

Comparison Of The Effectiveness And Complications Of Transobturator Tape and Transvaginal Tape Methods In The Treatment Of Stress Urinary Incontinence

Stres Üriner İnkontinans Tedavisinde Transobturator Teyp ve Transvajinal Teyp Yöntemlerinin Etkinliğinin ve Komplikasyonlarının Karşılaştırılması

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ABSTRACT

Aim: Comparison of the effectiveness and complications of transobturator tape and transvaginal tape methods in the treatment of stress urinary incontinence.

Method: Clinical records of 106 patients who underwent surgery in Istanbul Kanuni Sultan Suleyman Training and Research Hospital due to stress urinary incontinence between January 2015 and December 2016 were retrospectively analyzed. Trans obturator tape (TOT) was classified as Group 1, and transvaginal tape (TVT) was classified as Group 2. The urogenital distress inventory-6 (UDI-6) and the incontinence impact questionnaire-7 (IIQ-7) were used to determine the severity of preoperative and postoperative incontinence and objectively compare the quality of life in all patients.

Results: There was a significant difference between the two groups in terms of mean age, menopausal status, complications, and duration of surgery ($p<0.05$). In both groups, there was a significant improvement in postoperative UDI-6 and IIQ-7 tests evaluating the negative effects of urinary incontinence on daily life.

Conclusion: A significant improvement was observed in UDI-6 and IIQ-7 scores after TOT and TVT operations. There is no significant difference between TOT and TVT methods in terms of efficacy and success in the treatment of stress urinary incontinence.

Key Words: Transobturator tape, Trans vaginal tape, Stress urinary incontinence, UDI-6, IIQ-7

ÖZET

Amaç: Stres üriner inkontinans tedavisinde transobturator teyp ve transvajinal teyp yöntemlerinin etkinlik ve komplikasyonlarının karşılaştırılması.

Yöntem: Ocak 2015-Aralık 2016 tarihleri arasında İstanbul Kanuni Sultan Süleyman Eğitim Eğitim ve Araştırma Hastanesinde stres üriner inkontinans (SUI) nedeniyle opere edilen 106 hastanın klinik kayıtları retrospektif incelendi. Transobturator teyp (TOT) Grup 1 ve gerilimsiz trans vajinal teyp (TVT) Grup 2 olarak sınıflandırıldı. Hastalarda preoperatif ve postoperatif inkontinans şiddetini ve operasyon başarı düzeylerini değerlendirmek için Q tip test, pet test, rezidü idrar ölçümü, stres testi ve yaşam kalitesini karşılaştırmak için ürogenital distress envanteri-6 (UDI-6) ve inkontinans etki anketi-7 (IIQ-7) kullanıldı.

Bulgular: İki grup arasında ortalama yaş, menopoz durumu, inkontinans süresi, eş zamanlı yapılan cerrahiler, mesane perforasyonu ve ameliyat süresi açısından anlamlı fark saptandı ($p<0.05$). Her iki grupta inkontinansın günlük yaşama olumsuz etkilerini değerlendiren postoperatif UDI-6 ve IIQ-7 testlerinde anlamlı düzelme saptandı.

Sonuç: TOT ve TVT ameliyatlardan sonra UDI-6 ve IIQ-7 skorlarında belirgin düzelme gözlemlendi. Stres üriner inkontinans tedavisinde etkinlik ve başarı açısından TOT ve TVT yöntemleri arasında anlamlı bir fark yoktur.

Anahtar Kelimeler: Transobturator teyp, Transvajinal teyp, Stres üriner inkontinans, UDI-6, IIQ-7

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Introduction

Stress and mixed urinary incontinence, the most frequent types of incontinence in women, have become significant public health problems affecting the quality of life. Stress urinary incontinence (SUI) is the uncontrollable urine leakage in women caused by actions that increase intraabdominal pressure, such as vomiting, breathlessness, laughing, and carrying heavy loads. Urinary incontinence occurs when the intravesical pressure exceeds the urethral closure pressure without detrusor contraction [1,2]. It is due to urethral hypermobility and pelvic floor muscle or sphincter insufficiency. After the loss of urethral support in the bladder neck was described as the main mechanism in the pathophysiology of stress urinary incontinence, tension-free vaginal tape (TVT) surgery, which provides hammock-like support to the ureterovesical junction, was described by Ulmsten and Petros in 1995 [3]. Although the short-term success rate of this surgery is quite high, different techniques were developed to prevent vital complications that may occur with the blind passage of the needle or trocar from the retropubic region, and the trans obturator tape (TOT) technique was recommended in 2001 [4]. The trocar or needle does not pass through the retropubic area in the trans-obturator tape technique. The trans-obturator tape method is reliable, effective, and easy to apply [5].

