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ORIGINAL ARTICLE

TVT and TVT-O for surgical treatment of primary stress urinary incontinence: prospective randomized trial

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Abstract
Introduction and hypothesis A study was conducted to compare the efficacy and complications of TVT and TVT-O.
Methods This study is a prospective randomized trial involving 300 women with primary SUI; 149 received TVT, and 151 patients were treated with TVT-O. At the 1 year follow-up, 141 TVT patients and 147 TVT-O patients (dropout, 5.3% and 2.6%) were evaluated using urodynamic studies, validated questionnaires, and a 1-h pad test.
Results The mean operating time was shorter in the TVT-O group ($p<0.001$). Urinary retention was not significantly different ($p>0.05$). Inner thigh discomfort was reported by 5.4% of TVT-O patients. In the TVT and the TVT-O groups, respectively, 90.1% and 88.4% women were objectively cured. The satisfaction with the surgical outcome reflects the significant decrease in the questionnaire mean symptom scores in both groups. Postoperative de novo urgency was significantly more common in the TVT-O patients ($p=0.015$).
Conclusion The groups showed comparable objective and subjective cure rates.

Keywords Female stress urinary incontinence · Prospective randomized study · Tension-free vaginal tape · Transobturator tape

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Introduction

The minimally invasive midurethral slings have radically affected the surgical treatment of female stress urinary incontinence (SUI). Since the introduction of tension-free vaginal tape (TVT) procedure by Ulmsten in 1996, it has gained widespread acceptance. Numerous reports have shown that the cure rate for TVT ranges between 80% and 90% in multiple patient groups during follow-up periods of more than 3 years [1]. In 2008, Nilsson published the results of an 11-year follow-up of a prospectively investigated cohort of 90 women who underwent the TVT procedure. Although 90% were objectively cured, 77% were found to be subjectively cured [2].

The minimal invasiveness of the procedure and long-term objective success rate have established TVT as a gold standard for SUI treatment [3]. However, despite the high success rate, there are concerns regarding the operative safety of TVT in relation to the bowel and major blood vessels, bladder and urethral perforations, and postoperative voiding dysfunction [4, 5].

In 2001, Delorme described the placement of a synthetic polypropylene mesh via a transobturator route as a method to prevent these complications. Tape is inserted through the obturator foramina from the outside to inside. Ninety percent of patients were cured with no perioperative complications and no postoperative voiding difficulties [6]. Although the transobturator outside to inside technique (TOT) is believed to be safer than retropubic procedures, there are nevertheless several clinical reports suggesting that urethral and bladder injuries may still occur with this procedure [7]. In 2003, de Leval described a technique in which the tape is passed through the obturator foramen from the inside to the outside (TVT-O). Using newly

designed surgical instruments, damage to the urethra and bladder can be prevented [8].

The current randomized, non-blinded study was undertaken to prospectively compare the TVT procedure with TVT-O, concerning the effectiveness and safety.

Materials and methods

This study was approved by the local ethics committee of the Institute for the Care of Mother and Child. All study participants provided informed consent before being enrolled in this study. From January 2005 to December 2006, a total of 300 women were prospectively, randomly assigned to the study. We used the method of block randomization with a random-number generator. The transvaginal midurethral sling TVT (Gynecare® TVT, Ethicon, USA) was inserted into 149 patients, and 151 patients received the inside-out transobturator midurethral sling TVT-O (Gynecare® TVT Obturator System, Ethicon, USA). All three surgeons involved were experienced in the field of urogynecology and well trained in TVT and TVT-O surgery.

All women who had urodynamically proven primary SUI including a positive stress test were candidates for inclusion. Surgery was only offered if conservative therapy was unsuccessful. Exclusion criteria were: (1) predominant urge incontinence, (2) urodynamic detrusor instability, (3) preoperative use of anticholinergic medication, (4) previously failed antiincontinence surgery, (5) previous prolapse or radical pelvic surgery or radiotherapy, (6) postvoid residual volume (PVR) greater than 100 mL, and (7) a diagnosis of stage II, III, or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system [9]. Women with concomitant operations were also excluded from the study.

