# ARE THE EFFECTIVENESS AND COMPLICATION RATES OF TRANSOBTURATOR AND TENSION-FREE VAGINAL TAPE SIMILAR?

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## ABSTRACT

Introduction: The aim of this study was to compare the effectiveness and complication rates of transobturator tape (TOT) with those of tension-free vaginal tape (TVT).

Materials and Methods: Patients who underwent midurethral sling procedure between 1999 and 2006 were included in the study. Long term complications and patients' continence status were determined according to the follow up protocol. Statistical analyses were done using Mann-Whitney and Chi-square tests.

Results: A total of 180 patients (95 TVT and 85 TOT) were included in the study. Cure rates were similar for TOT and TVT groups (91.8% vs. 91% respectively) at the 12 months of follow-up (p>0.05). The overall complication rate was significantly lower for women who underwent TOT (7 vs 32%), (p=0.000). Ninety-four percent of the patients were satisfied with the operation in both groups.

Conclusion: Our data suggest that TOT is equally effective and safe method to treat women with SUI. Key words: Stress urinary incontinence, Tension-free vaginal tape, Transobturator tape, TOT, TVT

## ÖZET

Çalışmanın amacı transobturator teyp (TOT) ile tansiyonsuz vajinal teypin (TVT) etkinlikleri ve istenmeyen yan etki oranlarını karşılaştırmaktı.

Çalışmaya 1999-2006 arası orta üretra gevşek sling ameliyatı geçiren hastalar alındı. Uzun dönem istenmeyen yan etkileri ve hastaların idrar kaçırma durumu takip protokolüne göre saptandı. İstatistiksel analizler Mann-Whitney ve Ki-kare testleri ile yapıldı.

Toplam 180 hasta (95 TVT ve 85 TOT) çalışmaya alındı. 12 aylık izlem sonrası TVT ve TOT için iyileşme oranları benzer ve sırası ile %91,8 ve %91 idi (p>0,05). TOT geçiren kadınlar için istenmeyen yan etki oranı anlamlı ölçüde daha düşüktü (%7'ye %32), (p=0,000). Her iki grupta da hastaların %94'ü ameliyattan memnun kaldılar.

Verilerimiz, stres tip idrar kaçırması (STİK) olan kadınlarda TOT'un eşit ölçüde etkin ve güvenilir bir yöntem olduğunu öngörmektedir.

Anahtar kelimeler: Stres tip idrar kaçırma, Tansiyonsuz vajinal teyp, Transobturator teyp, TVT, TOT

## INTRODUCTION

Stress urinary incontinence (SUI) is a common condition among women, with a prevalence of 35.5% in urology, obstetrics and gynecology outpatient clinics in Turkey<sup>1</sup>. It is similar to the prevalence of 35% in other European countries<sup>2</sup>.

The main goal of the surgical treatment of SUI is to restore continence with minimal morbidity. New and minimal invasive surgical methods are defined and performed continously for the treatment of female SUI. Tension-free vaginal tape (TVT), is a minimal invasive technique, was described in 1995 by Ulmsten and has been used for the treatment of SUI in women<sup>3</sup>. Despite the high success rates that were notified for TVT ranging from 84 to 95%<sup>4-7</sup>, there are concerns regarding its operative safety. Most perioperative complications of the TVT procedure were associated with penetration into the retropubic space<sup>8,9</sup>. Due to TVT's

perioperative and postoperative complications, transobturator tape (TOT) which was described by Delorme in 2001 was adopted<sup>10</sup>.

The aim of this study was to compare the effectiveness and complication rates of TOT with TVT, performed in our institution since 1999 for the surgical treatment of SUI.

## **MATERIALS and METHODS**

Patients with urodynamic SUI who underwent midurethral sling procedure between October 1999 and November 2006 were included in the study. In our institution, the proposed operation for these patients was TVT from 1999 to February 2005 and TOT from February 2005 to November 2006. Patients with severe urogenital prolapse which required concomitant surgical treatment and patients who were postoperatively followed-up for less than 6 months were excluded.

