ABSTRACT

Aim To compare two different operative techniques for stress urinary incontinence in women, transvaginal tape obturator (TVT-O) and retropubic transvaginal tape (TVT).

Methods The study included 63 women, of which 32 received TVT-O and 31 were treated with TVT. Follow-up for all patients was done after 1, 3, 6 and 12 months, and yearly thereafter. Each visit included objective evaluations (post-void residual and stress test).

Results The average operating time was 13.19±3.72 minutes in TVT-O group and 26.92±4.77 minutes for TVT. Average time of catheter removal was 1.19±0.4 and 1.26±0.44 for TVT-O and TVT, respectively. Average hospital stay was 2.38±0.75 days in TVT-O group and 2.03±0.91 for TVT. Appearance of complications such as trauma of urethra, bladder perforation, injury of vessels, hematoma and wound infection were not registered. Two (6.3%) of the patients who underwent TVT-O had urinary infection. One (3.1%) of the patients who underwent TVT-O had pelvic pain. De novo urgency appeared in five (15.6%) patients for TVT-O and in four (12.9%) patients for TVT. The success rate in TVT-O group was 90.6% and 90.3% for TVT.

Conclusion Both procedures had a very high success rate, with a low rate of perioperative and late postoperative complications.

Key words: TVT, TVT-O, surgery, objective success
INTRODUCTION

Stress urinary incontinence (SUI) is a common pathological condition affecting women, with prevalence rates ranging from 12.8% to 46.0% (1). It is defined as unintentional loss of urine from the urethra that occurs during physical activity such as coughing, sneezing, laughing, or exercise. Many different surgical approaches for treatment of SUI have been suggested with varying degrees of success. Ulmsten described the tension-free vaginal tape (TVT) in 1996 (2). Delorme described a new mid-urethral sling using an outside-in transobturator approach, where the tape is inserted through the skin and the obturator foramen into the vagina Obturator-transvaginal tape (TOT) (3). DeLeval developed a similar approach in 2003, where the tape is inserted inside-out from vagina through the obturator foramen and the skin transvaginal tape obturator (TVT-O) (4). Both techniques were designed to avoid the retropubic passage and thus reduce the risk of urethral and bladder injuries.

The aim of the present study was to compare efficacies and complication rates of TVT and TVT-O in the treatment of stress urinary incontinence in females. This study will give useful information to urologists and gynecologists regarding surgical treatment of stress urinary incontinence.

PATIENTS AND METHODS

In this retrospective study two clinic participated, namely, the Clinic of Urology and Institute of Obstetrics and Gynecology, Clinical Center of Serbia, Belgrade. Informed consents were obtained from all the patients with simple SUI prior to operation, 31 of whom were treated with the TVT procedure in the Clinic of Urology and 32 with the TVT-O procedure in the Institute of Obstetrics and Gynecology from January 2010 to February 2012.

The patients were assigned to two groups in a non-randomized manner, according to operative prevalence of each institution. Inclusion criteria were isolated SIU (according to the International Continence Society classification) (5), indication for surgical treatment of SIU, positive cough stress test (cough stress test was performed in sitting and upright position after filling of the bladder through the catheter with sterile liquid until capacity of at least 300 mL) and at least 25 years of age. Exclusion criteria were a higher than the first stage urogenital prolapse (POP-Q ICS), concomitant pelvic organ prolapse surgery, concomitant hysterectomy, previous incontinence surgery and previous radiation therapy of the pelvis. The transvaginal mid-urethral sling TVT (Gynecare TVT, Ethicon, USA) was inserted into 31 patients and 32 patients received the inside-out transobturatorium-urethral sling TVT-O (Gynecare TVT Obturator System, Ethicon, USA). The TVT and TVT-O procedures were performed as previously described in detail by Ulmsten (2) and de Leval (4), respectively. Cystoscopy was performed in the TVT group upon each retropubic pass of TVT needle. All surgeons involved were experienced in the field of the urogynecology and well trained in TVT and TVT-O surgery.

The procedures were performed in local, regional and general anesthesia. Prophylactic antibiotics were given 1 hour before of the operation, a single dose of cefuroxime 1.5 g.

