ACCEPTED MANUSCRIPT

Accepted manuscripts are the articles in press that have been peer reviewed and accepted for publication by the Editorial Board of the Vojnosanitetski Pregled. They have not yet been copy edited and/or formatted in the publication house style, and the text could still be changed before final publication.

Although accepted manuscripts do not yet have all bibliographic details available, they can already be cited using the year of online publication and the DOI, as follows: article title, the author(s), publication (year), the DOI.

Please cite this article SURGICAL OUTCOME OF THE TRANSOBTURATOR TAPE PROCEDURE FOR MANAGEMENT OF FEMALE URINARY INCONTINENCE- SINGLE CENTER EXPERIENCE

ISHOD HIRURŠKOG LEČENJA URINARNE INKONTINENCIJE KOD ŽENA PRIMENOM TRANSOBTURATORNIH TRAKA - ISKUSTVO JEDNOG CENTRA


UDC:

DOI: https://doi.org/10.2298/VSP181206018K

When the final article is assigned to volumes/issues of the Journal, the Article in Press version will be removed and the final version appear in the associated published volumes/issues of the Journal. The date the article was made available online first will be carried over.
SURGICAL OUTCOME OF THE TRANSOBTURATOR TAPE PROCEDURE FOR MANAGEMENT OF FEMALE URINARY INCONTINENCE- SINGLE CENTER EXPERIENCE

ISHOD HIRURŠKOG LEČENJA URINARNE INKONTINENCE KOD ŽENA PRIMENOM TRANSOBTURATORNIH TRAKA - ISKUSTVO JEDNOG CENTRA


*Department of Urology, †Department of Anaesthesiology, Military Medical Academy, Belgrade; ‡Faculty of Medicine of the Military Medical Academy, University of Defence, Belgrade, Serbia;

Correspondence to: Branko Košević, Department of Urology, Military Medical Academy, Belgrade, Crnotravska 17, 11 040, Belgrade, Serbia. Phone: +381641125744. E-mail: bkosevic@gmail.com
Abstract

**Introduction.** The trans-obturator tape (TOT) procedure is considered as a gold standard 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 were operated with predominantly stress urinary incontinence by a 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 stress urinary incontinence 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 (5%) patients had still the need for an indwelling catheter because of significant PVR and 2 (5%) patients had a positive urine culture. At the three and six months, postoperative assessment 3 (7.5%) patients still had a positive cough test. After six months 36 (90%) patients were considered as cured, 1 (2.5%) patient improved and 3 (7, 5%) patients were classified as a failure. **Conclusion.** These present study results concur with the results of 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:**
female, stress urinary incontinence, suburethral slings, treatment outcome.

Apstrakt.

**Uvod.** Procedura plasiranja trake suburetralno transobturatornim putem (TOT) predstavlja jedan od zlatnih standarda hirurškog lečenja stres urinarne inkontinencije (SUI) kod žena. Cilj ove studije je da se odredi efikasnost ove procedure u hirurškom lečenju SUI analizom kratkoročnih rezultata dobijenih iz jednog centra. **Metoda.** U periodu od aprila 2011. do januara 2018 operisano je standardnom TOT tehnikom 40 pacijentkinja sa preovlađujućom stres urinarom inkontinencijom. Polipropilenska traka je pozicionirana u visini srednje uretre prekutanim transobturatornim pristupom. Postoperativna procena je sprovedena nedelju dana, jedan, tri i šest meseci nakon operacije. Inicijalna procena (nedelju dana po operaciji) je podrazumevala test kašljanja i odredjivanje rezidualnog volumena urina nakon mokrenja (PVR) sa dodatim kliničkim pregledom i urinokulturom mesec, tri i šest meseci. **Rezultati.** Prosečna starost pacijentkinja je bila 58 (42-78) godina. Sa stres inkontinencijom je bilo 32 (80%) a sa mešovitim inkontinencijom 8 (20%) pacijentkinja. Na inicijalnoj (prva nedelja) proceni test kašljanja je bio pozitivan kod 3 (7.5%) pacijentkinje a kod 4 (10%) pacijentkinje je zbog problema sa mokrenjem plasiran urinarni kateter. Na drugom kontrolnom pregledu 2 (5%) pacijentkinje su imale pozitivan test kašljanja, kod 2 (5%) pacijentkinja je ostavljen urinarni kateter zbog značajnog rezidualnog volumena urina i 2 (5%) pacijentkinje su imale pozitivnu urinokulturu. Na
tromesečnoj i šestomesečnoj postoperativnoj proceni 3 (7,5%) pacijentkinje su i dalje imale pozitivan test kašljanja. Nakon 6 meseci 36 (90%) pacijentkinja su smatrane izlečenima, 1 (2,5%) poboljšanom a 3 (7,5%) pacijentkinje sa neuspehom operativnog lečenja. **Zaključak**
Rezultati naše studije se slažu sa rezultatima drugih objavljenih kratkoročnih studija gde je analiziran hirurški ishod TOT procedure u lečenju ženske urinarne inkontinencije. Ovo nam dozvoljava da potvrdimo da je TOT procedura sigurna, efikasna i jednostavna procedura nakon adequate obuke.