Date of First Application: 23.08.2008 Accepted: 14.12.2008

Patients presenting with stress or mixed (stress+urgency) urinary incontinence were evaluated including medical history, physical examination, urinalysis, urine culture, 3-day bladder diary and multichannel urodynamic studies. Provocative stress test was performed in all patients and uretral mobility and pelvic organ prolapse were evaluated. The urodynamic study consisted of uroflowmetry, meausurement of post-void residual (PVR) urine, 1-h pad test, cystometry and measurement of Valsalva leak point pressure (VLPP). In all the urodynamic definitions the standarts of International Continence Comittee was taken as reference<sup>11</sup>.

Preoperative patient characteristics, type of anesthesia, time of surgery, duration of hospitalization and complications (immediate and short term) were identified from the patient chart records. Long term complications and patients' continence status were determined according to the follow up protocol in both groups.

Surgeries were performed according to the Ulmsten's technique for TVT<sup>1</sup> and Delorme's technique for TOT<sup>6</sup> by 3 experienced surgeons. The tapes in TVT and TOT groups were TVT system (Gynecare; Ethicon, Sommerville, NJ, USA) and ObTryx system with curved needle (Boston Scientific, Natick, MA, USA), respectively. All patients received intravenous antibiotic at the begining of the operation. The operations were performed under local, general or epidural anesthesia in TVT group and under general anesthesia using laryngeal mask in TOT group. Cystoscopy was performed in all TVT patients, but non of the TOT patients. The catheter was removed in the evening of the operation day in TVT group and immediately after the operation in TOT group. When PVR volume was more than 100 ml or when the patient could not void, the patient was asked to perform clean intermittent catheterization (CIC) until PVR was less than 100 ml. The patients in TVT and TOT groups were followed up and evaluated postoperatively at 1 week, 1, 3, and 6 months and biannualy thereafter according to our protocol. Evaluation consisted of filling out a questionnaire, vaginal examination including a provocative stress test, measurement of PVR by a bladder scan, and urodynamics in failed cases. A nurse from the urodynamic unit helped the women to fill out the questionnaires. Anti-incontinence surgery questionnaire (ASQ) designed by our institution (Appendix 1) was used in TVT group. ICIQ-SF (International Continence Society Questionnaire-Short Form) with addition of 3 more questions (Question 8-10 in ASQ) was used in TOT group.

**Appendix 1.** The questionnaire designed for evaluating the antiincontinence surgery (ASQ).

- 1. Do you leak urine after the operation?
- a. Yes b. No (proceed to question 5)
- 2. Do you wear protective pads? If yes, how many?
- a. No
- b. 1 pad per day or less
- c. 2-3 pads per day
- d. More than 3 pads per day
- 3. Do you leak urine when you cough, sneeze or lift a heavy object?
- a. Yes b. No
- 4. Do you leak urine as you are not able to postpone urination?
- a. Yes b. No
- 5. How frequently do you urinate during the daytime?
- a. Less than every 2 hours
- b. Between every 1-2 hours
- c. Between every 30-60 minutes d. More than every 30 minutes
- 6. Do you need to strain in order to initiate micturation?
- a. Yes b. No
- 7. Do you need catheterization in order to empty your bladder?
- a. Yes b. No
- 8. Compare your present situation in terms of continence with that before the operation.
- a. Completely satisfied
- b. Improved
- c. Same
- d. Worse
- 9. Would you undergo this operation again if it were indicated? a. Yes b. No
- 10. Would you recommend this operation to your relatives or friends?
- a. Yes b. N

Women who declared that they did not leak at all postoperatively were considered as "cure". Women who dispensed one pad or less daily and/or declared complete satisfaction or improvement were considered "improvement" in TVT group. Women who reported a small amount of leakage and/or declared complete satisfaction or improvement were considered "improvement" in TOT group. Any other degree of leakage was regarded as "failure". At the 12th month of follow-up questionnaires were assessed.