In both groups a bladder catheter was kept in place for 24 hours. After catheter removal, patients were instructed to urinate three times before a bladder scan was performed to measure post-void residual (PVR). When the PVR was greater than 100 mL or there was complete retention, a Foley catheter was inserted for further 24 hours. Patients were discharged when residual urine volume was less than 100 mL.

Follow-up for all patients was done at 1, 3, 6 and 12 months and yearly thereafter and each visit included objective evaluations. The objective surgical outcomes were evaluated by the cough stress test as cured or failed. Those who were considered “cured” showed negative results and no reports of urine leakage during stress; those who were defined “improved” did not leak during the cough stress test but presented occasional urine leakage during stress, which did not influence their daily activities or require further treatment; those who failed to meet the criteria above were considered to have had a “failed” treatment (6).

All results are presented as mean ± standard deviation (SD), median (minimum-maximum) or frequency (%). Variables were compared using the Student’s T test and χ² test. All p values less than 0.05 were considered significant.
RESULTS

No patients were lost on the follow-up at the 1-, 6- and 12-months follow-up intervals. Some demographics characteristics of both groups of patients were presented in Table 1.

Table 1. Sociodemographic characteristics of patients

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>TVT-O</th>
<th>TVT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>54.4±12.7</td>
<td>57.2±10.11</td>
<td>0.329</td>
</tr>
<tr>
<td>Parity</td>
<td>2 (1-3)</td>
<td>2 (0-5)</td>
<td>0.192</td>
</tr>
<tr>
<td>Menopause</td>
<td>23 (71.9%)</td>
<td>20 (64.5%)</td>
<td>0.530</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>19 (59.3%)</td>
<td>14 (45.16%)</td>
<td>0.259</td>
</tr>
</tbody>
</table>

TVT, retropubictransvaginal tape; TVT-O, transvaginal tape obturator

The mean operating time was 13.19±3.72 minutes and 26.9±4.77 minutes for TVT-O and TVT, respectively (Table 2). There was also a significant difference in the type of anesthesia used. In the TVT group all patients had regional anesthesia, but in the TVT-O group two (6.2%) had local anesthesia, eight (25%) had regional anesthesia and 22 (68.8%) had general anesthesia.

Table 2. Operative characteristics of patients

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TVT-O</th>
<th>TVT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>spinal</td>
<td>8 (25.0%)</td>
<td>31 (100%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>local</td>
<td>2 (6.3%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>general</td>
<td>22 (68.8%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Duration of procedure (min)</td>
<td>13.18 ± 3.72</td>
<td>26.93 ± 4.77</td>
<td>0.001</td>
</tr>
</tbody>
</table>

TVT, retropubictransvaginal tape; TVT-O, transvaginal tape obturator

There were no major perioperative complications such as bladder perforation, urethral injury, vaginal wall laceration during the scissor dissection, nerve injury, bowel injury, significant blood loss and symptomatic hematoma.

After catheter removal, the PVR was greater than 100mL in three (9.7%) patients after TVT and in two (6.3%) after TVT-O. Average time of catheter removal was 1.19 days in the TVT-O group and 1.26 days in the TVT group. Mean hospital stay in the TVT-O group was 2.38±0.75 days, while in the TVT group it was 2.03±0.91 days. These differences were not statistically significant. Only one (3.1%) of the patients from the TVT-O group reported pelvic pain, while this complication was not reported in the TVT group. De novo urgency occurred in five (15.6%) and four (12.9%) patients in the TVT-O and TVT group, respectively. Two (6.3%) patients in the TVT-O group had urinary tract infection (UTI) that required antibiotic treatment, while there was no UTI in TVT group. In terms of UTI there was no statistically significant difference. There were no other complications, such as wound infection, intravesical or intraurethral tape protrusion (Table 3).

