



## Surgical outcome of the transobturator tape procedure for management of female urinary incontinence – A single center experience

Ishod hirurškog lečenja urinarne inkontinencije kod žena primenom transobturatornih traka – iskustvo jednog centra

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### Abstract

**Background/Aim.** The transobturator tape (TOT) procedure is considered as a gold standard of surgical treatment option for stress urinary incontinence (SUI). The aim of this study was to determine the efficacy of this procedure in the surgical management of SUI by analyzing a single centre short-term results. **Methods.** From April 2011 until January 2018, 40 patients with predominantly SUI were operated by the standard TOT procedure. A polypropylene tape was placed in the mid-urethra by a percutaneous transobturator approach. The postoperative assessment considered cough tests and post-void residual urine volume at a week following the operation with additional clinical examination and urine culture at one, three and six months. **Results.** The mean age of the patients was 58 (42–78) years. Predominantly SUI was present in 32 patients (80%) and mixed urine incontinence in 8 patients (20%). At the initial (one week) assessment, the cough test was positive in 3 patients (7.5%), and 4 patients

(10%) needed an indwelling urethral catheter because of voiding difficulties. At the second follow-up, 2 (5%) patients still had a positive cough test, 2 patients (5%) had still the need for an indwelling catheter because of significant postvoid residual (PVR) urine volumes and 2 patients (5%) had a positive urine culture. At the three and six months, postoperative assessment. 3 patients (7.5%) still had a positive cough test. After six months 36 patients (90%) were considered as cured, 1 patient (2.5%) improved and 3 patients (7.5%) were classified as a failure. **Conclusion.** These results concur with the results of the other published short-term studies that analyzed the surgical outcome of the TOT procedure for female urinary incontinence. This allows us to confirm that the transobturator tape technique is a safe, effective and straightforward procedure after adequate training.

**Key words:** urinary incontinence, stress; female; surgical procedures, operative; suburethral slings.

### Apstrakt

**Uvod/Cilj.** Procedura plasiranja trake suburetralno, transobturatornim putem (engl. *transobturator tape* – TOT) predstavlja jedan od zlatnih standarda hirurškog lečenja stres urinarne inkontinencije (SUI) kod žena. Cilj ove studije bio je da se odredi efikasnost ove procedure u hirurškom lečenju SUI analizom kratkoročnih rezultata dobijenih u jednom centru. **Metode.** U periodu od aprila 2011. do januara 2018. godine, standardnom TOT tehnikom operisano je 40 bolesnika sa preovlađujućom SUI. Polipropilenska traka pozicionirana je u visini srednje uretre prekutanim transobturatornim pristupom. Postoperativna procena sprovedena je nedelju dana, jedan, tri i šest meseci

nakon operacije. Inicijalna procena (nedelju dana po operaciji) podrazumevala je test kašljanja i određivanje rezidualnog volumena urina nakon mokrenja sa dodatim kliničkim pregledom i određivanjem urinokulture posle jednog, tri i šest meseci. **Rezultati.** Prosečna starost bolesnica iznosila je 58 (42–78) godina. Sa SUI je bilo 32 (80%), a sa mešovitom inkontinencijom 8 (20%) bolesnica. Na inicijalnoj (prva nedelja) proceni, test kašljanja bio je pozitivan kod 3 (7,5%) bolesnice, a kod 4 (10%) je, zbog problema sa mokrenjem, plasiran urinarni kateter. Na drugom kontrolnom pregledu, 2 (5%) bolesnice su imale pozitivan test kašljanja, kod 2 (5%) bolesnice je ostavljen urinarni kateter zbog značajnog rezidualnog volumena urina, a 2 (5%) bolesnice su imale pozitivnu urinokulturu.

Na tromesečnoj i šestomesečnoj postoperativnoj proceni, 3 (7,5%) bolesnice su i dalje imale pozitivan test kašljanja. Nakon 6 meseci od operacije, kod 36 (90%) bolesnica je konstatovano izlječenje, kod jedne (2,5%) poboljšanje, a kod 3 (7,5%) bolesnice neuspeh operativnog lečenja. **Zaključak.** Rezultati naše studije slažu se sa rezultatima drugih objavljenih kratkoročnih studija gde je analiziran hirurški ishod TOT procedure u lečenju ženske urinarne

inkontinencije. Ovo nam dozvoljava tvrdnju da je TOT procedura sigurna, efikasna i jednostavna nakon adekvatne obuke.

