



Evaluation of the Effectiveness of Trans Obturator Tape Operation in the Treatment of Stress Incontinence

Stres İnkontinans Tedavisinde Trans Obturator Bant Operasyonunun Etkisinin Değerlendirilmesi

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Abstract

Objective: In this study, we aimed to assess the effectiveness of transobturator tape operation in the treatment of stress incontinence

Material and Method: We retrospectively evaluated 454 patients who had TOT operations due to stress urinary incontinence between January 01.01. 2017, and December 31.12.2020, at the Training and Research Hospital. The basic clinical characteristics of the participants were recorded. The number of daily pads, values of Q-type test and urinary retention, and scores of urogenital disorder inventory-6 and impact of incontinence inquiry form at the clinical evaluation perioperatively and 6 months after the operation. Data analysis of the study was done with the SPSS version 24.0 package program. Kolmogorov-Smirnov test was used for normality analysis. Wilcoxon test was used for the comparisons of preop and postop data. It was considered statistically significant when the P value was below 0.05

Results: The study was conducted on 454 patients aged 26-83 years with a mean age of 50.3±10 years. The overall complication rate was 15.9. The rate of those who recovered six months after the operation was 89.6%. The number of daily pads, values of Q-tip test and urinary retention, and scores of questionnaires were significantly reduced after surgery (p=0.001).

Conclusion: The TOT operation can be preferred in treating stress incontinence with acceptable success and outcome. The scales of questionnaires successfully determine patient satisfaction with surgical efficacy for SUI.

Keywords: Stress urinary incontinence, transobturator tape operation, urogenital disorder inventory-6, the impact of incontinence inquiry

Öz

Amaç: Bu çalışmada, stres inkontinans tedavisinde transobturator bant operasyonunun etkinliğini değerlendirmeyi amaçladık.

Gereç ve Yöntem: 1 Ocak 2017-31 Aralık 2020 tarihleri arasında bir il Eğitim ve Araştırma Hastanesi'nde stres üriner inkontinans nedeniyle TOT ameliyatı olan 454 hasta retrospektif olarak değerlendirildi. Katılımcıların temel klinik özellikleri kaydedildi. Operasyonun klinik değerlendirmesi perioperatif ve 6 ay sonra günlük ped sayısı, Q-tipi test ve idrar retansiyonu değerleri, ürogenital bozukluk envanteri-6 puanları ve inkontinans sorgulama formu ile yapıldı. Çalışmanın veri analizi SPSS versiyon 24.0 paket programı ile yapılmıştır. Normallik analizi için Kolmogorov-Smirnov testi kullanıldı. Ameliyat öncesi ve sonrası verilerin karşılaştırılmasında Wilcoxon testi kullanıldı. P değeri 0.05'in altında olduğunda istatistiksel olarak anlamlı kabul edildi.

Bulgular: Çalışma yaş ortalaması 50.3±10 yıl olan 26-83 yaş arası 454 hasta üzerinde yapıldı. Genel komplikasyon oranı 15.9 idi. Ameliyattan altı ay sonra iyileşenlerin oranı %89,6 idi. Ameliyattan sonra günlük ped sayısı, Q-tip testi ve idrar retansiyonu değerleri ve anket puanları önemli ölçüde azaldı (p=0,001).

Sonuçlar: Stres inkontinans tedavisinde TOT operasyonu kabul edilebilir başarı ve sonuçlarla tercih edilebilir. Anket ölçekleri, SUI için cerrahi etkinlik ile hasta memnuniyetini başarılı bir şekilde belirler.