Table 3. Postoperative outcome and complications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TVT-O</th>
<th>TVT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective success of the operation</td>
<td>29 (90.6%)</td>
<td>28 (90.3%)</td>
<td>0.967</td>
</tr>
<tr>
<td>Average time of catheter removal, days</td>
<td>1.19±0.40</td>
<td>1.26±0.44</td>
<td>0.508</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>2.38±0.75</td>
<td>2.03±0.91</td>
<td>0.108</td>
</tr>
<tr>
<td>Postoperative retention</td>
<td>2 (6.3%)</td>
<td>3 (9.7%)</td>
<td></td>
</tr>
<tr>
<td>Urinary tract Infection</td>
<td>2 (6.3%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>1 (3.1%)</td>
<td>0</td>
<td>0.321</td>
</tr>
<tr>
<td>De novo urgency</td>
<td>5 (15.6%)</td>
<td>4 (12.9%)</td>
<td>0.759</td>
</tr>
<tr>
<td>Wound infection</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Intravesical or intraurethral tape protrusion</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

TVT, retropubictransvaginal tape; TVT-O, transvaginal tape obturator

All patients had a follow-up of at least one year. In the TVT group the objective success rate of the operation was 90.3%, while in the TVT-O it was 90.6%, at one year follow-up. Objective response classified as “improved” was not reported in any of our patients. Otherwise, 3 patients in each group had objective failure following operation.

DISCUSSION

This study conducted by two institution compared two relatively new procedures, which have been performed for the past eight years in Belgrade, e.g., objective success of the procedure, perioperative and postoperative complications up to one year. Both groups of patients had similar demographic characteristics.

Our study assessed objective success of the two procedures (TVT vs. TVT-O), which included negative stress test and residual urine less than 100mL. In both our groups success rate was very high. Th, reason for this may be our inclusion criteria (isolated SUI, no previous surgery or radiotherapy in pelvis and no concomitant pelvic disorders). Groutz et al. found t 5-year cure rate of 74% in the group of 61 women who had undergone TVT-O, but the authors did not exclude women with mixed urinary incontinence (7). Latthe et al. presented in a prospective multicentric study that objective success rate for TVT goes from 83.9% to 100% and for TVT-O from 85.7% to 97.6% (8). Mean operating time was significantly longer in the TVT group. This difference could be attributed to the need for cystoscopy during the TVT procedure. Lapis et al. used cystoscopy during
the TVT-O procedure and the operating time was nearly similar to TVT (9).

In both groups average time of catheter removal and hospital stay was short. There was no statistical difference. These data presented that hospital stay after both procedures was short, so patients could quickly go back to their normal activity. Sola et al. established four times longer hospital stay for TVT (10).

There were no injuries of bladder or urethra in any of the groups of patients. Bladder perforation is most common with the TVT procedure, with an incidence of 0.7-24% reported in literature (11), although there are reports of this complication after obturator slings (12,13). Tamussino et al. showed a low rate of such complications in their study, which included 2541 patients, finding 10 bladder and 2 urethral injuries (14). There is also a report from the FDA MAUDE database published by Deng et al. that found 14 unrecognized bladder perforations and 7 unrecognized urethral injuries, this paper included 11,806 patients (15). Morey et al. recommended intraoperative cystoscopy when performing obturator slings in case of extensive pelvic surgery or when needle passage is difficult and suggest that the smaller helical needle may provide a higher safety margin for avoiding pelvic organs (16).

We did not identify any serious intraoperative bleeding or appearance of postoperative hematoma in both of groups. Previous studies have shown, although the TVT procedure is partly a blind one, the risk of severe perioperative bleeding (>500ml) and hematoma formation in the Retzius space is rare (0.9-2.5%) (17).

Midurethral slings can be complicated with postoperative bladder outlet obstruction. The literature presented percentage of voiding difficulties after TVT from 1.4% to 9% and for TVT-O it was from 3% to 13% (18). In our study, postoperative retention was similar in both groups and without statistically significant difference. All cases with postoperative retention were treated conservatively and with intermittent catheterization, within 24h. Although, there are some data in literature that presented a higher risk of postoperative retention 1 day after surgery in TVT-O patients compared to TVT patients (6.6% vs. 2.7%, respectively)(19).