At preoperative and 1 year postoperative follow-up, patient evaluations included urine dipstick and culture, a detailed urogynecological history, and a physical examination. Additionally, a multichannel urodynamic workup that consisted of urethrocystometry, a stress test (cough provocation) in sitting and standing positions with a bladder volume of 300 mL; urethral pressure profilometry and uroflowmetry with a weight transducer type flowmeter (Medical Measurement System, SOLAR®) was also conducted at each follow-up. All patients self-evaluated the severity of their incontinence symptoms with the use of a visual analog scale (VAS) ranging from 0 to 10, with 0 corresponding to no symptoms and 10 to the maximum severity [10]. Prior to and 1 year after the surgery, all patients answered standardized questionnaires to assess their quality of life (QoL): the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI SF) and the CONTILIFE form [11, 12]. We used the Czech version of the QoL questionnaires, which had been translated forwards and backwards. Patients were also asked to rate their overall satisfaction after the operation with three possible choices: very satisfied, satisfied, or not satisfied.

Surgical procedures

We used the TVT technique described by Ulmsten et al. [13]. Specifically, the procedure was performed under local anesthesia supplemented by intravenous analgosedation. Cystoscopy was routinely performed, and a cough test was performed with the patient coughing repeatedly with a bladder volume of 300 mL. The TVT-O procedure was performed according to the original technique described by de Leval [8]. For the current study, the procedure was performed under spinal or local anesthesia supplemented by intravenous analgosedation. Hydrodissection was performed routinely only in case of local anesthesia. The Gynecare Winged Guide was regularly used, but the cough test and cystoscopy were not. To avoid excess tension during the plastic sheath removal, Babcock forceps were used to grasp the tape in the middle and create a small, 5-mm-long tape loop.

In both groups, for all patients, a bladder catheter (16-French Foley) was kept in place for 24 h. After catheter removal, patients were instructed to urinate three times before a bladder scan was performed to measure PVR. When the PVR was greater than 100 mL or there was complete retention, a Foley catheter was inserted for 24 h. Patients were discharged when the residual urine volume was less than 100 mL. All subjects received intravenous prophylactic antibiotic treatment consisting of 2 g cefazoline, administered at the beginning of the surgery.

The operative and postoperative data that were evaluated included the operating time (from first incision to last suture), type of anesthesia used, estimated intraoperative blood loss (vacuum aspiration), perioperative complications (bladder perforation, vascular injury), early postoperative complications (fever, pain, hematoma), and late postoperative complications (tape erosion, pain, and voiding difficulty). In the early postoperative period (1–7 days), time to resumption of spontaneous voiding was recorded. Patients were re-evaluated 6 weeks after the procedure as well as 3, 6, and 12 months postoperatively. All patients were evaluated at follow-up by three urogynecologists, blinded to the different procedures. In the TVT group, 141/149 patients returned for a 1-year follow-up (dropout rate of 5.3%), and in the TVT-O group, 147/151 patients were present for the 1-year follow-up (dropout rate of 2.6%).

Criteria of cure

The success rate was assessed 12 months postoperatively. The success rate was defined as an objective cure: a negative cough stress test with 300 mL of saline solution in the bladder during a multichannel urodynamic examination and a 1-h pad test weight of less than 1 g. Objective improvement was defined as a negative cough stress test and a 1-h pad test weight of less than 5 g. Failure was defined as a positive cough stress test and urine leakage of more than 5 g on the 1-h pad test. Subjective evaluation of the procedure was made using the ICIQ-UI SF questionnaire (scored item 1: assessment of frequency /0–5/). Subjective cure was defined by no leakage of urine after surgery (tick-box "never" was checked after surgery). Subjective improvement: if assessment of frequency of urine leakage after the surgery was lower than before. Subjective failure occurred if the urine leakage frequency before and after the surgery was identical or worse.