Table 1. Preoperative patient	characteristics with respect to	ypes of anti-incontinence	e surgery		
		TOT	TVT		
Number of women		85	95	p	
Mean age (year)		53.5 (23-80)	51.3 (33-69)	0.133*	
Mean number of pregnancies		4.6 (1-12)	5.0 (1-28)	0.188*	
Mean number of deliveries		3.3 (1-12)	3.2 (1-10)	0.372*	
Previous anti-incontinence surgery		12 (14.1%)	14 (14.7%)	0.906**	
Type of incontinence	Stress	36 (42.3%)	27 (28.4%)	0.050**	
	Mixt	49 (57.6%)	68 (71.6%)		
Severity of incontinence	Mild + moderate	52 (61.2%)	66 (69.4%)	0.242**	
	Severe	33 (38.8%)	29 (30.5%)		
Valsalva leak point pressure	<60 cmH20	25 (29.4%)	41 (43.2%)	0.056**	
	≥60 cmH20	60 (70.6%)	54 (56.8%)		
<b>Detrusor overactivity</b>	-1	9 (10.5%)	7 (7.4%)	0.449**	

<sup>\*:</sup> Mann-Whitney U; \*\*: Chi-square

	TOT		TVT		
	n	%	n	%	р
Overall complications	6/85	7.1	31/95	32.6	0.001*
Immediate complications	-	-	3	3.1	
• Hemorrhage	-	-	1	1.0	
Bladder perforation	-	-	2	2.1	
Short term complications	6	7.1	28	29.5	
• Voiding Dysfunction	3	3.6	10	10.5	
• Infections	-	-	5	5.3	
• Pain	3	3.5	11	11.6	
Skin infection and erosion	-	-	2	2.1	

<sup>\*:</sup> Chi-square

Urodynamic evaluations were planned at the 6th month for those who was regarded as failure. The complications were discussed in three groups as immediate, short term and long term complications as proposed by The 3rd International Consultation on Incontinence<sup>12</sup>.

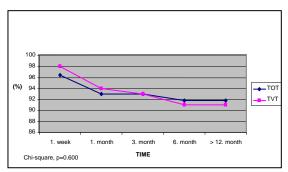
Statistical analyses to compare cure and complication rates for TVT and TOT groups were done using Mann-Whitney U and Chi-square tests.

#### RESULTS

A total of 180 patients (95 in the TVT group and 85 in the TOT group) were included in the stu-

dy. Preoperative clinical, demographic and urodynamic characteristics of the patients in both groups are summarized in Table 1. The median follow-up period was 71.9 (34-96) mo for TVT group and 20.8 (7-33) mo for TOT procedure (p=0.000). No significant differences were observed the groups regarding age, parity, previous surgery for SUI, severity of incontinence and preoperative urodynamic parameters. Local, general or epidural anesthesia were used in 53 (56%), 39 (41%), and 3 (3%) women, respectively for TVT group. General anesthesia using laryngeal mask and epidural anesthesia were prefered in 82 (96.5%) and 3 (3.5%) of

the women in TOT group, respectively. The mean operation time and duration of hospitalization were significantly shorter in TOT group compared with TVT group (14.8 (10-32) vs. 34.2 (20-70) minutes and 0.7 (0.5-1.5) days vs. 1.2 (1-5) days, respectively), (p=0.000). The rates of cure (91.8% vs. 91%), improvement (2.3% vs. 6%) and failure (5.9% vs. 3%) were similar for TOT and TVT at 12 months follow-up, respectively, (p>0.05). Cure rates in corresponding months of follow-up are shown in Figure 1.



