ ). Zaključak. Procedura u kojoj se primenjuje TOT poboljšava kvalitet života bolesnika sa USI i može smanjiti morbiditet. Neophodna su dodatna istraživanja da bi se potvrdili rezultati ove studije i utvrdili dugoročni efekti.

## Ključne reči:

žene; trake, suburetralne; hirurgija, operativne procedure; inkontinencija, urinarna, stress.

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## Introduction

Stress urinary incontinence (SUI), which can cause social and hygienic problems, affects 14–35% of women <sup>1, 2</sup>. It is the involuntary leakage of urine after increased intraabdominal pressure in certain situations, such as exercise, sneezing, coughing, and laughing, without bladder detrusor muscle contraction <sup>2, 3</sup>. SUI causes a significant public health problem by reducing the quality of life, causing sexual dysfunction, and increasing the cost of care due to increased morbidity <sup>4, 5</sup>. Old age, obesity, interventional vaginal delivery, positive family history, smoking, diabetes mellitus, stroke, menopause, genitourinary surgery, cognitive impairment, and dementia are all risk factors for urinary incontinence <sup>6, 7</sup>.

Urethral hypermobility and intrinsic sphincteric deficiency are the two main mechanisms involved in the etiopathogenesis of SUI<sup>8,9</sup>. In urethral hypermobility cases, there is insufficient support from the suburethral and vaginal connective tissue and pelvic floor muscles to the bladder neck, which results in increased intraabdominal pressure while coughing or sneezing, or in the loss of connective tissue and pelvic muscular strength due to a particularly interventional vaginal delivery<sup>8</sup>. In intrinsic sphincteric deficiency cases, neuromuscular damage occurs due to pelvic or incontinence surgery, aging, and menopause<sup>9</sup>.

The aim of the SUI treatment is to relieve the symptoms and improve the quality of life of the female patient. Both conservative and surgical options are available for the treatment of SUI. The conservative approach includes the elimination of certain factors that cause SUI, such as smoking, the use of certain types of pessaries, pharmacological therapy, and physiotherapy. Kegel exercises are the primary physiotherapy treatment for SUI <sup>10–12</sup>.

Marshall et al. 13 first described the simple vesicourethral suspension technique as a surgical treatment for SUI. Subsequently, in 1961, Burch <sup>14</sup> developed a technique that included hanging the vesicourethral tissues on Cooper's ligament. Instead of hanging the vesicourethral tissues, Tanagho<sup>15</sup> suggested a colpocystourethropexy technique to prevent postoperative voiding dysfunction. However, suburethral sling procedures are the basis of the surgical treatment of SUI. These procedures consist of either midurethral or bladder neck slings. The slings placed in this area do not always correct SUI, can cause bladder hyperactivity or even bladder obstruction occasionally, and produce a bladder emptying difficulty. Mid-urethral slings include retropubic mid-urethral slings (e.g., tension-free vaginal tape), transobturator tape (TOT) mid-urethral slings, and singleincision mid-urethral slings. Bladder neck slings, also called proximal urethral slings, are fixed to Cooper's ligament or anterior rectus muscle fascia via an abdominal or vaginal incision <sup>16</sup>. The mid-urethral sling procedure was performed for the first time in 1996 using a mesh through the retropubic space with the aid of trocars <sup>17</sup>. In 2001, TOT slings were introduced by Delorme in order to avoid retropubic insertion complications, such as bladder perforations, vascular injuries, and bowel injuries <sup>18</sup>.

The aim of this study was to compare intra- and postoperative results and complication rates with the TOT procedures used for SUI treatments in a tertiary center located in central Turkey.

## Methods

This prospective cohort study included 220 TOT procedures carried out between January 1, 2015, and December 31, 2020, at the Gynecology Department of Konya Education and Research Hospital, a tertiary institution serving as a referral center for Konya and middle Anatolia in Turkey. This study was approved by the institution's local Ethics Committee from September 30, 2016 and written informed consent for all of the gynecological operations was obtained. The ethical principles for medical research involving human subjects stipulated in the 18<sup>th</sup> World Medical Association Declaration of Helsinki were applied. Because of the learning curve, the surgical procedures were all performed by two senior consultant gynecologists.

The inclusion criteria for this procedure were patients with symptomatic SUI who had occult SUI and who had no contraindications for lithotomy. We excluded the TOT procedures used for patients with urge incontinence, active urinary tract infections, current pregnancies, and anticoagulant treatments to prevent the risk of hematoma formation.

