

*Full Length Research Paper*

# Investigation of influence of inside out transobturator vaginal tape (TVT-O) procedure on objective, subjective cure rates and different quality of life tests in stress urinary incontinence treatment

Murat BOZKURT<sup>1\*</sup> and A. Ender YUMRU<sup>2</sup>

<sup>1</sup>Universal Malatya Hastanesi Turgut Özal Bulvarı Ankara Asfaltı 6 km No: 219 44000 Malatya, Turkey.

<sup>2</sup>Taksim Education and Research Hospital, İstanbul, Turkey.

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This study was aimed at investigating the influence of the transobturator tape (TOT) procedure used in surgical treatment of stress urinary incontinence on objective and subjective cure rates, as well as quality of life. A total of 156 patients who were diagnosed as stress incontinence and mixed incontinence with stress predominancy, underwent a TOT operation under spinal anesthesia by one surgeon or two surgeons of the team. Transobturator vaginal tape (TVT)-obturator inside out material (TVT-O® (Gynecare) was used in the operation. All patients underwent preoperative and postoperative urodynamic tests and pad tests, and the results were compared. The objective and subjective cure rates were investigated in mean of 30.3 months of follow-up. The objective cure was evaluated with negative cough test and less than 8 g 24-h pad test, while the subjective cure was evaluated with Patient Global Impression of Improvement (PGI). All patients were given IIQ-7, UDI-6, UISS and VAS tests at least once and the influence of the operation upon quality of life was investigated. According to the result obtained, the mean follow up time was  $30.3 \pm 7.4$  months (range 17 - 42). The objective cure rate was found to be 84.6% (132 patients), the subjective cure rate was found to be 89% (139 patients) and the failure rate was found to be 10.8% (17 patients). Preoperative and postoperative pad test results of the patients were found to be statistically significant ( $38 \pm 22.3$  vs.  $1 \pm 2.6$   $p < 0.05$ ). Among urodynamics and symptoms evaluated pre- and postoperatively, a statistically significant difference was detected between the Q tip test (43.60 vs. 20.8), leaks over 24 h (4 vs. 0), daytime frequency/nocturia (0.95 vs. 0.58) and maximum urethral closure pressure (57.3 vs. 35) ( $p < 0.05$ ). The preoperative and postoperative incontinence impact questionnaire-short form (IIQ-7) (11 vs. 0.6), urogenital distress inventory-short form (UDI-6) (14 vs. 7), urinary incontinence severity score (UISS) (11 vs. 2.8) and the visual analogue scale (VAS) (68 vs. 8) quality of life tests showed a significant difference ( $p < 0.05$ ). Summarily, the objective and subjective cure rates of the TOT procedure in the surgical treatment of female stress incontinence were quite high, thus it is an effective technique. The influence of this operation on quality of life scores evaluated with various parameters is satisfying.

**Key words:** Transobturator tape (TOT), objective and subjective cure rates, urinary incontinence.

## INTRODUCTION

Since the first reports from the Ulmsten group, Tension-

free Vaginal Tape (TVT®, Gynecare), the first polypropylene mid-urethral sling put on the market, has become one of the most commonly performed procedures worldwide due to the ease of performance and high success rates. And to date, several hundred thousand TVT procedures have been performed.

\*Corresponding author. E-mail: [jindrmb@yahoo.com](mailto:jindrmb@yahoo.com). Tel: 904222382828/1546. Fax: 904222382600.