Anahtar Kelimeler: Stres üriner inkontinans, transobturator bant operasyonu, ürogenital bozukluk envanteri-6, inkontinans sorgulamasının etkisi



INTRODUCTION

Urinary incontinence is an objectively demonstrable involuntary event that causes a social or hygienic problem, according to the definition of the International Continence Association.^[1] Although the prevalence of urinary incontinence increases with age, it should not be accepted as the natural course of old age. The most common types of urinary incontinence are stress incontinence 45%, urgency incontinence 25%, and mixed types 28%.^[2] Stress and mixed urinary incontinence, the most frequent causes in women, have become significant public health problems affecting the quality of life. Urodynamically, it develops due to intravesical pressure exceeding the urethral closure pressure without detrusor contraction.^[3,4] The main mechanism in the emergence of stress urinary incontinence is the loss of bladder neck and urethral support. In 1995, Ulmsten and Petros described tension-free vaginal tape (TVT) surgery, which provides hammock-like support to the ureterovesical junction.^[5] Non-tight support of the mid-urethra has yielded more than 80% success.^[6] The TVT procedure had been shown to have the same efficacy as Burch colposuspension.^[7] In tension-free vaginal tape surgery, the needle or trocar passes blindly through the retropubic space. To avoid life-threatening complications and develop different techniques, the trans obturator tape (TOT) technique was proposed in 2001.^[8] In the transobturator band technique, the trocar or needle does not pass through the retropubic area. The tape is placed between the two obturator foramen. (trans obturator tape method (TOT)). Studies have reported that the success of TOT and TVT in providing continence is similar, and the complication rate of the TOT technique is lower.^[9] The TOT operation has been widely used because of its safe, effective, easy to apply, high treatment success rate of 84%-95%, and low complication rates.^[10] In this study, we aimed to assess the effectiveness of Transobturator Tape Operation in the treatment of Stress Incontinence.

MATERIAL AND METHOD

We retrospectively evaluated the patients who had TOT operations due to stress urinary incontinence between January 1, 2017, and December 31, 2020, at the Training and Research Hospital. The study was conducted on 454 patients, 398 (87.7%) with pure stress urinary incontinence and 56 (12.3%) with mixed urinary incontinence. This study was conducted by the 2013 revision of the Declaration of Helsinki. The study was carried out with the permission of Istanbul Kanuni Sultan Süleyman Training and Research Hospital (KAEK/2021.05.168). The requirement for patient consent to participation and publication was waived due to the retrospective nature of the study. Written informed permission for treatment was obtained from all patients.

Demographic characteristics of the patients were recorded. Urogenital distress inventory-6 and incontinence impact questionnaire-7 were used to determine incontinence severity preoperatively and postoperatively in all patients.^[11] Urodynamic testing was only used to confirm the absolute

diagnosis of mixed-type urinary incontinence. All patients were subjected to detailed physical, urogynecological, and neurological examinations, and pelvic organs were evaluated with pre-and post-operative urinalysis, urine culture, post-void residual urine measurement, and ultrasound. To detect urethral hypermobility, a Q-tip test was performed with 200 mL of urine in the bladder in the lithotomy position. Bladder neck mobility was evaluated as positive when the amount of angle change in the straining and resting states of the cotton swab, the tip of which was placed in the internal urethral meatus, was above 30 degrees. When the bladder was full of saline, the patient coughed in the examination position or outpatient. It was checked whether there was urinary incontinence. The stress test was considered positive in cases with urinary incontinence. Urinary tract infections were treated with appropriate antibiotics.

Postoperative cases were called for controls in the 1st, 3rd, and 6th months, and urogynecological examinations were performed, Urogenital distress inventory-6 and incontinence impact questionnaire-7, stress test, examination findings, neurological evaluation, residual urine, and Q-tip test. The patients were re-evaluated with the number of daily pads, and the operational success and perioperative complications were evaluated and recorded

After the operation, those who had a post-operative stress test (-), whose residual urine amount was below 100 mL, and who had complete continence were as 'full recovery'; Those who had a post-operative stress test (+) but did not incontinent were considered as partial recovery. Patients evaluated as having 'full recovery,' and 'partial recovery' were accepted as successful, and patients with a post-operative stress test (+) and incontinence continued were considered 'TOT failure.'^[12] The women included in the study such as diagnosed with stress incontinence, who did not plan to give birth in the next life, who did not have urinary system infection, who did not show a bleeding tendency, who had no anti-incontinence surgery before, who had involuntary urine leakage with coughing, sneezing, had urethral hypermobility more than 30 degrees with Q-type test, had preoperative residual urine volume of less than 100 mL and had no neurological disease