## Presurgical preparation

Each patient undergoing a TOT procedure was admitted to the outpatient clinic of the hospital one day before their scheduled operation. A standard preoperative assessment (cell blood count, coagulation tests, and electrocardiography) was performed, and prophylactic intravenous antibiotics (1 g of cefazolin) were administered to all patients as premedication by a senior nurse approximately 30 min before the surgery. A bladder catheter was inserted during the surgical procedure and was withdrawn 6–8 hrs after the patient's mobilization.

## TOT surgical procedure

After the patient was placed in the dorsal lithotomy position, disinfection and sterile coverage were performed. Local anesthetic with epinephrine was injected paraurethrally into the lower parts of the vaginal wall. The TOT procedure was carried out externally to internally, as described by Delorme <sup>18</sup>. Polypropylene mesh tape covered with a plastic sheath and helical trocars (I-STOP; CL Medical, Lyon, France) were used for this procedure. The duration of the TOT procedure was measured from the time of administering the local anesthetic to the moment of closing sutures, and the duration was recorded.

#### Data analysis

The sociodemographic characteristics included age, body mass index (BMI), gravity, parity, duration of symp-

toms (years), episiotomies performed, Cesarean sections performed, number of patients in menopause, menopausal period (years), systemic diseases, hypertension, diabetes, goiter, chronic obstructive pulmonary disease, educational level, economic status, residence, smoking status, alcohol consumption, caffeine consumption, cell phone usage, and drug abuse. The preoperative and postoperative (at the first week, third month, sixth month, and first year) cystometry values regarding the first urinary urge, maximum capacity, Q-tip angle, residual volume, maximum flow rate (Qmax) (mL/s), average flow rate (Qave) (mL/s), number of urinations during the daytime, and number of urinations at nighttime were evaluated. In addition, the operative outcome parameters in terms of surgical success, operation duration (min), preoperative hemoglobin (Hb), postoperative Hb, hospital stay, and complications were also checked. The patients were called for a control examination every three months in the first year after surgery. The absence of urine incontinence during stress maneuvers in the pelvic examination postoperatively in the third month was considered a success of the surgery.

#### Statistical analysis

We used the Statistical Package for the Social Sciences version 15 (SPSS Inc., Chicago, IL, USA) for the statistical analyses. The distributions of all continuous variables for the normal or nonnormal distributions were tested using the Kolmogorov-Smirnov test. The homogeneity of the variances was evaluated using the Levene test. Metric discrete and continuous variables were expressed as the mean  $\pm$  standard deviation where applicable. The nominal data were expressed as the number of cases and percentages. Although the normally distributed variables between the groups were compared using a paired-sample *t*-test, the Wilcoxon test was applied to the nonnormally distributed variables. A *p*-value of < 0.05 was considered statistically significant.

## Results

Seventy-nine of the 299 patients evaluated between January 1, 2015, and December 31, 2020, were not eligible for the study and were thus excluded (urge incontinence, urinary tract infection, current pregnancy, and/or anticoagulant treatment). The remaining 220 patients were analyzed, as shown in Figure 1. All of the patients were observed from the start of the surgery until they were discharged from the hospital.

The demographic and clinical characteristics of the study participants are presented in Table 1. The mean age of the patients was  $53.87 \pm 6.22$  years, and the BMI was  $30.95 \pm 3.13$  kg/m<sup>2</sup> at the end of the study. The systemic disease incidence was 128, and the mean duration of symptoms was  $6.20 \pm 2.72$  years.



Fig. 1 – Enrollment and follow-up of the study subjects.

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#### Table 1

Demographic and clinical characteristics of the study participants (n = 220)