Data were analyzed using the statistical software program SPSS, version 11.5 for Windows, (SPSS Inc., Chicago, IL, USA). Descriptive statistics for measured variables were calculated. All results are expressed as the mean, standard deviation, and frequency distribution. Variables were compared using of Student's t test and χ^2 test, and a p value<0.05 was considered significant. Actual p values are presented in the tables. Pearson's correlation coefficient (r) was used to compare the VAS with overall patient satisfaction after surgery. A preliminary power calculation indicated that a sample size of 172 women (86 in each group) would lend a statistical power (1-β) of at least 80% at $\alpha=0.05$ for the detection of 15% differences of cure rates between the TVT and TVT-O group. Anticipating the drop out at the level of 10% of patients in each arm, we planned to include at least 190 patients. However, due to the high concentration of SUI patients in our institute, we exceeded this amount.

Results

All participants in this study were Caucasian. There were no significant differences in age, body mass index, parity, cesarean section rates, infant birth weight, or history of surgery for gynecological disorders among the study participants (Table 1). Preoperative urodynamic and QoL parameters were also not significantly different (Table 1).

Perioperative and early postoperative data

Mean operating time was significantly shorter in the TVT-O group, and there was also a significant difference in the type of anesthesia used (Table 2). The mean blood loss, hemoglobin, and C-reactive protein concentration on the first day after surgery did not significantly differ between the two groups. Furthermore, there were no major perioperative complications. Though there was one bladder perforation in the TVT group, no other complications, such as urethral injury, vaginal wall laceration during the scissor dissection, nerve injury, or bowel injury, were reported in either group. After catheter removal, the PVR was greater than 100 mL in four (2.7%) patients after TVT and ten patients (7.4%) after TVT-O. This difference was not statistically significant. One patient from each group developed severe urinary retention (0.7% vs.0.6%). Also, a symptomatic retropubic hematoma was diagnosed in one TVT patient on the second day following the operation. There were no reports of clinical hematomas in the TVT-O group. With respect to pain associated with the procedure, postoperative suprapubic discomfort was observed in six (4.5%) women in the TVT group, while postoperative inner thigh discomfort was noted in eight (5.4%) women in the TVT-O group. Urinary tract infections were more frequent in the TVT-O group, but the difference was not statistically significant (Table 2).

Urinary tract infections that required antibiotic treatment were more frequent in the TVT-O group, but the difference was not statistically significant.

Long-term postoperative data

At the 1-year follow-up, 127 (90.1%) and 130 (88.4%) women were objectively cured in the TVT and TVT-O groups, respectively. Regarding the parameter of subjective cure, where we analyze the questionnaire parameters before and after surgery in each patient, we found statistically lower values (t test, $p<.031$). Subjective cure rates of both procedures were similar (78.7% of TVT vs. 76.2 of TVT-O; Table 3). After TVT or TVT-O, the majority of patients were very satisfied (85.1% of TVT vs. 81.6% of TVT-O) with the outcome. Additionally, 14.9% of the TVT group reported they were satisfied. In the TVT group, at the 1-year follow-up, no patient evaluated her continence status as "not satisfactory." In the TVT-O group, 17% of the women were satisfied with their continence status. One year post-TVT-O, only two (1.4%) patients were not satisfied with their continence status. The overall patient satisfaction with the surgical outcome reflects the significant decrease in the mean VAS score and ICIQ-SF questionnaire symptom score in both groups. There were statistically significant correlations between VAS scores and subjective satisfaction evaluation ($r=0.666$; $p<0.001$). For CONTI-LIFE QoL, all of the six scales demonstrated significant decrease (Table 3). Urodynamic parameters at the 12-month follow-up visit are shown in Table 3. In comparison to preoperative urodynamic data, the mean maximum flow

Table 1 Preoperative patient characteristics, urodynamic parameters, and quality of life data (QoL)