Although these methods were compared in literature, objective quality-of-life tests were used in very few studies before and after the operation. Incontinence impact questionnaire-7 (IIQ-7) and Urogenital distress inventory-6 (UDI-6) were used to determine incontinence severity preoperatively and postoperatively in all patients [6].

In this study, we aim to compare the effectiveness and complications of these methods by using quality-of-life tests in patients who underwent trans obturator tape and transvaginal tape operations due to stress urinary incontinence.

Material and Methods

Clinical records of 106 patients who underwent surgery in Istanbul Kanuni Sultan Suleyman Training and Research Hospital due to stress urinary incontinence between January 2015 and December 2016 were retrospectively analyzed. Patients who underwent TOT were assigned to Group 1 and TVT to Group 2. UDI-6 and the IIQ-7 tests were used to assess the severity of preoperative and postoperative incontinence and compare the patient's quality of life. Age, parity, body mass index (BMI), menopausal status, duration of operation, residual volume after micturition, additional vaginal surgery, intraoperative and postoperative hematoma, reoperation, postoperative urinary retention, de-novo

urge incontinence, pelvic pain, and complications were recorded. All patients were subjected to detailed physical, urogynecological, and neurological examinations and evaluated in terms of complete urinalysis, urine culture, voiding diary, urinary ultrasound, and post-void remnant urine measurements conducted before and after the operation. A Q-tip test with 200 ml of urine stored in the bladder in the lithotomy position was performed to detect vesicourethral mobility. Bladder neck mobility was evaluated as positive when the change of angle 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. The provocative stress test was performed while on the lithotomy table and standing with a full bladder. A urodynamic test confirmed the diagnosis in undiagnosed patients with mixed urinary incontinence. The patients who were diagnosed with urinary infections were given antibiotics.

Inclusion criteria: Female patients who did not plan to give birth in their future life between the ages of 35-75 with stress incontinence complaints, without urinary tract infection or neurological disease, not prone to bleeding, who had involuntary urinary leakage by coughing and sneezing, vesicourethral mobility more than 30 degrees, stress incontinence and whose residual urine was less than 100 milliliters were included in the study.

Exclusion criteria: Patients with urge incontinence, overactive bladder, urinary tract infection, chronic cystitis, who were prone to bleeding, planning birth, had a history of anti-incontinence surgery, and missing file information were excluded from the study.

For prophylactic treatment, 2 gr cefazolin sodium was administered intravenously approximately one hour before and six hours after the operation. All operations were performed with Obtryx™ (Boston Scientific, Natick, MA, USA) brand kit.

Surgical Technique: TOT operations were carried out under spinal anesthesia. The dorsal lithotomy position was used to prepare the patient, and the operation was performed with a classic technique [7]. TVT operations were carried out under spinal anesthesia. The dorsal lithotomy position was used to prepare the patients, and the operation was performed with a classic technique.

Cystoscopy was applied to all patients who underwent TVT. Complications that occurred during the operation were recorded and treated. Post-void residual urine was measured. Catheterization persisted for 6-8 hours in patients with more than 100 ml of remnant urine. Patients with less than 100 ml of remnant urine were discharged with oral antibiotics. [8].

After the operation, patients with a negative postoperative stress test, residual urine amount less than 100cc, and

full continence were considered as “complete recovery”; those with a positive postoperative stress test but did not describe incontinence were considered as “partial recovery”. Patients evaluated as “full recovery” and “partial recovery” were accepted as successful, while patients with positive postoperative stress tests and incontinence continued as “failure”.