**Ključne reči:**  
**inkontinencija, urinarna, stres; žene; hirurgija, operativne procedure; trake, suburetralne.**

## Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society (ICS) as “the complaint of any involuntary loss of urine on effort or physical exertion (e.g sporting activities) or on sneezing or coughing”<sup>1</sup>. Petros and Ulmsten<sup>2</sup> with their 'Integral theory' and DeLancey<sup>3</sup> with his 'Hammock hypothesis' determined the anatomical and structural factors for female continence and its impact on the pathophysiology of female incontinence. As a result of their research, a great variety of surgical procedures for the treatment of SUI have been developed. Recently proposed new aspect that takes into consideration that the active reflex urethral closing mechanism is the most important factor in the pathophysiology of incontinence is still too to be verified<sup>4</sup>. The appearance and development of mid-urethral slings (MUS) had an impact on the change of approach for surgical management of SUI. Based on the 'Integral theory' by Ulmsten and Petros<sup>5</sup>, the retropubic tapes (TVT) were released and introduced in 1996. Their role was to imitate the pubourethral ligament and became widely adopted<sup>6</sup>. Taking into consideration the complications associated with the retropubic approach, Delorme<sup>7</sup> promoted the TOT outside-in and de Leval<sup>8</sup> the TOT inside-out approach based on the 'Hammock hypothesis'<sup>3, 7, 8</sup>. No superiority between these two variations of the TOT procedure has been determined<sup>9</sup>.

Clinical practice and worldwide publications of results for this procedure have led to that TOT is considered as one of the gold standard surgical treatment options for SUI<sup>10</sup>.

## Methods

This is a case series study that presents a single centre experience of 40 patients who underwent surgical treatment for female urinary incontinence performing the TOT procedure from April 2011 until January 2018. Patients with SUI and mixed incontinence were included. Following initial evaluation proposed by the guidelines, all patients were conservatively treated before the definitive decision for surgical treatment of urinary incontinence. This included appropriate lifestyle changes, weight reduction in obese patients and enforcement of pelvic muscle floor training (PFMT). Duration of conservative treatment in accordance with the guidelines must not be less than 8 to 12 weeks<sup>11, 12</sup>. Our experience showed that the duration of this treatment option was exceeded in all of the patients due to the fact that the majority of them were referred from other medical institutions. In all of the patients diagnosed with

mixed urinary incontinence (MUI) by initial evaluation, it was defined that they had stress-predominant MUI. In accordance with the guidelines, all were conservatively treated that also included application of antimuscarinics. The treatment not lasted less than 12 weeks. In these patients, the specialized assessment included urodynamic studies – filling cystometry. No detrusor overactivity (DO) was registered by filling cystometry in these patients. The absence of DO does not exclude MUI and in 40% of female patients with MUI, it is possible not to identify DO<sup>13, 14</sup>. According to the guidelines for specialized management after initial management failure, one of the possible treatment options is MUS surgery<sup>11, 12</sup>.

Preoperative evaluation of all the patients consisted of previous medical history, clinical uro-gynecological examination, urine dipstick and urine culture, measurement of post-void residual (PVR) urine by ultrasound and cough test. In our study one patient was with concomitant vaginal prolapse (cystocele). Eight patients had previously undergone a hysterectomy. All patients with previous hysterectomies underwent cystoscopy in preoperative assessment.

All of the patients were operated on by the standard operative technique described by Delorme<sup>7</sup> (TOT outside-in) using a monofilament polypropylene tape and tunnellers for the tape to be exteriorized. The patients were operated under general or spinal anesthesia. A Foley catheter 16 Fr was left in place overnight and all of the patients were discharged the first postoperative day. The patients were operated on by two surgeons who finished a hands-on training course. The learning curve patients were also included in our study.

Postoperative assessment of the patients was performed in an outpatient setting a week, month, three and six months subsequently. Initial assessment performed one week after surgery included cough test and ultrasonic post voiding urine residual measurement followed by additional clinical examination and urine culture (one, three and six months after operation). The provocation cough tests were performed in the supine position with a full bladder (ultrasound confirmed).

The outcome of the operation, on the registered follow-ups, was then classified as cured, improved or failure. Cured was defined if the patient declined that there was leakage in everyday activities and during the provocation cough tests, improved if the leakage was less than prior to the operation and used less protection, and failure was considered if there was no postoperative improvement.

Prior to the operation, a written consent form was obtained from all of the patients included in this case series.