Vaginal erosion did not occur in any of the patients from the two groups. Deval et al. reported higher incidence of vaginal erosion in TVT-O patients compared to TVT patients (13.8% vs. 0.7%, respectively) (20).

Our study did not show statistical difference regarding UTI. Rates of UTI after sling procedures vary widely and are reported in the literature to range from 4% to 43% depending on the definition used to diagnose infection (21-23). Ingber et al. published that patients with a UTI after surgery were more likely to have a higher preoperative PVR than those without a UTI (24).

Pelvic pain is a late complication for both of the procedures, our results are presented in table 3. Laurikainen et al. presented that this complication appears more often after TVT-O, 16%, while it appears in 1.5% of cases after TVT (25). TVT-O trocars pass through the groin muscles during insertion, which explains their significant risk of postoperative thigh and groin pain.

De novo urgency is a common complication of both procedures that occurred in both of our groups with no significant difference. Ballert et al. reported incidence of de novo urgency after TVT from 0.2% to 15%, while after TVT-O it was from 2.1% to 13.9% (26). Transobturator tape provides a less circumferential compression of the urethra, which may lead to fewer postoperative bladder irritation symptoms (27). Although, according to Deval et al., the frequency of de novo urinary urgency was three times higher with TVT then with obturator slings and is linked to changes in paraurethral collagen metabolism and sclerosis around the prolene tape (20).

The results reported in this paper can be considered as preliminary. Therefore, the limitations of our study include a relatively small number of patients with SUI submitted to two different modes of operative treatment and a short period of postoperative follow-up.

Both procedures are very safe, with a low rate of perioperative and late postoperative complications. Objective success is very high for both procedures. It takes less time to perform TVT-O compared to TVT procedure. Both procedures are minimally invasive and hospital stay is short, so patients can go back to normal life shortly after the surgery.
ACKNOWLEDGEMENT

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REFERENCES


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TRANSPARENCY DECLARATION

Competing interests: None to declare.


Hirurško lečenje urinarne stres inkontinencije kod žena: retropubična transvaginalna traka vs. obturatorna transvaginalna traka

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SAŽETAK

Cilj Uporediti dve različite hirurške metode u rešavanju stres urinarne inkontinencije kod žena: transvaginalna traka (TVT) vs. obturatorna transvaginalna traka (TVT-O).

Metode Studijom su obuhvaćene ukupno 63 žene; od toga je kod 32 urađen TVT-O, a kod 31 je rađen TVT. Pacijentkinje su kontrolisane nakon mesec dana, te tri i šest meseci, a potom godišnje. Na kontrolnim pregledima pacijentkinjama je rađena proba na stres i merenje rezidualnog urina kateterizacijom.

Rezultati Prosечно vreme trajanja intervencije iznosilo je 13.19 ± 3.72 minute, a za TVT 26.92 ± 4.77 minuta. Prosечно vreme nošenja katetera iznosilo je 1.19 ± 0.4 dana za TVT-O, a za TVT 1.26 ± 0.44 dana. Prosечно vreme trajanja hospitalizacije iznosilo je 2.38 ± 0.75 dana za TVT-O, a za TVT 2.03 ± 0.91 dana. Pojave komplikacija, kao što su povreda uretre, perforacija bešike, povreda krvnih sudova, intrahospitalne infekcije, kao i pojave hematom, nisu ustanovljene ni kod jedne operisane pacijentkinje. Dve (6,3%) pacijentkinje, kojima je rađen TVT-O, imale su pojavu urinarne infekcije. Jedna (3,1%) pacijentkinja, kojoj je rađen TVT-O, imala je pojavu bola u predelu male karlice. De novo urgenčija pojavila se kod 5 (15,6%) pacijentkinja kojima je rađen TVT-O i kod 4 (12,9%) pacijentkinja kojima je rađen TVT. Uspešnost operacije za TVT-O iznosila je 90,6%, a za TVT 90,3%.

Zaključak Obe metode pokazale su visoku stopu uspešnosti, s malom učestalošću perioperativnih i kasnih postoperativnih komplikacija.

Ključne reči: TVT-O, TVT, operativno lečenje, objektivna uspešnost