**Klučne reči:**
ženska, stres urinarna inkontinencija, suburetralna trake, ishod lečenja.

**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” (1). Petros and Ulmsten with their Integral theory and DeLancey 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 (2, 3). 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 be verified (4). The appearance and development of mid-urethral slings (MUS) had an impact on the change of approach for surgical management of stress urinary incontinence. Based on the Integral theory by Petros and Ulmsten the retropubic tapes (TVT) were released and introduced in 1996. Their role was to imitate the pubourethral ligament and became widely adopted (5,6). Taking into consideration the complications associated with the retropubic approach, Delorme et al (2001) promoted the TOT outside – in and de Leval (2003) the TOT inside – out approach based on the Hammock hypothesis (3,7,8). No superiority between these two variations of the TOT procedure has been determined (9).

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

**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 a TOT procedure from April 2011 until January 2018. Patients with stress urinary incontinence 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 to12 weeks (11,12). Our experience has shown 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 the 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 (13,14). According to the guidelines for specialized management after initial management failure, one of the possible treatment options is MUS surgery (11,12).

Preoperative evaluation of all the patients consisted of previous medical history, clinical uro-gynaecological examination, urine dipstick and urine culture, measurement of post-void residual urine by ultrasound (PVR) 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 by the standard operative technique described by Delorme (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 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 (month, three and six months). 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. 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 patient characteristics are shown in (Table 1).

All of the patients in preoperative assessment had a positive cough test, negative urine culture and without significant post void 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 can confirm that there is no significant difference in the positive cough test in 3 (7.5%) patients throughout the postoperative assessment periods, decrease in patients with significant PVR in the first two assessment periods with no abnormalities diagnosed in the additional clinical examination.
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 can confirm that 36 (90%) patients are considered cured from the second and unchanged throughout the following postoperative assessment periods.

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 (15,16). Studies have proven that the outcome of MUS procedures is independent of the specific type of anaesthesia used. Previously there was a conviction that the use of spinal anaesthesia was important to achieve the adequate tensioning of the sling and control of continence performing the cough test during the procedure (17). As in other studies, in our study, the use of general or spinal anaesthesia was in accordance with the surgeons or anaesthesiologists preference and the anaesthesiologic requirements with no proven impact on the surgical outcome. The decision whether to use general or spinal anaesthesia was in general brought by the anaesthesiologist 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 haemorrhage (18). The reported overall complication rates for TOT is in the range from 10 % to 31.3% (19). Laurikainen et al. in their randomized controlled trial (RCT) in the short term follow up in the TOT group (131 patients) there were no significant intraoperative complications. Vaginal perforation occurred in 2.3% of patients (20). 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 K et al in their study analyzed the influence of different prolapse repairs taking into consideration compartments (anterior, posterior, vault or uterine prolapse) 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 TOT surgery may have an influence on decreasing the incidence of recurrent SUI (21). 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 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 (18). Observed risk factors can be preoperative voiding difficulties or exceeding the
tension on the tape. Ahn et al. in their study reported 10.5% 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 (22). Kim et al. in their study reported an incidence of 9.5% of patients with transient retention (TR) and suggested that preoperative PVR can be noted as a risk factor for developing TR (23). In our study one week after the operation four patients (10%) because of voiding difficulties, transient incomplete or complete urinary retention needed an indwelling urethral catheter. In two of these patients, the catheter was taken out between the two initial follow-ups. On the first month follow-up, two 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) two 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.

