



## ARAŞTIRMA / RESEARCH

# Perioperative outcomes of female stress urinary incontinence treated with transobturator tape

Transobturator tape ile tedavi edilen kadın stres inkontinansın tedavisinin ameliyat sonuçları

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### Abstract

**Purpose:** To identify peri-operative clinical outcomes of transobturator tape procedure and also to analyze the effectiveness of this procedure.

**Materials and Methods:** In this prospective study, 47 women with stress urinary incontinence underwent transobturator tape procedure at Gulhane Education and Research Hospital. Patients' groups were compared in terms of their peri-operative outcomes (duration, changes of hematoctrit (HTC) levels, post-operative complications, residual urine volume changes, hospital stay).

**Results:** Out of 47 patients underwent transobturator tape procedure, 46 (97.9%) mid-urethral slings were successful and the rest one (2.1%) had persistence of stress urinary incontinence after the procedure. In two patients out of 47, pre-operative residual urine volume was 60 ml and the others' residual urine volume was <50 ml; post-operative residual urine volume was <50 ml in all of the patients at the sixth post-operative week. There was a significant statistically difference between pre-operative and post-operative residual urine volumes. There was no complication in our study.

**Conclusion:** Transobturator tape seems to be a feasible surgical procedure with good relief symptoms and lower intra/post-operative complications.

**Key words:** Stress incontinence, transobturator tape, voiding function.

### Öz

**Amaç:** Transobturator tape prosedürünün ameliyat sonuçları belirlemek ve bu işlemin etkinliğini analiz etmek.

**Gereç ve Yöntem:** Bu prospektif çalışmaya, stress inkontinans tanısı ile Gülhane Eğitim ve Araştırma Hastanesi'nde transobturator tape ameliyatı yapılan 47 kadın dahil edildi. Hasta gruplarının, perioperatif sonuçları (ameliyat süresi, hematokrit (HTC) düzeylerindeki değişiklikler, ameliyat sonrası komplikasyonlar, rezidüel idrar hacmi değişiklikleri, hastanede kalış süresi) açısından karşılaştırıldı.

**Bulgular:** Transobturator tape operasyonu yapılan 47 hastadan, 46 (97.9%) 'sının mid-üretral slingleri başarılı oldu. Bir (2.1%) hastanın stress inkontinansı operasyona rağmen devam etti. 47 hastadan ikisinin (4,2%) operasyon öncesi rezidü üriner volume 60 ml, diğerlerinin ise 50 ml' nin altında idi. Operasyon sonrası altıncı haftada yapılan ölçümlerde ise bütün hastaların rezidü üriner volümleri 50 ml' nin altında saptandı. Operasyon öncesi ve sonrası rezidü idrar volümlerinde istatistiksel olarak anlamlı farklılıklar izlendi. Çalışmamızda komplikasyon gözlenmedi.

**Sonuç:** Transobturator tape; iyi sonuçları ve düşük intra-/post- operatif komplikasyon oranları ile uygulanabilirliği kolay cerrahi yöntemdir.

**Anahtar kelimeler:** Stres inkontinans, transobturator tape, işeme fonksiyonu.

## INTRODUCTION

Stress urinary incontinence (SUI) is described as urine leakage related to physical exertion, such as coughing, laughing, sneezing or jumping which

cause an increase in abdominal pressure<sup>1</sup>. It is estimated that its frequency in female patients approximately between 4.5% and 53% with significant psychological and financial consequences<sup>2</sup>. SUI most generally occurs when

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urethra is hypermobile, secondary to pelvic floor muscles weakness<sup>3</sup>.

There are various kinds of treatment modalities described for patients with SUI<sup>2</sup>. These modalities are pessaries, pharmacologic therapy, mechanical devices, physiotherapy and surgery<sup>4,5,6,7,8</sup>. Physiotherapy involving Kegel's exercises is the primary treatment modality for patients with SUI<sup>7</sup>. But in recent years, surgery for SUI with mid-urethral sling procedure is recommended treatment modality with higher rates of improvement and cure<sup>8</sup>. In 2001, Delorme defined a mini-invasive technique in the treatment of patients with SUI which was named as transobturator tape (TOT)<sup>9</sup>. This technique was described for avoiding the complications of the other mini-invasive technique; tension-free vaginal tape (TVT) procedure (bowel perforations, vascular injuries and lacerations etc.)<sup>10</sup>.

In this study, we aimed to identify peri-operative clinical outcomes of TOT procedure and also to analyze the effectiveness of this procedure.

## MATERIALS AND METHODS

Ethical committee approval (permission with EGT.OGT:50687469-1491-534-15/1648.4-1985 registration number) for this prospective study was obtained from Gulhane Education and Research Hospital Ethical Committee in November 24, 2015. This prospective study included the patients, presented at our clinics due to urine involuntary between December 2015 and June 2016. All patients with SUI were explained about the disease and treatment modalities. Out of 53 patients with SUI, 47 patients who were willing for an operative treatment, provided written consent and were assigned to the study. One experienced consultant gynecologist performed the operations.