Parameter	TVT™ (n=149)	TVT O™ (n=151)	p value
Age, years	57.19±10.65	57.82±10.35	NS[a]
Body mass index, kg/m^2	27.82±3.2	28.21±5.7	NS[a]
Parity			
Para 0	12 (8.0%)	9 (5.9%)	NS[b]
Para I	28 (18.8%)	26 (17.2%)	NS[b]
Para II	90 (60.4%)	82 (54.3%)	NS[b]
Para III	15 (10.1%)	27 (17.9%)	NS[b]
Para≥IV	4 (2.7%)	7 (4.6%)	NS[b]
History of cesarean section	4 (2.7%)	2 (1.3%)	NS[c]
Birth weight of children, grams	3549.12±472.39	3581.32±549.51	NS[a]
Prior hysterectomy			
Abdominal	31 (20.8%)	32 (21.2%)	NS[b]
Vaginal	11 (7.4%)	13 (8.6%)	NS[b]
Uterus present	107 (71.8%)	106 (70.2%)	NS[b]
Preoperative urodynamic parameters			
Maximum cystometric capacity, mL	385.39±51.59	387.25±51.08	NS[a]
First sensation, mL	191.75±78.15	199.18±72.78	NS[a]
Maximal urethral closure pressure, cmH_2O	49.33±21.92	37.16±18.81	NS[a]
Functional urethral length, mm	23.46±5.15	24.02±8.89	NS[a]
Maximum flow rate, mL/s	34.02±19.27	35.28±29.45	NS[a]
Preoperative QoL			
VAS	7.86±1.61	7.91±1.82	NS[a]
CONTILIFE			
Daily activities	19.82±5.29	22.38±5.96	NS[a]
Effort activities	17.62±3.48	16.22±2.62	NS[a]
Self-image	17.56±4.82	18.39±5.51	NS[a]
Emotional impact	22.74±6.56	24.95±6.52	NS[a]
Sexuality	8.90±4.06	8.62±4.62	NS[a]
Well-being	3.47±0.93	3.46±0.93	NS[a]
ICIQ-SF	13.28±15.83	13.76±4.78	NS[a]

Values are given as mean±SD

NS Not significant (p>0.05)

[a] Student's t test

[b] χ^2 test

[c] Fisher's exact test

rate (Qmax) decreased significantly in each group, and in the TVT-O group, the postoperative maximum cystometric capacity (MCC) was lower in comparison to the preoperative MCC. Additional parameters showed no statistically significant difference between the two groups.

Nine TVT patients (6.4%) and 20 TVT-O patients (13.6%) developed postoperative de novo urge incontinence symptoms. During the long-term follow-up, vaginal mesh erosion was reported in two patients from the TVT group (1.4%) and in two patients from the TVT-O group (1.4%). There were no other complications, such as wound infection, intravesical, or intraurethral tape protrusion.

Discussion

In this study, we demonstrated that the TVT and TVT-O procedures were both minimally invasive and similarly effective and had comparable morbidity. The operating time was significantly longer for the TVT group. However, this difference could be attributed to the need for cystoscopy during this procedure. When Liapis et al. used cystoscopy during the TVT-O procedure, the operating time was nearly similar to TVT [14]. During TVT-O surgeries, we did not perform routine cystoscopy. This is in agreement with common opinion, which recommends performing cystoscopy only in case of technical difficulties during the procedure when injury of the bladder wall is suspected. DeTayrac recommends that a cystoscopy be performed for the "outside-in" transobturator procedure in patients with an associated cystocele [15].