**Figure 1.** The cure rates changing with follow-up time in TOT and TVT groups

Thirty-one complications were observed in 27 women of TVT group (Table 2). Complication rates were significantly lower for women who underwent TOT (7.1%) compared to those who underwent TVT (31.5%), (p=0.000).

There were 2 bladder perforations and 1 hemorrhage in the TVT group and none in the TOT group. Spontaneous voiding was achieved postoperatively in 85 (89.5%) women from TVT and 84 (%98.8) women from TOT group. Two other patients with bladder perforation in TVT group urinated normally after removing the catheters. Ten women from TVT group and 1 from TOT group performed clean intermittent catheterization (CIC) for a certain period of time (1 week to 1 month). In majority of the women (80% in TVT and 100% in TOT group) spontaneous voiding was restored within 1 month. The tape was cut in two cases either unilaterally or bilaterally in TVT group. During follow-up, both achieved spontaneous voiding and complete continence without any PVR.

In women with mixed incontinence, symptoms of urgency and urge incontinence disappearred postoperatively in 59 of 68 (87%) women in TVT and 45 of 49 (91.8%) women in TOT group.

The tape was cut at 1 month postoperatively in one patient in TVT group who had increasing storage lower urinary tract symptoms (LUTS) and did not respond to medical treatment. She was devoid of the storage LUTS and had improvement in her incontinence. None of the women who had pure stress incontinence presented with de novo urgency symptoms in TVT group. However 2 of 85 (2%) women in TOT group developed de novo urgency after surgery, but responded to medical treatment.

Eleven women (11.5%) in TVT group defined long-term stretching inguinal pain 1 week postoperatively which responded to anti-inflammatory treatment and 3 (3.6%) in TOT group declared perineal pain.

Two women in TVT group had skin infection and erosions 6 and 8 months postoperatively, one at the suprapubic incision site and the other 2 cm below it. These women were treated with appropriate antibiotics and the protruding parts of the tapes were cut. None of the women in both groups presented with vaginal or urethral erosion. Five women (5.3%) with urinary tract infections in TVT group were treated with appropriate antibiotics. Urodynamic investigation at the sixth month confirmed persistence of SUI in 3 failed cases in TVT and 5 in TOT.

Eighty-nine of 95 women (93.6%) in TVT group and 80 of 85 women (94.1%) in TOT group were satisfied with the operation, 87 from TVT (91.5%) and 78 from TOT (91.7%) group declared that they could accept the operation again and recommend it to their relatives or friends.

## DISCUSSION

TOT has been compared with TVT previously in the literature. Latthe included 11 RCTs in his review<sup>13</sup>, 5 of which compared TVT-O (TVT Obturator) with TVT, and the remaining 6 compared TOT with TVT. All these comparative studies reported that TVT and TOT were equally effective for surgical treatment of SUI with similar success rates. In a recent multi-centre randomised trial the overall objective cure rate for TVT and TOT were found to be 71.4% and 77.3%, respectively. However when dry plus wet but improved were accepted as operative success, then the rates increased to 90% and 90.6%<sup>14</sup>. In our study, the rates of cure were 91.8% and 91% in TOT and TVT groups res-

pectively at 12 months of follow-up (p>0.05). Moreover, the cure rates which have changed during the follow-up period, seem to be almost identical in both groups. The operative time and duration of hospital stay were significantly shorter in TVT group in our study. Falkert had also obtained similar results and concluded that TOT was more cost effective than TVT, however the difference between the operative time was not statistically significant in some other series<sup>14,15</sup>.