Postoperative cases were followed up for six months, and urogynecological examinations were performed. In addition, the patients were reevaluated with quality-of-life tests (UDI-6 and IIQ-7), examination findings, neurological evaluation, residual urine measurement, Q-tip test, and pads. These scales used to report patients’ urinary incontinence symptoms and to obtain concrete evidence of the effects of urinary incontinence on patients’ lives [9].

Ethics approval: This study was conducted according to the 2013 revision of the Declaration of Helsinki and was approved by the Ethics Committee of Istanbul Kanuni Sultan Süleyman Training and Research Hospital (KAEK 2021.12.321). The requirement for patient consent for participation and publication was waived owing to the retrospective nature of the study. Written informed consent for treatment was obtained from all patients.

Statistical analysis: The data was analyzed using the Statistical Package for Social Sciences (SPSS Inc, Chicago, Illinois, USA) for Windows 24.0 package program. Mean and standard deviation values were used as descriptive statistics. In addition, an independent t-test was used to compare two groups of continuous data and chi-square

analysis was utilized to compare two groups of categorical data; p-values less than 0.05 were considered statistically significant in the study.

Results

106 patients who underwent TOT and TVT operations for stress urinary incontinence in a tertiary hospital between January 1, 2015, and December 31, 2016 were included in this retrospective study. 56 patients underwent TOT, and 50 patients underwent TVT. Table 1 shows the analysis of patient characteristics according to the group. The mean age was 53.32 ± 10.8 years in the TOT group, and 47.18 ± 7 years in the TVT group ($p=0.01$). There was a statistically significant difference between the two groups in terms of mean age, menopausal status, and duration of incontinence but not in terms of mean parity, body mass index, incontinence type or smoking. The difference in simultaneous operations between the TOT and TVT groups was significant ($p=0.03$). Colporrhaphy anterior (CA) was more common in the TVT group. Vaginal hysterectomy with colporrhaphy anterior/posterior and sacrospinous fixation (SSF) were more common in the TOT group.

Table 2 shows the recovery rates, quality-of-life tests, and clinical test results (preoperative and postoperative sixth-month follow-up). The levels of operational success in the TOT and TVT groups were not different. In the TOT group, 47 (83.92%) patients recovered completely, 8 (14.28%) recovered partially, and 1 (1.78%) patient did not recover

Table 1. Characteristics of patients

	TOT	TVT	p-value
Age, years (mean \pm SD)	53,32 \pm 10,8	47,18 \pm 7	0,01*
Parity, n (mean \pm SD)	3,74 \pm 2,09	3,74 \pm 2,06	0,99
BMI, kg/m ² (mean \pm SD)	25,04 \pm 2,17	25,96 \pm 2,36	0,13
Duration of incontinence, years (mean \pm SD)	6,22 \pm 4,21	4,16 \pm 2,61	0,01*
Smoking status			
Smoker, n (%)	16 (32%)	22 (44%)	0.08
Non-smoker, n (%)	34 (68,0%)	28 (56%)	
Menopausal status			
Postmenopausal, n (%)	15 (30,0%)	28 (56,0%)	0.02*
Premenopausal, n (%)	35 (70%)	22 (44,0%)	
Incontinence type			
Stress urinary incontinence, n (%)	8 (14,3%)	7 (14,0%)	0.09
Mix urinary incontinence, n (%)	48 (85,7%)	43 (86,0%)	

TOT: transobturator tape, and TVT: transvaginal tape.

Independent t-test was used to compare the two groups of continuous variables.

Chi-square test was used to compare these two groups of categorical variables.

*Statistically significant, $p < 0.05$.