Bladder perforation is the most common complication observed with midurethral sling procedures via the retropubic approach, with an incidence of 0.8–21% reported in the literature [14, 15]. In our study, the incidence of bladder perforation in the TVT group was low and not significantly

Table 2 Perioperative data and early postoperative complications

Parameter	TVT™ (n=149)	TVT-O™ (n=151)	p value
Duration of procedure, min	32.62±9.3	23.76±12.01	<0.001[a]
Type of anesthesia			
Regional	10 (6.7%)	128 (84.8%)	<0.001[b]
Local with sedation	139 (93.3%)	23 (15.2%)	<0.001[b]
Estimated blood loss, mL	31.57±31.92	32.26±34.80	NS[a]
Hemoglobin, g/L	130.93±10.18	132.27±10.92	NS[b]
CRP	11.24±12.11	10.35±14.40	NS[b]
Perioperative complications			
Bladder injury	1 (0.7%)	0 (0%)	NS[b]
Urethral injury	0	0	–
Vaginal wall perforation	0	0	–
Bowel injury	0	0	–
Postoperative retention of urine (24 h)			
PVR>100 mL	4 (2.7%)	10 (6.6%)	NS[b]
PVR<100 mL	139 (98.6%)	137 (93.1%)	NS[b]
Hematoma	1 (0.7%)	0 (0%)	NS[b]
Urinary tract infection			
Symptom + bacteriuria = 10^6	5 (3.4%)	8 (5.4%)	NS[b]
Slings needing release	1 (0.7%)	1 (0.6%)	NS[b]
Postoperative pain			
Suprapubic discomfort	6 (4.5%)	0	NS[b]
Inner thigh discomfort	0	8 (5.4%)	

Values are given as mean±SD

NS Not significant (p>0.05)

[a] Student's t test

[b] χ^2 test

[c] Fisher's exact test

higher in comparison to TVT-O patients (0.7% vs. 0%, respectively). Basically, this complication does not represent a major problem if diagnosed early enough. The bladder perforation can be missed intraoperatively when the 70° cystoscope optic is not used. Formerly, it was thought that the risk of bladder perforation during the transobturator technique was negligible. However, several cases of intraoperative bladder injury during the transobturator technique procedure have been reported [7]. Published anatomical studies have shown that in the "outside-in" transobturator approach, the needle passes through the retropubic space, which may result in bladder injury [16], while there are no reported cases of bladder injury when the "inside-out" approach is used [8, 17–19]. Cadaver studies suggest that perioperative cystoscopy is not required during the "inside-out" approach [20]. Well-trained surgeons, who performed the surgical technique using hydrodissection, may be the reason for the low incidence of cystotomy in our TVT group. Also, the selection of patients for surgery was based on stringent exclusion criteria. A systematic meta-analysis of transobturator and retropubic tape complications (data from randomized controlled trials (RCTs)), where both groups had a cystoscopy, showed that TVT-O/TOT reduced the risk of bladder injury. The OR for bladder perforation during TVT is 0.13 (95% CI=0.02–0.69) [21].

The mean intraoperative blood loss during the surgery was not significantly different, correlating with the patients' hemoglobin level 1 day after surgery. However, we did not identify any serious intraoperative bleeding that would require surgical intervention in any case. In the early postoperative period, we also did not report bleeding into the retropubic space or abdominal cavity that would have required surgical intervention, with the exception of one case of small retropubic hematoma in the TVT group. The hematoma measured 5 cm and was treated conservatively. Previous studies have demonstrated that, although the TVT procedure is a partly blind one, the risk of severe perioperative bleeding (>500 mL) and hematoma formation in the Retzius space is rare (0.9–2.5%) [4]. Our data are in agreement with these findings.

Postoperatively, the risk of urinary tract infection (UTI) was higher in the TVT-O group, but in comparison to TVT, this complication early after surgery was not statistically significant (5.4% vs. 3.4%, respectively). It has been shown that postoperative UTI varies somewhat. One of the highest reported rates of UTI after TVT, 17%, was published in a paper by Tamussino et al. [22].