The women were excluded from the study such as those diagnosed with no stress incontinence, who planned to give birth in the next life, who had urinary system infections, who showed a bleeding tendency, who had anti-incontinence surgery before, who had no involuntary urine leakage with coughing, sneezing, had urethral hypermobility less than 30 degrees with Q-type test, had preoperative residual urine volume of more than 100 mL and had a neurological disease

An informed consent form was obtained from all patients before the operation. For prophylactic treatment, a total of 2 g of cefazolin sodium was administered IV approximately one hour before and 6 hours after the operation. All procedures were performed with an outside-in Obtryx™ (Boston Scientific, Natick, MA, USA) brand kit.

Surgical technique

Spinal anesthesia was used in surgical procedures, and a vertical incision of approximately 1.5-2 cm was made about 1 cm distal to the external urethral meatus. With Metzenbaum scissors, sharp and blunt dissections were made, and the periurethral fascia was dissected approximately 1 cm laterally. The ischiopubic ramus was palpated with the index finger, and two 0.5 cm skin incisions were made in both genito-inguinal folds at a distance of approximately 2 cm at the clitoris level. A hook-shaped needle was inserted through the incision. Simultaneously, the index finger was inserted through the paraurethral area to guide the hand, and the needle was removed from the paraurethral site by passing it through the obturator foramen. Here, a polypropylene sling material was applied with its attachment to the needle tip, and then it was pulled back, and the same procedure was applied on the opposite side of the urethra. While removing the sling material, a clamp was placed between the urethra and mesh to ensure that the mesh was not tight, and the ends were cut at the subcutaneous level above. The incision in the urethral region was sutured with soluble 2/0 Vicryl.^[13] Complications that occurred during the operation were recorded. The bladder was filled with 400 mL of physiological saline to measure the amount of residual urine. After the patient urinated, the catheter was inserted again, and the amount of urine remaining in the bladder was measured. Catheterization was continued for an additional 6-8 h in patients with more than 100 mL of residual urine. Patients with less than 100 mL residual urine volume were discharged with oral antibiotics. All patients were recommended sexual abstinence for 45 days.

Statistical analysis

Data analysis of the study was done with IBM SPSS for Windows 24.0 package program (IBM SPSS Inc, Chicago, Illinois, USA). Kolmogorov-Smirnov test were used for normality analysis. Descriptive statistics are numbers and percentages for categorical variables, mean with standard deviation as normally distributed numeric variables, or median with minimum and maximum as appropriate. Wilcoxon test was used for the comparisons of preop and postop data. It was considered statistically significant when the P value was below 0.05

RESULTS

During the study period, 481 patients with stress incontinence were included. Of the study population, 27 were excluded because of postoperative loss to follow-up. **Table 1** shows the selected clinical characteristics of the study population undergoing surgical management of stress incontinence.

Approximately 48% of study participants whose clinical and incontinence data were analyzed were in menopause. However, the age of surgery ranged from 26 to 83 years. Chronic disease history rates such as diabetes mellitus, hypertension, and heart and thyroid diseases were between 5.3% and 23.8%.

Table 1. Selected clinical characteristics of participants with stress incontinence (n=454).

		min-max
Age (year)	50.3 (9.8)	26-83
Parity	3.5 (1.7)	0-11
History of		
Diabetes mellitus	74 (16.3%)	
Hypertension	108 (23.8%)	
Heart disease	24 (5.3%)	
Thyroid disease	39 (8.6%)	
Number of vaginal delivery	3.4 (1.8)	0-11
History of macrosomia	123 (27.1%)	
Menopause	220 (48.5%)	
Smoking	58 (12.8%)	
BMI (kg/m ²)	27.0 (3.0)	20.5-40.6
Duration of incontinence (year)	4.0 (2.6)	1-20
Type of incontinence		
Stress	399 (87.9%)	
Mixed	55 (12.1%)	
Surgery procedure		
only TOT	364 (80.17%)	
TOT with colporrhaphy anterior	44 (9.69%)	
TOT with colporrhaphy posterior	14 (3.1%)	
TOT with vaginal hysterectomy	32 (7.04%)	
Operation time (min)	45.2 (22.0)	25-115
Hospital stay (day)	2.4 (1.3)	2-6
Complications (total)	72 (15.9%)	
Hemorrhagia (more than 200 m)	6 (1.3%)	
Mesh erosion	12 (2.6%)	
Urinary retention	7 (1.5%)	
Bladder perforation	4 (0.9%)	
Perineal pain	12 (2.6%)	
De novo urge incontinence	14 (3.1%)	
Vaginal perforation	5 (1.1%)	
Dyspareunia	12 (2.6%)	
Success of surgery		
Compleat recovery	382 (84.1%)	
Partial recovery	25 (5.5%)	
No recovery	47 (10.4%)	