**Table 1.** Preoperative and postoperative urodynamic evaluations of patients.

Urodynamic evaluation	Preoperatif	Postoperatif
Q-tip test (°)	43.60 ± 20.4	20.8 ± 14.9*
First desire to void (ml)	185 ± 78.3	209.8 ± 45.2
Maximum detrusor pressure (cm H <sub>2</sub> O)	17.48 ± 6.03	20.2 ± 3.6
ALPP (cm H <sub>2</sub> O)	80.80 ± 25.57	75.1 ± 19.63
Cystometric capacity (ml)	496.80 ± 65.63	488 ± 75.8
Compliance (ml/cm H <sub>2</sub> O)	58.61 ± 20.83	60.13 ± 25.72
Residual urine (ml)	13.2 ± 8.9	14.8 ± 18.5
Maximum urethral closure pressure	57.3 ± 9.4	35 ± 7.3*
Leaks over 24 hours	(1 - 6)	0*
Peak flow	25.8 ± 7.1	28.4 ± 6.4
Daytime frequency/nocturia	0.95 ± 1.46	0.58 ± 0.62*

ALPP: Abdominal leak- point pressure; \*statistically significant difference p<00.5.

Moreover, several devices have been introduced onto the market to ensure that mid-urethral sling procedures are now even less invasive, including the Suprapubic Arc (SPARC™ Sling System [American Medical Systems UK Ltd, Brentford, UK]) sling, the intravaginal (IVS) sling, transobturator slings, pre-pubic TVT and, more recently, the so-called mini-slings (the TVT-Secur and Mini-Arc slings).

The choice of the best surgical approach for each patient with stress urinary incontinence depends on several issues, including the patient's age, expectations and co-morbidity, previous reconstructive procedures, symptom severity, risk of intraoperative and postoperative complications, recovery time and long-term success rate. The transobturator tape (TOT) procedure has been recently developed as a new minimally invasive sling procedure. It is thought to have the benefits of easy performance and decreased risk of bladder and visceral injury. Two types of TOT have been performed, the inside-out (TVT-O) and the outside-in transobturator tape (TOT) approaches with the choice of the surgical approach predominantly driven by the surgeon's preference. This study was aimed at Investigating of the influence of the transobturator tape (TOT) procedure used in surgical treatment of stress urinary incontinence on objective and subjective cure rates, as well as quality of life.

## MATERIALS AND METHODS

A total of 156 patients with stress incontinence who were admitted to the Gynecology and Obstetrics Clinics of Taksim Research and Training Hospital and Şirnak İlil State Hospital between May 2005 and January 2010 were included in this retrospective study. A detailed anamnesis, including duration and severity of stress incontinence was obtained from the patients. All patients had experienced these symptoms for more than 4 years. Symptoms were found to be grade 2 (grade 1-3) according to Ingelman-Sundberg scale. All patients underwent vaginal examination and transvaginal ultrasonography. All menopausal patients were

administered a local estrogen treatment (estriol vaginal cream, Assos pharmaceuticals). For urogynecologic evaluation, a stress test was applied in standing and lying positions after the urinary bladder had been expanded with 300 ml isotonic solution. In addition, 24 and 48 h pad follow ups were performed.

Urodynamic tests such as cystometry were used in all patients for the discrimination of stress and urge urinary incontinence. Urodynamic evaluation as shown in Table 1, was done using Laborie and Medical Measurement System (MMS) urodynamic devices. A sterile 8 French dual channel cystometry catheter was placed into the urethra and a rectal catheter with 5 ml balloon was placed into the rectum when the patient was in lithotomy position. Cystometric assessment was done after residual urine measurement had been performed. The urinary bladder was filled with saline solution at room temperature at the rate of 50 ml/min and the patient was asked to cough after each 100 ml filling. Urinary incontinence occurring in this time was detected and the diagnosis of stress incontinence was made. Urodynamic diagnosis of detrusor instability (urge incontinence) was made upon detection of an elevation 15 cm H<sub>2</sub>O or above in basal detrusor pressure in cystometry. All patients were administered 2 g parenteral cefazolin preoperatively for antibacterial prophylaxis. While the patients who would undergo only TOT did not have vaginal lavage applied, this procedure was applied preoperatively to the patients who would undergo additional surgery (cystocele). The TOT procedure was performed as described by Leval. Patients who were applied general or local anesthesia, who underwent vaginal surgery except anterior repair, who desired to have a baby, and who had severe systemic diseases or mixed urinary incontinence with urge incontinence predominancy were excluded from the study. All patients were administered with regional (spinal) anesthesia.