In our study, we did not observe any complications involving the obturator compartment or any severe lower extremity complications. With respect to pain associated with the procedure, postoperative suprapubic discomfort was reported by six TVT patients (4.5%), and eight women (5.4%) in the TVT-O group reported postoperative inner thigh discomfort. This type of postoperative pain was

Table 3 Objective and subjective cure rates, late postoperative complications, postoperative urodynamic parameters, and quality of life data (QoL)

Parameter	TVT™ (n=141)	TVT-O™ (n=147)	p value
Objective cure rates			
Cured	127 (90.1%)	130 (88.4%)	NS[b]
Improvement	12 (8.5%)	14 (9.5%)	NS[b]
Failure	2 (1.4%)	3 (2.0%)	NS[b]
Subjective cure rates			
Dry no leakage	111 (78.7%)	112 (76.2%)	NS[b]
Improvement	27 (19.1%)	31 (21.1%)	NS[b]
Failure	3 (2.1%)	4 (2.7%)	NS[b]
Overall patient satisfaction			
Very satisfied	120 (85.1%)	120 (81.6%)	NS[b]
Satisfied	21 (14.9%)	25 (17.0%)	NS[b]
Not satisfied	0 (0%)	2 (1.4%)	NS[b]
Tape erosion	2 (1.4%)	2 (1.4%)	NS[b]
Urge incontinence symptoms			
De novo	9 (6.4%)	20 (13.6%)	= .015
Anticholinergic use postoperatively	7 (4.9%)	15 (10.2%)	
Postoperative urodynamic parameters			
Maximum cystometric capacity, mL	367.93±77.33	339.87±73.51	NS[a]
First sensation, mL	205.54±60.50	182.42±78.17	NS[a]
Maximal urethral closure pressure, cm H_2O	45.28±18.83	35.16±16.74	NS[a]
Functional urethral length, mm	24.34±4.67	22.73±8.97	NS[a]
Maximum flow rate, mL/s	23.85±7.39	24.57±12.96	NS[a]
Postoperative QoL			
VAS	2.14±1.45	2.16±1.88	NS[a]
CONTILIFE			
Daily activities	10.32±5.14	10.62±4.21	NS[a]
Effort activities	9.64±3.25	10.52±2.19	NS[a]
Self-image	9.07±3.52	10.31±4.21	NS[a]
Emotional impact	10.39±4.97	11.91±6.29	NS[a]
Sexuality	5.57±1.37	5.07±1.97	NS[a]
Well-being	1.48±0.83	1.91±1.12	NS[a]
ICIQ	3.00±4.92	3.5±3.47	NS[a]

Values are given as mean±SD

NS Not significant (p>0.05)

[a] Student's t test

[b] χ^2 test

[c] Fisher's exact test

treated with a prescription of analgesics, and in all cases, symptoms disappeared by the first follow-up visit. De Leval reported that 15.9% of women in his study described moderate pain or discomfort in the thigh folds immediately following the TVT-O procedure. More severe pain persisted for a week in only 1.9% of the patients, and pain was not reported 1 month after the operation [8]. In the French registry data on 984 women following TVT-O, a 2.7% incidence of bilateral or unilateral thigh pain was reported, making this the most common type of pain in the cohort [19]. In the meta-analysis of complications, the OR of groin/thigh pain associated with tape insertion by the transobturator route was 8.28 (95% CI=2.7–25.4) [21].

Midurethral slings can be complicated by postoperative bladder outlet obstruction. The percentage of voiding difficulties after TVT was reported to be 1.4% to 9%, whereas, for TVT-O, it was reported to be 3% to 13% [23]. In the current study, we found a higher risk of postoperative urinary retention 1 day after surgery in TVT-O patients compared to TVT patients (6.6% vs. 2.7%, respectively). This difference was not statistically significant. All patients required self-catheterization; however, the voiding dysfunction resolved within two weeks. Long-term retention is a rare complication of these types of procedures and, after TVT, the incidence ranges from 0.6% to 3.8% and is generally equally infrequent in the transobturator population [21, 24]. Cases of severe obstruction were reported in both the TVT and TVT-O groups—0.7% and 0.6%, respectively. This complication was managed by cutting the vaginal tape seven weeks after the procedure. Urine derivation during this time was facilitated with a suprapubic epicystostomy. Continence status after the tape cut was not altered. These results are in agreement with other published reports [25]. It is necessary that the postoperative risk for obstruction be

included in the informed consent and that the patients are carefully monitored.