Parameter	Values
Mean age (years)	
mean $\pm$ SD	$53.87 \pm 6.22$
median (min-max)	53.00 (45.0-65.0)
BMI (kg/m <sup>2</sup> )	
mean $\pm$ SD	$30.95 \pm 3.13$
median (min-max)	31.00 (24.0-38.0)
Gravity	
mean $\pm$ SD	$4.18 \pm 1.47$
median (min-max)	4.00 (2.0-7.0)
Parity	
mean $\pm$ SD	$3.23 \pm 1.16$
median (min-max)	3.00 (1.0-6.0)
Duration of symptoms (years)	
mean $\pm$ SD	$6.20\pm2.72$
median (min-max)	6.00 (2.0-15.0)
Patients with performed episiotomy, n (%)	148 (67.3)
Patients who delivered via Cesarean section, n (%)	21 (9.5)
Patients in the menopausal period of life, n (%)	155 (70.5)
Menopausal period (year)	
mean $\pm$ SD	$7.61 \pm 4.40$
median (min-max)	7.00 (1.0-17.0)
Systemic diseases, n (%)	
hypertension	42 (19.1)
diabetes mellitus	21 (9.5)
goiter	12 (5.5)
chronic obstructive pulmonary disease	16 (7.3)
hypertension + diabetes mellitus	16 (7.3)
hypertension + goiter	11 (5.0)
hypertension + chronic obstructive pulmonary disease	6 (2.7)
diabetes mellitus + goiter	4 (1.8)
Education level (%)	
illiterate	8 (3.6)
primary or secondary school	147 (66.9)
high school	43 (19.5)
university	22 (10.0)
Economic status, n (%)	
Lower level (< 5,000 dollars/year)	60 (27.3)
Intermediate level (5,000–10,000 dollars/year)	122 (55.4)
High level (> 10,000 dollars/year)	38 (17.3)
Residence lives, n (%)	
village	73 (33.2)
town	67 (30.5)
city	80 (36.4)
Smoking status, n (%)	84 (38.2)
Alcohol consumption, n (%)	16 (7.3)
Caffeine consumption, n (%)	41 (18.6)
Cell phone usage, n (%) Drug abuse, n (%)	183 (83.2) 7 (3.2)

BMI – body mass index; SD – standard deviation; min – minimum; max – maximum.

The preoperative and postoperative cystometry values are shown in Table 2. While no significant difference was noted between the preoperative and postoperative periods with respect to residual volume, there were significant differences in terms of the first urinary urge (p < 0.001), maximum bladder capacity (p < 0.001), the Q-tip angle (p = 0.001), Qmax (p < 0.001), Qave (p < 0.001), number of urinations during the daytime (p < 0.001), and number of urinations at nighttime (p < 0.001).

The operative outcome parameters of the patients are summarized in Table 3. The mean operation duration was  $18.43 \pm 3.98$  min, the preoperative mean Hb level was  $11.20 \pm 0.94$  g/dL (normal range 12-16 g/dL), the postoperative mean Hb level was  $10.97 \pm 0.95$  g/dL, and the mean hospital stay was  $1.02 \pm 0.13$  days. While there was no bladder, ure-thral, bowel, or vascular injury or pelvic hematomas during the surgical procedures, there was groin pain in 4 patients, urinary tract infections in 3 patients, vaginal injuries in 2

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#### Table 2

Preoperative and postoperative cystometry values at first year

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Parameter	Preoperative	Postoperative	<i>p</i> -value
First urine urge (cc)	$142.61 \pm 20.25$	$145.64 \pm 20.91$	< 0.001
Maximum bladder capacity (cc)	$423.70 \pm 38.43$	$402.32 \pm 39.46$	< 0.001
Q-tip angle	$45.54\pm5.33$	$43.81 \pm 6.15$	0.001
Maximum flow rate (mL/s)	$37.65 \pm 11.54$	$24.38 \pm 9.26$	< 0.001
Average flow rate (mL/s)	$19.92 \pm 9.64$	$14.77\pm8.71$	< 0.001
Residual volume (cc)	$27.09 \pm 8.51$	$26.01 \pm 3.51$	0.125
Number of urinations in daytime	$7.29 \pm 1.35$	$6.58 \pm 1.29$	< 0.001
Number of urinations at nighttime	$1.48 \pm 1.01$	$0.92\pm0.83$	< 0.001

cc - cubic centimeters.

# Table 3

<b>Operative outcome parameters of the patients</b>		
Parameter	Values	
Success of surgery, n (%)	211 (95.6)	
Duration of operation (min)		
mean $\pm$ SD	$18.43\pm3.98$	
median (min-max)	18.00 (13.0-23.0)	
Preoperative Hb (g/dL)		
mean $\pm$ SD	$11.20 \pm 0.94$	
median (min-max)	10.70 (9.0–13.0)	
Postoperative Hb (g/dL)		
mean $\pm$ SD	$10.97\pm0.95$	
median (min-max)	10.60 (9.0–13.0)	
Hospital stay (days)		
mean $\pm$ SD	$1.02 \pm 0.13$	
median (min-max)	1.00 (1.0–2.0)	
Complications, n (%)	15 (6.8)	
Groin pain	4 (1.8)	
Urinary tract infection	3 (1.3)	
Vaginal injury	2 (0.9)	
Dyspareunia	2 (0.9)	
Urine retention	2 (0.9)	
Mesh erosion	2 (0.9)	