Cystoscopy was performed to evaluate the bladder and urethra after the procedure. Patients who would undergo cystocele operation had the additional intervention performed after the prolene band had been placed. Afterwards, a stress test was applied, the band level was adjusted and the operation was terminated. The duration of TOT, cystoscopy and any additional operations, if performed, were recorded. All patients were monitored with the Foley catheter for bladder drainage for 24 h. The catheter was removed if residual volume was below 100 ml at the end of 24 h and intermittent catheterization was performed if post-voiding residual volume was above 100 ml. Similar protocols were applied for pre, peri and post-operative assessments in both clinics. All surgical procedures were performed by one or two members of the surgical team. Postoperative controls were done at 2, 6, 12, 24 and 48 months. The objective cure was evaluated with a negative

cough test and a 24-h pad test's being less than 8 g; the subjective cure was evaluated with Patient Global Impression of Improvement (PGI).

The influence of TOT on quality of life of the patients was evaluated with the Incontinence Impact Questionnaire-Short Form (IIQ-7), urogenital distress inventory-short form (UDI-6), urinary incontinence severity score (UISS) and the visual analogue scale (VAS), tested pre- and postoperatively. The last studied objective, subjective cure rates and quality of life scores were used in the study. Assessments done within the first postoperative 2 months could be applied to all patients. So those first assessments were taken essentially in the patients who were last to be followed up on. Statistical analyses were done using the Statistical Package for Social Science (SPSS Inc, Chicago, Illinois, USA) 15.0 program. Constant data were given as mean  $\pm$  standard deviation (SD) and analyzed with the Wilcoxon's signed rank test for statistical significance. Categorical data were given as numerical values and in percentages. A p level  $<0.05$  was accepted as statistically significant.

## RESULTS

The mean duration of follow up was  $30.3 \pm 7.4$  (range 17 - 42) years. The mean age of the patients was found as  $48.43 \pm 6.24$  years (range 42 - 68). The mean parity of the patients was  $5.24 \pm 2.86$  (min 2 – max 13) and the mean body mass index was found to be  $23.7 \pm 4.8$  (Table 2).

## DISCUSSION

Urinary incontinence (UI) is a prevalent condition that affects approximately 27% of women worldwide, with far-reaching physical, psychological, social, and economic implications. Incontinence has been found to reduce health-related quality of life to roughly the same degree as chronic conditions such as depression and Type I diabetes (Milsom, 2009; Stach-Lempinen et al., 2004). Personal consequences include restriction of physical and social activity, self-imposed social isolation and sexual dysfunction (Oh et al., 2008). The transobturator tape (TOT) procedure has recently been developed as a new minimally invasive sling procedure. It is thought to have the benefits of easy performance and decreased risk of bladder and visceral injury (Ward and Hilton, 2004). Spinosa and Dubuis (2005) followed up 117 patients who underwent TOT for 16.3 months, and the complete and partial subjective cure rates were found as 92.3% (n:108) and 4.2% (n:5), respectively. Overall, four patients stated that their condition did not change. In another study that 120 patients were followed up for one year, 80% patients reported that they were completely dry and 12% reported that they had recovered almost totally. Globally, 78% patients reported that their incontinence improved well during daily activities, exertion and sexual intercourse (Roumeguère et al., 2005). Waltregny et al. (2006) found complete cure rate of 91% after TVT-O procedure on one-year follow up. A significant improvement was also detected in the quality

**Table 2.** Diagnosis and distribution of the patients.

Data	Total number of patient
Stress Incontinence	100 (64.1%)
Mixed Incontinence	56 (35.9%)
Previous incontinence surgery	20 (12.8%)

The mean operative time was found to be  $13.8 \pm 5.16$  min in patients who underwent only TOT and TOT-anterior repair.

of life and severity of incontinence in most patients. In another study with a mean of 4 months follow up, the objective and subjective cure rates were found to be 92 and 97%, respectively. An improvement was observed in the quality of life of 96% patients (Cindolo et al., 2004). In an additional study including 94 patients with a mean of 12.8 months of follow up, the cure rate was found to be 95% (Mellier et al., 2004).