The overall complication rates were signifycantly lower for women who underwent TOT (4.7 %) compared with those who underwent TVT (31.5%), in our study (p=0.000) and majority of the complications were minor and none of them required laporotomy. Bladder perforation was observed in only 2.1% of the patients in TVT group and none in TOT group. Although the bladder perforation rate in TVT patients was reported to be 23 % in some series, it was found to be between 2.7-3.8% in two large national registries<sup>8,16,17</sup>. The importance of recognizing the perforation per-operatively makes cystoscopy absolutely necessary in TVT patients. Anatomical dissections of cadavers showed the safety of the TOT procedure regarding bladder perforation and peri-operative cystoscopy was not recommended routinely<sup>18</sup>. Morever, Latthe in his review of 11 randomized controlled trials, has not seen any bladder perforations in TOT or TVT-O groups compared to TVT group<sup>13</sup>. In the current study, we did not use cystoscopy during the TOT procedure and mean operative time was shorter in TOT than TVT group (14.8 vs. 34.2 minutes). However, intraoperative cystoscopy was recommended by some authors in patients with a history of previous extensive pelvic surgery or requiring concomitant prolapse surgery<sup>19,20</sup>. Besides. it may be used when needle passage is difficult<sup>20</sup>.

Perioperative hemorrhage was seen only in 1 patient in TVT and none in TOT group. The incidence of intra-operative blood loss over 200 cc was reported to be 1.9 % in TVT group<sup>8,22</sup>. Flock speculated that guiding the TVT trocar closer to the symphysis to avoid bladder perforation resulted in a higher likelihood of vessel injury and bleeding<sup>21,22</sup>. Falkert found that the number of complicated intra-operative bleedings (hemoglobin loss >1.5 g /dl) were slightly higher in the TVT group<sup>15</sup>.

After TVT, 8-17% of patients<sup>9,10,23</sup> had postoperative voiding dysfunction as transient urine retention and 5-15% of patients<sup>24-26</sup> had de novo urgency. They were reported in 1.6-3.8% and in 1.1-2.5% of patients after TOT, respectively<sup>27,28</sup>. In his meta-analysis Latthe also demonstrated that incidence of voiding difficulty was significantly lower in TOT and TVT-O tape groups<sup>13</sup>. However it was also reported that there was no significant difference in the incidence of postoperative voiding difficulties between TVT and TOT groups in a recent prospective randomized trial<sup>14</sup>. In our study, incidence of transient postoperative voiding difficulty was significantly higher in the TVT group (11 vs. 1.8%) and we had to cut the tapes in two cases (2%) in this group. De novo urgency is the most bothersome complication and no significant differrences between two groups was demonstrated in most of the series 13-15. De novo urgency developed in 2 cases in the TOT group and none in the TVT group, while symptoms of urgency and urge incontinence disappeared postoperatively in 59 of 68 (87 %) women with mixed incontinence in TVT group and 31 of 35 (88%) in TOT group.

Our data seemed appropriate for comparing the outcomes and complication rates in TVT and TOT groups, as no significant differences were observed between the groups regarding age, parity, previous anti-incontinence surgery and preoperative urodynamic parameters. The differences in the mean follow-up times in TVT and TOT groups might cause a potential bias. However, instead of using the results of the mean follow-up times, we used the changing cure rates in the first 12 months to compare the two procedures. We think, the second potential bias in our study might be due to use of a non-validated questionnaire to analyse the effectiveness of the procedure and postoperative satisfaction of the patients in TVT group (Appendix 1). We published the results of our series with the non-validated questionnaire<sup>29</sup>, because at that time there was no validated questionnaire in our language. After validation of the Turkish version in 2004 ICIO-SF was used in TOT group by adding questions 8-10 of the non-validated questionnaire in order to compare the two groups<sup>30</sup>.

In conclusion, TOT appears to be as effective as TVT for the surgical treatment of SUI and has fewer complications and shorter operative and hospitalization time than TVT. However prospective randomized studies are required to determine any differences in long-term surgical outcomes and complications.

## **CONCLUSION**

The cure plus improvement rates were similar in TVT and TOT groups. In addition, TOT offered the advantage of a shorter operative and hospitalization time with low complication rates. Therefore, we conclude that TOT is equally effective and safer in treatment of women with SUI.

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