Data are expressed as mean (standard deviation) or count (%).

Our data supported the impact of many vaginal deliveries, history of macrosomic deliveries, menopausal status, smoking, and being overweight and obese. Duration of incontinence before surgical treatment changed from 1 to 20 years with a mean value of 4 years. This highlighted the importance of time incontinence as a determiner of surgical success. Of the study participants, about 88% had only stress incontinence and the rest had mixed incontinence; for this condition, the physicians paid attention while giving information about the surgical treatment of patients and relatives. The complication rate was about 16%, and the complete success of the surgery was about 84%. Considering the clinical characteristics of study participants, stress incontinence and its surgery have many complex aspects encountered during urogynecological management.

Table 2 shows the Preoperative and postoperative 6-month follow-up results of the patients

Table 2: Preoperative and postoperative 6-month follow-up results of the patients			
	Preoperative	Postoperative	P value
(UDI-6)	10,9±0,7	2,1±1,6	0,001
(IIQ-7)	15,6±2,2	1,56±1,2	0,001
Average number of pads/d	2,5±2,2	0,3±0,6	0,001
Amount of residue urine /ml	66,30±11,5	28,4,2±8,4	0,001
Q type test	62,9±1,4	27,5±8,1	0,001
Stresstest(+)	%100	72(%15,9)	0,001

Mean ,SD, standard deviation,d,days,ml milliliter,(+) positive.

Compared to the pre-operative period, the number of pads used daily decreased, and the Q-type test results improved significantly. There was a significant decrease in residual urine volume.

Of the study population, the variables measured preoperatively and postoperatively were shown in **Figures 1** and **2**. The scores of urogenital disorder inventory-6, and incontinence impact inquiry forms preoperatively were significantly reduced after surgery ($p=0.001$).

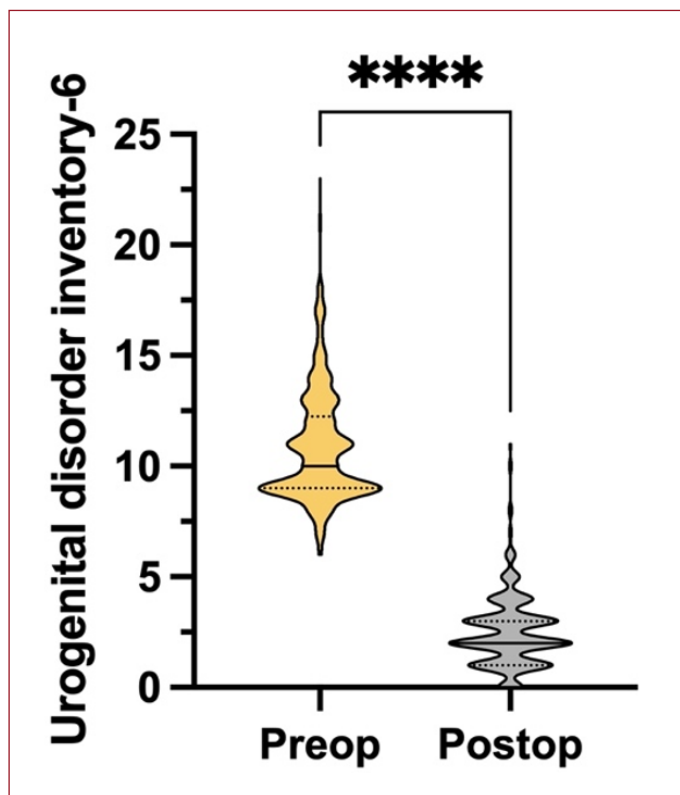


Figure 1. Scores of urogenital disorder inventory-6 measured in the study participants with stress incontinence. Data are expressed as median with a 25-75 interquartile range. The score of urogenital disorder inventory-6 preoperatively was significantly reduced after surgery ($p=0.001$).