## Results

In the monitored group, 40 patients underwent surgical treatment for urinary incontinence by the standard TOT outside-in operative technique. The baseline patients' characteristics are shown in Table 1.

**Table 1**  
**Baseline patients' characteristics**

Parameter	Values
Age (years), mean (range)	58 (42–78)
Type of incontinence, n (%)	
SUI	32 (80)
MUI	8 (20)
Type of anesthesia, n (%)	
general	33 (82.5)
spinal	7 (17.5)
Previous hysterectomy, n (%)	8 (20)

**SUI – stress urinary incontinence;**

**MUI – mixed urinary incontinence.**

All of the patients in preoperative assessment had a positive cough test, negative urine culture and without significant postvoid urine volume (< 100 mL).

The results of postoperative assessment performed one week, a month, three and six months following the operation are shown in Table 2. Analyzing these results, we could confirm that there was no significant difference in the positive cough test in 3 (7.5%) of the patients throughout the postoperative assessment periods, and decrease in patients with significant PVR in the first two assessment periods with no abnormalities diagnosed in the additional clinical examination.

**Table 2**  
**Postoperative assessment**

Parameter	Week 1 n (%)	Month 1 n (%)	Month 3 n (%)	Month 6 n (%)
Positive cough test	3 (7.5)	2 (5)	3 (7.5)	3 (7.5)
Significant PVR	4 (10)	2 (5)	0	0
Positive urine culture	/	2 (5)	0	0
Clinical examination	/	NAD	NAD	NAD
Total patients	7 (17.5)	6 (15)	3 (7.5)	3 (7.5)

**NAD – no abnormality detected;**

**PVR – postvoid residual urine.**

Throughout the postoperative assessment, no vaginal extrusion or urethral erosion by the tape was reported. Transitory pain in the route of the TOT was reported in 6 patients which spontaneously resolved in all of the patients during the first month following the operation.

The objective cure rate results determined at the time of postoperative assessment are shown in Table 3. Analyzing the cure rates, we could confirm that 36 (90%) of the patients

were considered cured from the second, and unchanged throughout the following postoperative assessment periods.

**Table 3**  
**Objective cure rate**

Cure rate	Week 1 n (%)	Month 1 n (%)	Month 3 n (%)	Month 6 n (%)
Cured	33 (82.5)	36 (90)	36 (90)	36 (90)
Improved	/	/	1 (2.5)	1 (2.5)
Failure	7 (17.5)	4 (10)	3 (7.5)	3 (7.5)

## Discussion

Following the relevant guidelines for surgical management of female urinary incontinence, the TOT procedure has its clear indications (SUI and MUI), complications (perioperative and postoperative), cure rates (subjective and objective) and unfortunately failure rates<sup>15,16</sup>. Studies have proven that the outcome of MUS procedures is independent of the specific type of anesthesia used. Previously, there was a conviction that the use of spinal anesthesia was important to achieve the adequate tensioning of the sling and control of continence performing the cough test during the procedure<sup>17</sup>. As in other studies, in our study, the use of general or spinal anesthesia was in accordance with the surgeons or anesthesiologists preference and the anesthesiological requirements with no proven impact on the surgical outcome. The decision whether to use general or spinal anesthesia was in general brought by the anesthesiologist taking into consideration the patients age and comorbidities and, in most events, their preference.

Besides the fact that the TOT procedure was designed to avoid and decrease the TVT intraoperative complication rates (bladder perforation and vascular injury), it still has its registered complications. The most frequent intraoperative complications are bladder and vaginal perforations and hemorrhage<sup>18</sup>. The reported overall complication rates for TOT are in the range from 10 % to 31.3%<sup>19</sup>. Laurikainen et al.<sup>20</sup> in their randomized controlled trial (RCT), in the short term follow-up in the TOT group (131 patients), showed that there were no significant intraoperative complications. Vaginal perforation occurred in 2.3% of the patients. In our study, no intraoperative bladder perforation or excessive bleeding (> 200 mL) were reported. This can be explained by adequate surgical training and experience of the conducting surgeon. Intraoperatively, one case of perforation of the lateral vaginal fornix by the tunneller was recognized and immediately resolved by repositioning the tunneller and with an additional suture of the perforated vaginal fornix wall. Stav et al.<sup>21</sup> in their study analyzed the influence of different prolapse repairs taking into consideration compartments (anterior, posterior, vault or uterine prolapse) and concluded that they had no significant influence on the success rate. But, when they analyzed them as one group (any repair), they proposed that concomitant prolapse and the TOT surgery could have an influence on decreasing the incidence of recurrent SUI. In our study, in one patient with concomitant anterior vaginal wall prolapse (cystocele),

beside the TOT procedure, an anterior colporrhaphy was performed simultaneously. She was the only patient in our study that had a significant concomitant anterior vaginal wall prolapse and the decision was made to perform both procedures at the same time.