Note: Normal range for hemoglobin (Hb) is 12–16 g/dL. SD – standard deviation; min – minimum; max – maximum.

patients, dyspareunia in 2 patients, urine retention in 2 patients, and mesh erosion in 2 patients, and all of them were observed in the early stage. The patients were given medical treatments for groin pain, urinary tract infections, and dyspareunia, and the vaginal lacerations were primarily repaired. The mesh erosions were followed-up because they were asymptomatic. The urine retention cases were treated with bladder catheterizations for one week on average, and then, the symptoms disappeared. The success of the surgery was determined at 95.6% in the third month. No complications were observed during the long-term follow-up.

# Discussion

In this study, we assessed the results of the TOT procedures used for SUI treatments and compared the intra- and postoperative results and complication rates. Significant differences were seen in terms of the first urinary urge, maximum bladder capacity, the Q-tip angle, Qmax, Qave, number of urinations during the daytime, and number of urinations at nighttime. With the increased life expectancy, SUI remains a major health problem. SUI is generally more common in women in the middle to older age groups and during the postmenopausal period. The average age of the women who underwent TOT procedures due to SUI ranged from 46 to 58 years in various studies  $^{10, 19-21}$ , and in our study, the average age was  $53.87 \pm 6.22$  years. Additionally, 155 (70.5%) participants were in the postmenopausal period. The reason that SUI is more common in the menopausal period may be due to the rapid decrease of the higher estrogen levels during the reproductive period with the onset of menopause. These results were similar to those from the study conducted by Ulubay et al. <sup>20</sup>.

The TOT procedure has a very short operative time and hospitalization stay compared to the other sling procedures. In various studies, the operation time varied between 12 and 23 min <sup>22, 23</sup>. In accordance with the literature, the operation duration in our study was  $18.43 \pm 3.98$  min and the hospitalization time was  $1.02 \pm 0.13$  days.

A woman with normal bladder function can fully discharge more than 80% of the bladder volume, with a postvoid residual volume of less than 50 cc<sup>24</sup>. There was no significant difference between the participants in terms of the residual volumes during the preoperative and postoperative periods. In sling procedures, postoperative edema and painful urination may cause retention. If this retention lasts longer than one week, the sling tape should be loosened using the same vaginal incision line as soon as possible <sup>25, 26</sup>. Transient urinary retention was observed in 2 (0.9%) patients following the surgical procedure. These patients underwent bladder catheterizations for an average of one week, and the urine retention symptoms disappeared.

The most important characteristic that separates a TOT procedure from other sling operations is its low complication rate. While voiding difficulty is the most prominent complication in the Burch <sup>14</sup> procedure, groin pain, urinary tract infections, vaginal injuries, dyspareunia, urine retention, and mesh erosion are the common complications in sling procedures. The most frequent and important complications of the retropubic mid-urethral sling placement procedure are bladder perforation, voiding dysfunction, and the development of urinary urgency symptoms. Similar to retropubic slings, TOT slings may result in voiding dysfunction <sup>27, 28</sup>. The reason for less frequent voiding disorders in the TOT procedure is that the tape passes horizontally through the suburethra and thus makes no kink. Additionally, the major complication rate is quite low compared to other sling procedures since the surgical maneuvers in the TOT procedure are far from the retropubic region <sup>18, 20</sup>. While no major complications were observed in any of the participants in our study, the most common complication observed was groin pain which was resolved within the first 2 weeks.

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The limitations of the current study were that there were no comparisons with other sling procedures, and there was a lack of long-term follow-up results. The strengths of the present study include the sufficient number of participants and the representative sample from central Turkey. Therefore, the results of this study could be generalized to the majority of the country. Another strength of our study is that it was a prospective investigation, and the same senior surgeons performed the TOT procedures.

#### Conclusion

In conclusion, this study demonstrated that the TOT procedure is an easy-to-apply, minimally invasive technique with low peri- and postoperative complication rates and a high success rate in appropriate and correct indications. Additionally, the TOT procedure improves the quality of life of the patient and reduces morbidity. Nevertheless, further studies with larger cohorts are needed to validate the results of the current study and determine the longterm effects.

#### **Conflict of Interest**

The authors declare no conflict of interest.

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