In our study including 156 patients with a mean follow up time of 30.3 months, the objective and subjective cure rates were found to be 84 and 89%, respectively (Table 3). The objective and subjective cure rates seem lower than the aforementioned studies. We considered that this is due to the follow-up period. Cure rates decline as the duration of follow up increases. In parallel with this, Giberti et al. (2007) reported an 80% cure rate with 2 years of follow up, while Waltregny et al. (2008) reported an 88% cure rate with a 3 year follow up period. Clues were obtained about mid-term outcomes of this procedure with an 82.4% cure rate with 4 years of follow up with a group of 74 patients who underwent TVT-O (Liapis et al., 2010). The fact that 35.9% of the patients in our study group had mixed incontinence without detrusor overactivity may have affected success rates. Holmgren et al. (2005) detected low cure rates in patients with mixed urinary incontinence. The success rate of 60% in 4 years was seen to decline to 30% in 4-8 years. However, the success rate of pure stress urinary incontinence is 82% in this study (Holmgren et al., 2005). Paick et al. (2007) did not detect a statistically significant difference between pure and mixed stress urinary incontinence in terms of cure rates. In a review, it was stated that mixed urinary incontinence could be successfully treated with mid-urethral slings; however, persistent urge symptoms could severely affect the quality of life for the patients (Fong and Nitti, 2010). Similar to our study, in a study also including the effect of the operation done after TOT procedures, a significant difference was detected between preoperative and postoperative assessment scores. In this study, a significant improvement was seen in UISS, DIS, VAS, IIQ-7, UDI-6 scores tested preoperatively and 2 months postoperatively (Table 4). In our study, all quality of life tests except DIS were used and similar results were obtained (Laurikainen et al., 2007). Shalom et al. (2011) stated that mid-urethral sling placement via suprapubic route provided better quality of life scores compared to transvaginal route in female

**Table 3.** Objective, subjective cure rates and failure in patients who underwent TOT.

Data	Total number of patient (%)
Objective cure rate	132 (84.6)
Subjective cure rate	139 (89.1)
Failure	17 (10.8)

Preoperative and postoperative pad test results of the patients were found to be statistically significant ( $38 \pm 22.3$  vs.  $1 \pm 2.6$  g;  $p=0.021$   $p<00.5$ ).

**Table 4.** Preoperative and postoperative quality of life tests of the patients.

Quality of life test	Preoperative	Postoperative
UISS	$11 \pm 4$	$2.8 \pm 1^*$
VAS	$68 \pm 24$	$8 \pm 2^*$
IIQ-7	$16 \pm 4$	$6 \pm 3^*$
UDI-6	$14 \pm 3$	$7 \pm 2^*$

UISS: Urinary incontinence severity score; VAS: visual analogue scale; IIQ-7: incontinence impact questionnaire-short form; UDI-6: urogenital distress inventory- short form. \*Statistically significant difference  $P<00.5$ .

stress urinary incontinence. While there was not a difference between preoperative UDI-6 scores in both groups, lower UDI-6 scores were found in postoperative suprapubic group.

In our study, when the high length of follow-up periods and the existence of mix incontinence and recurrent incontinence cases are considered, the objective and subjective cure ratios were found to be high compared to similar studies in the literature. Also, in all life quality scores evaluated by 4 different tests, a statistically significant improvement was seen after TOT operation.

## Conclusion

The objective and subjective cure rates of TOT procedure in surgical treatment of female stress incontinence are quite high, thus it is an effective technique. In addition, the influence of this operation on quality of life scores evaluated within the various parameters is also satisfying.

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