Table 2. Recovery rates and, quality-of-life tests and clinical test results

	TOT n (%)		TVT n (%)		p-value	
Full recovery	47 (%83.92)		41 (%82)		0.86*	
Partial recovery	8(%14,28)		8(%16)			
Failure	1(%1.78)		1 (%2)			
	Preoperative	Postoperative 6th month	P value	Preoperative	Postoperative 6th month	P value
	TOT X±SD	TOT X±SD		TVT X±SD	TVT X±SD.	
UDI-6	13,62±1,77	3,22±1,53	0.02*	14,21±1,42	3,40±1,50	0,01**
IIQ-7	12,68±2,79	3,03±1,73	0.02*	12,40±1,88	3,28±1,85	0,02**
Q Tip Test	48,9±10,18	41,9±10,18	NS	44,8±6,34	40,8±6,34	NS
Pad Test	1,3±1,1	0,3±0,6	0.02*	1,4±1,2	0,4±0,30	0,01**
Residue Urine	58,5±29,8	15.1±0,16	0.02*	54,1±20,2	6,8±0,78	0,01**
Stress Test (+)	56(100)	9 (16,07)	0.03*	50(100)	9(18)	0,03*

TOT: Transobturator tape, TVT: Transvaginal tape

TOT: Transobturator tape, TVT: Trans vaginal tape, SD: standard deviation, NS: not significant

IIQ-7: Incontinence impact questionnaire, UDI-6: Urinary distress inventory,

*Chi-square test was used to compare two groups of categorical data

**Independent t-test was performed to compare two groups of continuous data

Statistically significant, p<0.05.

(p=0.86). In the TVT group, 41 (82%) patients recovered completely, 8 (16%) recovered partially, and 2 (2%) patients failed (p=0.86). In both groups, there was a significant improvement in postoperative UDI-6 and IIQ-7 tests, which investigated the negative effects of urinary incontinence on daily life (p=0.01 and p=0.02, respectively). After micturition, the amount of postoperative residual urine was 15.1±0.16 ml in the TOT group and 6.8±0.78 ml in the TVT group, which were statically significant (p= 0.01). Table 3 shows the complications, length of hospital stays, and duration of operations. The TOT group had 9 (16.07%) complications, while the TVT group had 11 (22%). Furthermore, 1 (1.78%) patient in the TOT group had a bladder perforation, 2 (3.57%) had mesh erosion, 1 (1.78%) had a vaginal perforation, and 1 (1.78%) had bleeding more than 200 ml. De novo urge incontinence was found in 2 patients (3.57%), perineal pain in 1 (1.78%), and dyspareunia in 1 (1.78%). Bladder perforation occurred in 5 (10%) of the TVT patients, mesh erosion occurred in 2 (4%) patients, de novo urge incontinence occurred in 2 (4%) patients, more than 200 milliliters of bleeding occurred in 1 (2%) patient and urinary retention occurred in 1 (2%) patient. Patients in the TVT group had longer operation times than those in the TOT group (48.2±25.83 vs. 44.60±19.74, p=0.01*). There was no significant difference in the length of hospital stay between the TOT and TVT groups, which were 2.2±1.3 and 2.3±1.3 days, respectively. In terms of bladder perforation and operation times, there was a significant difference between the TOT and TVT groups (p=0.02* and p= 0.01*, respectively).

Discussion

A significant decrease was observed in UDI-6 and IIQ-7 tests after TOT and TVT operations. The stress test and pad test results were significantly decreased in both postoperative periods compared to the preoperative period. The risk of complications, especially bladder perforation, was higher in TVT than in the TOT. TVT had a longer operation time than the TOT procedure.

Mid-urethral sling methods are the most commonly used to treat stress urinary incontinence since they are simple to use, have a shorter learning curve, have fewer complications, and provide long-term success [10]. IIQ-7 and UDI-6 were used as quality-of-life tests in our clinic. Urinary symptoms were questioned with UDI-6 and daily activities such as physical activity, travel, social relationships, and mental health status with IIQ-7. The operational success rates were not different in TOT and TVT groups. While 83.94% were fully recovered, 16.04% were partially recovered, 1.78% did not recover in the TOT group, 82% were fully recovered, 16% were partially recovered, and 2% did not recover in the TVT group. Although the TVT offers long-term success, there is a risk of serious vascular, bowel, and bladder injury due to the blind passage of the needle through the retropubic area due to surgery. In TOT procedure, the needle is safer because it does not pass through the retropubic space. The success rates of TOT and TVT vary between 84% and 95% [11, 12]. Since the surgical success rates in mid-urethral sling surgeries are based on the definition of success and follow-up times, success