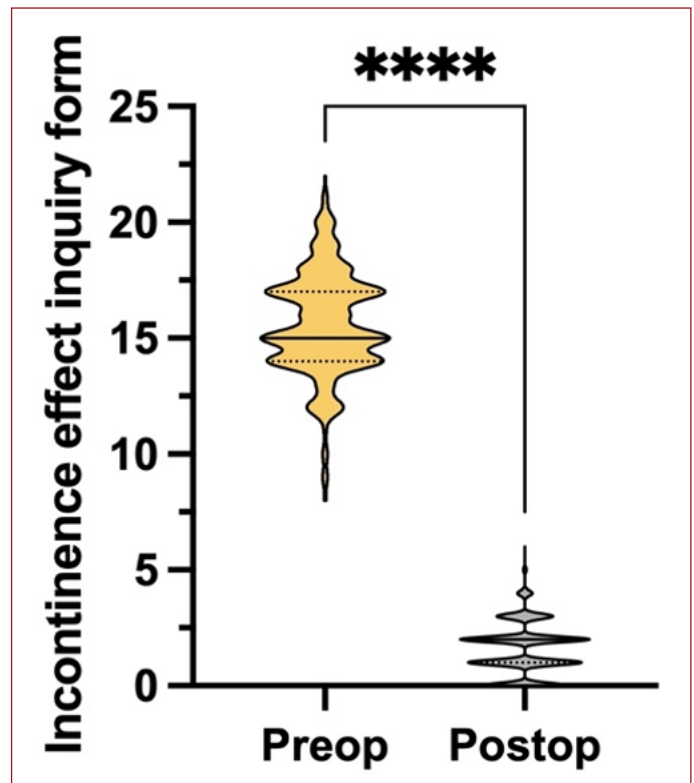


Figure 2. Scores of the impact of incontinence inquiry form measured in the study participants with stress incontinence. Data are expressed as median with a 25-75 interquartile range. The score of the impact of incontinence inquiry form preoperatively was significantly reduced after surgery ($p=0.001$).

DISCUSSION

TOT operation is effective in treating stress urinary incontinence, 89.6% at six months postoperatively.

After the TOT operation, The clinical severity of urinary incontinence improved meaningfully when considering a reduced number of daily peds, improved Q-tip test results, and decreased urinary residue volume. The scores of urogenital disorder inventory-6 and incontinence impact inquiry forms were also significantly reduced after surgery .

The most critical factors for stress urinary incontinence are genetic differences, previous gynecological operation, advanced age, hypoestrogenic, birth trauma, obesity, and smoking.^[14] With the decrease of estrogen hormone in menopause, stress urinary incontinence increases. Today, colposuspension and mid-urethral sling operations are most frequently performed to elevate and support the urethra-vesical junction. Mid-urethral sling methods are the most commonly used in the treatment of stress urinary incontinence because they are easy to apply, have a shorter learning curve, have common complications, and have successful long-term results.^[15] The necessity of performing urodynamic studies before stress urinary incontinence surgery is controversial.^[16] In our research, urodynamic testing was performed only on mixed-type urinary incontinence to confirm the diagnosis.