Considering transitory groin pain as a postoperative complication van der Doelen et al. reported a 7% incidence that resolved in 64% of these patients at the first follow-up (24). In our study transient pain in the route of the TOT was reported in 15% of patients which spontaneously resolved in all of the patients during the first month following the operation. In a systematic review and metanalysis conducted by Schimpf et al. the summary estimate of incidence for adverse events for TOT is erosion 2.7%, vaginal extrusion/exposure 2.2%, urinary tract infection 4.4% and de novo urgency 5.5% (25). In our study we had no vaginal extrusion or urethral erosion by the tape, one (2.5%) patient with de novo urgency and two (5%) patients had positive urine culture (E.Coli) and received antibiotic therapy in accordance with the antibiogram.

The previous hysterectomy can have as a result change of local anatomy, scaring 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 (26). Reviewing the adverse events in our series, eight (20%) 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 referment of the patients and analyzing their results (15,16).

Paick et al. 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 (27). Gamble et al. have reported a postoperative reduction of DO in 31.5% of patients with MUI who underwent surgical treatment by TOT (28). 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 (29).

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, is analyzed in various studies (30). In the Cochrane review of randomized controlled trials, the short-term results have shown an objective cure rate for TOT 85.7%, compared to 78% reported in the TOMUS study and 88% in the E-TOT study (31, 32, 33). In our study from the first month
follow up till the last postoperative assessment the objective cure rate is 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 that one patient (2.5%), after incision of the tape that was performed because of voiding difficulties and a significant PVR, 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 patients that underwent a TOT procedure and comparing them to data from referent studies no major differences have been 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.

**REFERENCES**


Table 1. Baseline patient characteristics. Data are presented as number (percentage).

<table>
<thead>
<tr>
<th>Parameter</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years.)</td>
<td>58 (42-78)</td>
</tr>
<tr>
<td>Type of incontinence</td>
<td></td>
</tr>
<tr>
<td>SUI</td>
<td>32 (80%)</td>
</tr>
<tr>
<td>MUI</td>
<td>8 (20%)</td>
</tr>
<tr>
<td>Type of anaesthesia</td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>33 (82.5%)</td>
</tr>
<tr>
<td>Spinal</td>
<td>7 (17.5%)</td>
</tr>
<tr>
<td>Previous hysterectomy</td>
<td>8 (20%)</td>
</tr>
</tbody>
</table>

SUI- Stress urinary incontinence; MUI- Mixed urinary incontinence

Table 2. Postoperative assessment. Data are presented as number (percentage).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Week 1</th>
<th>Month 1</th>
<th>Month 3</th>
<th>Month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive cough test</td>
<td>3 (7.5%)</td>
<td>2 (5%)</td>
<td>3 (7.5%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>Significant PVR</td>
<td>4 (10%)</td>
<td>2 (5%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positive urine culture</td>
<td>/</td>
<td>2 (5%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Clinical examination</td>
<td>/</td>
<td>NAD</td>
<td>NAD</td>
<td>NAD</td>
</tr>
<tr>
<td>Total (pt. / %)</td>
<td>7 (17.5%)</td>
<td>6 (15%)</td>
<td>3 (7.5%)</td>
<td>3 (7.5%)</td>
</tr>
</tbody>
</table>

NAD – No abnormality detected
Table 3. Objective cure rate. Data are presented as number (percentage).

<table>
<thead>
<tr>
<th>Cure rate</th>
<th>Week 1</th>
<th>Month 1</th>
<th>Month 3</th>
<th>Month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>33 (82.5%)</td>
<td>36 (90%)</td>
<td>36 (90%)</td>
<td>36 (90%)</td>
</tr>
<tr>
<td>Improved</td>
<td>/</td>
<td>/</td>
<td>1 (2.5%)</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Failure</td>
<td>7 (17.5%)</td>
<td>4 (10%)</td>
<td>3 (7.5%)</td>
<td>3 (7.5%)</td>
</tr>
</tbody>
</table>

Received on December 6, 2018.
Revised on February 11, 2019.
Accepted February 18, 2019.
Online First February, 2019.