Table 3. Operation time, hospital stay, and complications

	TOT	TVT	p-value
	n (%)	n (%)	
Bladder perforation	1(%1,78)	5(%10)	0,02*
Mesh erosion	2(%3,57)	2(%4)	NS
Vaginal perforation	1(%1,78)	0(%0)	NS
Perineal pain	1(%1,78)	0(%0)	NS
De novo urgency	2(%3,57)	2(%4)	NS
Bleeding	1(%1,78)	1(%2)	NS
Dyspareunia	1(%3,57)	0(%0)	NS
Urinary retention	0(%0)	1 (%2)	NS
Operation time (min)	44,60±19,74	48,2±25,83	0,01*
Hospital stay (d)	2,2±1,3	2,3±1,3	NS

min: minute, d: day, NS: not significant, n: number, %: percentage

* Statistically significant, p<0.05.

rates vary between 64% and 100% [13]. Treatment is considered unsuccessful if persistence and recurrence occur after stress incontinence surgery. The persistence of urinary incontinence after surgery is defined as persistence. On the other hand, recurrence is defined as a patient who has benefited from surgery becoming incontinent again [14]. Six-week cut-off between surgery and the onset of symptoms was used to differentiate recurrence and persistence [15].

The necessity of performing urodynamic studies before SUI surgery is controversial [16]. In our study, urodynamic testing was performed only in an undiagnosed group of patients with mixed urinary incontinence to confirm the diagnosis. Mesh erosion is a serious side effect of mid-urethral surgery. This rate varies between 3.8% and 15% in the literature [17]. In our study, mesh erosion was observed in 2 (3.57%) patients in the TOT group and 2 (4%) patients in the TVT group. The overall mesh complication rate was 3.77%, and the eroded mesh parts were resected.

Bleeding is an important complication seen in TOT and TVT operations. It is due to venous plexus injury during urethrovaginal dissection or blind interventions in the retropubic area. Major vessel injury, bleeding, and hematoma formation are complications that may be encountered more frequently in TVT. It usually stops with pressure and hemostasis. However, bleeding due to damage to the corona mortis vessel during TVT may disrupt the patients' hemodynamics and may require abdominal surgery [18]. In our study, two hemorrhages, one (1.78%) in the TOT group and one (2%) in the TVT group, were stopped with conservative approaches without additional surgical intervention.

Bladder perforation is rare during TOT operation. The incidence of bladder perforation was reported as 0-4.2% for TOT and 0.2-32.6% for TVT [19,20]. Bladder perforation was observed in 2.7% of 2795 multicenter TVT operations [21]. In our study, bladder perforation occurred in 1 (2%) patient after TOT surgery and 5 (10%) patients after TVT surgery. The bladder was sutured vaginally with 3/0 polyglactin as an intraoperative double layer. De novo urge-type incontinence is observed between 3-26% after mid-urethral sling operations [22]. The most important reason is that the mesh is tighter than normal, causing urethral obstruction, and anticholinergic drugs are effective in its treatment. In our study, de nova urge incontinence was observed in 4 (3.77%) patients in both groups. Dyspareunia was observed between 4.5% and 24% after mid-urethral sling [23]. In our study, dyspareunia was observed in 1 (1.78%) patient in the TOT group. In the literature, the average operation time for the TOT operation is 20-25 minutes [24]. In our study, TVT operations took longer time than TOT operations. This may be because all patients undergoing TVT had cystoscopies.

Limitations: Since the project was at a training and research hospital, the operations were performed by different surgeons and specialists. The study covers six months postoperatively. Longer follow-up periods are needed to assess the efficacy and safety of mid-sling operations. Another limitation of our study was the lack of randomization.

Conclusion: UDI-6 and IIQ-7 test scores were significantly lower after TOT and TVT procedures. Following TOT and TVT procedures, the patient's quality of life improved dramatically. Regarding efficacy and success in treating stress

urinary incontinence, there was no difference between TOT and TVT methods. UDI6 and IIQ-7 questionnaires can be used to evaluate the results of TOT and TVT methods. The TOT and TVT sling procedures were safe and effective in treating stress urinary continence, with no serious side effects. The TVT method was more likely to result in bladder perforation than the TOT method. The TVT operation took longer than the TOT operation.

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