Since the surgical success rates in mid-urethral sling surgeries are based on the definition of success, follow-up time, and subjective data, success evaluation is in a wide range in the literature. But generally, it varies between 64% and 100% (17). In the literature, the cure rate in the TOT procedure varies between 51-95%.^[18] Treatment is unsuccessful if there is persistence and recurrence after stress incontinence surgery. Persistence is defined as the persistence of urinary incontinence after surgery. On the other hand, recurrence can be defined as the patient who has benefited after surgery becomes incontinent again.^[19] To differentiate recurrence and persistence, the time between surgery and the onset of symptoms was expressed as six weeks.^[20] In our study, the scores of urogenital disorder inventory -6 and the impact of incontinence inquiry form-7 were used as quality of life measures to report patients' urinary incontinence symptoms and to obtain concrete evidence of its effects on their lives. Urinary symptoms with daily activities such as physical activity, travel, social relationships, and mental health status moderated these scores.^[21] Significant decreases were detected in these scores before and six months after the operation compared to the preoperative period. Recovery of urethral mobility is unnecessary in mid-urethral sling operations, and postoperative continuation of mobility allows the urethra to bend dynamically during stress.^[22] Our study in the post-operative period did not show a significant improvement in bladder neck mobility compared to the pre-operative Q-type test. The average operation time for the TOT operation is 20-25 minutes which is by the durations stated in the literature.^[23] The average operation time in our study is about 45 min. The reason for our longer operation time is that 90 (19.82%) patients underwent simultaneous prolapse surgery in addition to the TOT operation.

Complication rates reported after TOT operation ranged from 10.5% to 31.3%^[20], with 72 patients (15.9%) in our study. Mesh vaginal erosion is one of the critical complications that can be observed after TOT. The mesh quality used in the development of mesh erosion, the surgical technique applied, early sexual activity, individual hygiene, and postoperative follow-up period. Features such as foreign body reactions to mesh, infections and careless surgery, diabetes mellitus, corticosteroid use, and menopause are compelling. Erosion is less common in monofilament and macroporous meshes.^[24] As a result of 27 months follow-up of 233 cases after TOT operation, mesh erosion was detected in 17 patients (7.1%).^[25] Mesh erosion rate has been reported between 1% and 10.9% in the literature.^[26] Our study observed Mesh erosion in 12 (2.6%) patients. In cases with mesh erosion, the mesh was partially removed. In our study, six months post-operative patient follow-up and the use of macroporous mesh may be the reason for the low mesh erosion rate in Obtryx™ (Boston Scientific, Natick, MA, USA). Mesh erosion can occur years after TOT operation. Bladder perforation can

be seen in TOT operations (0-2.8%).^[27] In our study, urinary retention occurred in 7 1.5% of patients. After two more days of bladder catheterization, the patients improved. There was no situation requiring band loosening or cutting. Dyspareunia, seen between 4.5% and 24% after TOT.^[18] In our study, urinary retention occurred in 7 1.5% of patients. After two more days of bladder catheterization, the patients improved. There was no situation requiring band loosening or cutting. Dyspareunia, seen between 4.5% and 24% after TOT.^[28] was found to be 2.6% in our study. In previous studies, the incidence of de novo urge incontinence has varied from 2% to 15%.^[29,30] The most important reason is that it causes urethral obstruction because the mesh is tighter than usual. Anticholinergic drugs are effective in their treatment. In our study, de novo urge incontinence occurred in 14 (3.1%) patients. They were improved with anticholinergic medications.

The rate of bleeding more than 200 ml due to injury of the venous flexus during urethro-vaginal dissection in TOT operations has been reported as 0-2.8% in the literature.^[31] In our study, more than 200 ml of bleeding was seen in 6 (1.3%) patients and stopped with compression and hemostasis. One of the complications observed in the early period after TOT operation is a pain in the inguinal region. Studies have reported that this rate varies between 5% and 26%.^[32] Pain in most patients is usually temporary and resolves spontaneously within a few months. The causes of pain are foreign body reactions against the mesh passing near the branches of the obturator nerve and trauma to the obturator membrane and muscles.^[33]

CONCLUSION

The TOT operation can be preferred in treating stress incontinence with acceptable success and outcome. The scales of questionnaires successfully determine patient satisfaction with surgical efficacy for SUI.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Istanbul Kanuni Sultan Süleyman Training and Research Hospital (KAEK/2021.05.168).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

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