Postoperative complications of the TOT procedure can be immediate or late: voiding difficulties, groin pain, *de novo* urgency, urinary tract infections, urethral erosions and vaginal extrusions. Voiding difficulties can be presented as a weak stream with an intermittent flow pattern, straining, with a feeling of inadequate emptying that results with a significant PVR or even complete urinary retention<sup>18</sup>. Observed risk factors can be preoperative voiding difficulties or exceeding the tension on the tape. Ahn et al.<sup>22</sup>, in their study, reported that 10.5% of the patients had postoperative voiding difficulties, 2.2% needed prolonged catheterization due to retention, and 0.4% underwent sling incision as a definite solution of voiding difficulties. Kim et al.<sup>23</sup> reported that 9.5% of the patients had transient retention (TR) and suggested that preoperative PVR can be noted as a risk factor for developing TR. In our study, one week after the operation, 4 (10%) of the patients needed an indwelling urethral catheter because of voiding difficulties, transient incomplete or complete urinary retention. In 2 of these patients, the catheter was taken out between the two initial follow-ups. On the first month follow-up, 2 patients (5%) had still the need for an indwelling catheter because of significant PVR. Between the second and third follow-up after several tries without catheters and because of the patient incompliance for intermittent clean self-catheterization (CISC), 2 patients underwent tape incision. Following that procedure, one of the patients had recurrent incontinence and the second had minimal signs of incontinence, less than initial incontinence. In all of our patients, no preoperative PVR was determined in the preoperative assessment.

The previous hysterectomy can have, as a result, a change of local anatomy, scarring of the vaginal wall, or even neurophysiological damage. This has shown to have a possible influence on the success of the TOT procedure due to inadequate tape positioning or even change in the dynamics of the sphincter mechanism<sup>26</sup>. Reviewing the adverse events in our series, 8 (20%) of the patients had a history of previous hysterectomies in which all the adverse events occurred. This might be a part of the explanation of the cause of complications but must not be viewed isolated

from the fact that the majority of the complications occurred in the learning curve cases. A very important factor is the experience of the conducting surgeon that must be taken into consideration with referral of the patients and analyzing their results<sup>15, 16</sup>.

Paick et al.<sup>27</sup> presented a success rate for TOT procedures in patients diagnosed with MUI up to 94%. The only risk factor for failure is the simultaneous presence of DO. Gamble et al.<sup>28</sup> have reported a postoperative reduction of DO in 31.5% of the patients with MUI who underwent surgical treatment by TOT. In the conclusion of Committee 14 who considered TOT in special populations (MUI), it was specified that these patients have benefited from this procedure. They also have the largest improvement of problems related to urgency, decrease in DO as well as the lowest rate of *de novo* urgency<sup>29</sup>.

Defining the surgical outcome of the TOT procedure as cured, when the patient declines that there was leakage in everyday activities and during the provocation cough tests, has been analyzed in various studies<sup>30</sup>. In the Cochrane review of randomized controlled trials, the short-term results have shown an objective cure rate for TOT to be 85.7%, compared to 78% reported in the TOMUS study and 88% in the E-TOT study<sup>31-33</sup>. In our study, from the first month follow-up till the last postoperative assessment, the objective cure rate was 90% with just a slight decrease in the failure rate between the first and third month follow-up from 10% to 7.5%. This was a result of one patient (2.5%), after incision of the tape that was performed because of voiding difficulties and a significant PVR, and it was defined as improved (less than initial incontinence).

## Conclusion

Taking into consideration and analyzing our data (intraoperative/postoperative complications, postoperative assessment and cure rates) of the patients that underwent the TOT procedure and comparing them to data from referent studies, no major differences were established and confirmed. There might be some limitations of this study due to the short time of analyzed postoperative assessment. This can be resolved by future studies with a longer postoperative follow-up. We can conclude that the TOT procedure is a safe, effective and straightforward procedure after adequate training for surgical treatment of female urinary incontinence.

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