In the TOT procedure, all patients were positioned in a dorsal lithotomy position with 120 degrees hyperflexioned legs and underwent general anesthesia by laryngeal mask airway. A Foley catheter was inserted into the bladder after regional cleaning as a standard procedure. A vertical incision (1.5-2 cm) was made one cm below the urethral meatus. Subsequently, anterior vaginal mucosa and pubocervical fascia were dissected sharply and laterally to the ischiopubic ramus. Then, at the level of clitoris two small incisions (0.5 cm) were made in the inner thigh. The mesh was inserted into the

tunnel created around each side of the bladder neck and out through the thigh fold through two small skin incisions by a helical needle(I-STOP®, CL Medical, Lyon, France) (inside – out technique). At the end of each surgery, a control cystoscopy was performed to make sure the bladder and the urethra were intact. The incisions were closed in a standard fashion. All patients underwent intra-operatively antibiotic prophylaxis with Cefamezin 1000 mg IV flacons™ (cefazolin) and did not receive additional antibiotics post-operatively. The Foley catheter was extracted 6 hours later after surgery.

Patients' groups were compared in terms of their peri-operative outcomes (duration, changes of hematocrit (HTC) levels, post-operative complications, residual urine volume changes, hospital stay). The duration of procedure was considered as the time elapsing from anesthesia induction to awakening. Post-operative complications were noted during the hospital stay or later. The changes in HTC levels ( $\Delta$ -HTC) between pre-operative and 24 hours after the operation made it possible to evaluate blood loss.  $\Delta$ -HTC was calculated through (pre-operative HTC) – (post-operative HTC) formula. Pre- and post-operative residual urine volume was measured with bladder ultrasound after voiding. Post-operative residual urine volume was measured six weeks later after surgery.

## Statistical analysis

SPSS software (version 15.0 for Windows evaluation) was used for the data analysis. A *t* test was used to conclude the peri-operative outcomes of the study.

## RESULTS

Out of 53 patients with SUI, 47 patients were included in the study. Out of 47 patients underwent TOT procedure, 46(97.9%) mid-urethral slings were successful and the rest one (2.1%) had persistence of SUI after the procedure. There is no apparent cause could be found for persistence of SUI in these three cases.

The mean age of the patients underwent TOT in this study was 56.04 years (SD 22.6 years; range 40–82 years). Out of total 47 underwent surgery, only one (2.1%) were nulliparous women, 3 (6.4%) were primiparous women and 43 (91.5%) were

multiparous women. Out of the total 47 patients, 16 were premenopausal (34%) and 31 were postmenopausal (66%). (Table 1). The mean duration of surgery was 18.7 minutes (SD 5.43 minutes; ranges 15-25 minutes), and the mean  $\Delta$ -HTC was 3.9% (SD 1.98%; ranges 0.5–10.6 %).

There was no complication in this study. Out of 47 patients, 39 (83%) were discharged in the first post-operative day, seven (14.9%) between 24 and 48 hours post-operatively, and only one (2.1%) stayed in hospital for more than two days and these were the patients who were hospitalized for social factors.

**Table 1. Demographic features of patients**

Age at Surgery (years) mean (SD)	56.04 (22.6)
Age group % (N)	
40-55 years	53.1 (25)
56-70 years	34.1 (16)
71-82 years	12.8 (6)
Parity % (N)	
Nulliparous	2.1 (1)
Primiparous	6.4 (3)
Multiparous	91.5 (43)
Menopausal Status % (N)	
Premenopausal	34.0 (16)
Postmenopausal	66.0 (31)

In two patients out of 47, pre-operative residual urine volume was 60 ml and the others' residual urine volume was <50 ml; post-operative residual urine volume was <50 ml in all of the patients at the

sixth post-operative week. There was a significant statistically difference between pre-operative and post-operative residual urine volumes ( $p < 0.001$ ). The outcomes of this study were shown in Table 2.

**Table 2. The outcomes of TOT surgery**

Duration of Surgery (minutes) Mean (SD) / (Min–Max)	18.7 (5.43) / (15-25)
Hematocrit Level Changes (%) Mean (SD) / (Min–Max)	3.9 (1.98) / (0.5-10.6)
Complications (%)	none
Hospital Stay (hours) %(n)	
< 24 hours	83.0 (39)
24– 48 hours	14.9 (7)
>48 hours	2.1 (1)
Residual Urine Volume (ml)	
Pre-operative residual urine vol. (ml) Mean (SD) / (Min–Max)	28 (10.9) / (5-60)
Post-operative residual urine vol. (ml) Mean (SD) / (Min–Max)	3.5 (5.5) / (0-20)
$p$ value (Paired Samples $t$ -Test)	<0.0001
Success of Surgery %(n)	97.9 (46)

## DISCUSSION

In treating any female patient with SUI, the aim is to improve her quality of life and provide a cure for her symptoms. Over the last century, various treatment modalities have been used for SUI in female patients<sup>2</sup>. In the middle part of the last century, Marshall-Marchetti-Krantz described the first surgical technique for SUI by simple vesicourethral suspension to the symphysis pubis<sup>11</sup>. Then, in 1961, Burch modified the technique by

hanging vesicourethral tissues to the Cooper's ligament<sup>12</sup>.

In 1978, Tanagho suggested colpocystourethropexy technique instead of the hanging of vesicourethral tissues because of post-operative voiding dysfunction complications<sup>13</sup>. By these colposuspension techniques, the other procedure in treating SUI is suburethral sling procedures<sup>2</sup>. In early 20th century, since first suburethral sling procedure had been described, the technique has seen many changes<sup>14</sup>. In 1995, Ulmsten and Petros

described a new ambulatory procedure for treatment female SUI<sup>15</sup>. In 2001, Delorme defined a minimal invasive technique in the treatment of patients with SUI which was named as TOT with lower complications<sup>9</sup>.

It is quoted in English medical research literature TOT procedure has a high success rate in the treatment of SUI<sup>16</sup>. In our study, out of 47 patients underwent surgery, 46 mid-urethral slings were successful with the rate of 97.9% as a high rate coinciding with the literature. The rest 1 had persistence of SUI after the sling fixation but we could not find any apparent cause for that failure.

SUI is commonly seen in elderly or middle-aged women and is associated with post-menopausal status<sup>2,17</sup>. In our study, the mean age of the patients underwent sling fixation was 56.04 years (SD 22.6 years; range 40–82 years). The mean age of patients reported by Moore *et al.* in their study was 56.8 years (SD 11.7 years)<sup>18</sup>. Magon and Chopra, in their analysis of 59 patients had a mean age was 46.2 years (SD 11.2 years; range 24–70 years)<sup>16</sup>. In our study, out of the total 47 patients, 16 were in premenopausal status (34%) and 31 were in postmenopausal status (66%). This situation is usually considered a symptom ascribable to the change from the higher estrogen levels of reproductive age to the lower estrogen levels of post-menopausal status<sup>19</sup>.

By other SUI surgery techniques (especially retropubicurethropexy surgeries and TVT), TOT procedure can be accomplished in a short operative time with short hospitalization time<sup>16</sup>. The mean duration of surgery in our study was 18.7 minutes (SD 5.43 minutes; ranges 15–25 minutes) and 39 patients (83%) were discharged within 24 hours. Moore *et al.* reported the mean duration of surgery for sling fixation as 12.4 minutes<sup>18</sup>. Magon and Chopra, in their study of 59 patients had a mean time of surgery was 21.69 minutes (SD 6.41 minutes) and 45.8% patients were discharged within 24 hours of surgery<sup>16</sup>. Purnichescu *et al.* reported a mean time of surgery as 23 minutes<sup>20</sup>. The mean  $\Delta$ -HTC was 3.9% (SD 1.98%; ranges 0.5–10.6 %) in our study and this was associated with a very small blood loss (approximately 44 ml). Taweel and Rabah reported an average intra-operative blood loss of 57 ml in their analysis<sup>21</sup> while Moore *et al.* reported 36 ml in their study<sup>18</sup>. TOT is a minimal invasive surgery technique with small blood loss, so patients tend to recovery faster with these predictors.

A normal woman has an ability to void at least 80% of bladder volume and has a residual urine volume less than 50 ml after voiding<sup>22</sup>. In this study, two patients out of 47 had a pre-operative residual urine volume was 60 ml and the others' had a residual urine volume less than 50 ml; post-operative residual urine volume was less than 50 ml in all of the patients at the sixth post-operative week. There was a significant statistically difference between pre-operative and post-operative residual urine volumes ( $p < 0.001$ ). By these results, we say that TOT is a good minimal invasive surgery which can improve urinary retention symptoms.

In TVT procedure, some complications can be seen like bowel perforations, vascular – neural injuries and voiding dysfunction<sup>10,16</sup>. Voiding dysfunction is the most common complication that is seen mostly after TVT<sup>16</sup>; but in TOT procedure, sling fixation is made horizontally across the urethra, so this technique provides less chance for urethral kinking. This is the one of the important advantage of TOT procedure than TVT<sup>16</sup>. Another important advantage of TOT procedure is that allocates the retropubic area and thus also decreases the risk of major bowel, neural, and vascular injuries which are associated with the TVT. In our series, neither short-term voiding dysfunction, nor any other complications were developed.

Our study had some shortcomings. First of all, in our opinion, limited sample size (47 patients) can limit ability to comment on outcomes of the study. The second one, a comparison of TOT procedure with other sling procedures did not be done. The outcomes of this study will be compared with other sling procedures in a subsequent study. Third, a relatively short follow-up duration of our patients is another handicap of our study. This limited the long-term patient's satisfaction of TOT.

This study showed that TOT seems to be a good minimal invasive surgery technique with good relief symptoms, short duration of procedure and hospitalization and lower intra- / post-operative complications. Nevertheless, due to the lack of study and control groups, well-designed randomized controlled trials are required.

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