In our study population, there was a low, but statistically insignificant, risk of tape erosion (TVT 1.5% vs. TVT-O 1.4%). Recent studies have suggested that TVT erosion ranges between 0.4% and 1% [4]. A systematic review and meta-analysis of complications, published by Latthe et al., reported that, when compared with TVT patients, tape erosion occurred more often in TOT patients (OR=2.37, 95% CI=0.53–10.63) and less often in the TVT-O group (OR=0.86, 95% CI=0.17–4.35) [21]. In all four cases in our study, tape erosion was diagnosed during the first 4 months after the procedure, and all women were symptomatic (discharge, pain, dyspareunia). In these cases, the treatment of choice was the removal of the protruding part of the tape without vaginal suture. In response to local estriol application, these patients had complete vaginal healing.

In contrast to other studies, in our study population, there was a lower incidence of de novo urgency in TVT patients compared with TVT-O patients (6.4% vs. 13.6%, respectively; p=0.015). In TVT, the sling axis is in a different relation to the urethral axis in comparison to the transobturator tapes. Transobturator tape provides a less circumferential compression of the urethra, which may lead to fewer postoperative bladder irritation symptoms [16, 26]. Chêne et al. reported the long-term results of TVT where de novo bladder hyperactivity and urgency were limited at 8.5% and 6%, respectively [27]. In Nilsson's 7-year follow-up, only 5.5% of the women in that study were thought to have de novo urge symptoms unrelated to any known illness [3]. The incidence of de novo urge symptoms following transobturator procedures has been reported to be between 1.5% and 6.7% in the literature [8]. Prospective studies comparing TVT and TVT-O demonstrated no statistical differences with regard to de novo urgency.

According to Liapis et al., the risk of postoperative de novo urgency at the 1-year follow-up was 10.8% for TVT and 13.9% for TVT-O. That result was not statistically significant [14].

The lower incidence of de novo urgency in our TVT group may be explained by two factors. For all participants in our TVT group, the cough test was performed under local anesthesia, and this contributed to an improved final adjustment of the tape. Additionally, the hydrodissection we performed in the Retzius space made the removal of the plastic sheaths easier, with no additional tension. Second, though the sling orientation in TVT-O better resembles the natural hammock shape [28], the removal of the plastic sheath can lead to excessive tension in the absence of hydrodissection. Also, the more complicated pathway of lateral parts of the tape could contribute to this effect. The question is whether a routine stress test could be suitable for transobturator procedures. The cough stress test with the patient under regional (spinal/epidural) anesthesia is not useful as there is paralysis of the pelvic floor musculature. However, this stress test may be used when the TVT-O procedure is performed under local anesthesia. We probably cannot explain all the symptoms of urge and frequency occurring after the antiincontinence procedure by the linkage to the bladder outlet obstruction. According to the Integral Theory proposed by Ulmsten and Petros, these conditions are also attributed to failure of connective tissue support [24].

Objective evaluation of the urodynamic parameters demonstrated a slight but significant decrease in the Qmax in each group and a decrease of the MCC in the TVT-O group at the 1-year follow-up. The data showing the decrease in the Qmax are consistent with recent literature; Lee et al. demonstrated a significant decrease in the Qmax in the TVT and TVT-O groups, 27% and 33%, respectively [23]. Significant changes in the MCC were reflected by the high de novo urgency in the TVT-O group.

Our objective and subjective cure rates are consistent with findings from other randomized trials for the surgical treatment of stress urinary incontinence, i.e., the objective cure of 90.1% of TVT patients and 88.4% of TVT-O patients and the subjective cure of 83.7% of TVT patients and 82.3% of the TVT-O group [21]. Two (1.4%) patients in the TVT-O group were not satisfied due to de novo urgency symptoms. In a prospective randomized controlled trial with a mean follow-up of 18.2±6 months, Barber et al. reported an overall subjective cure rate of 60%. Improvement of their incontinence symptoms was reported by an additional 23% of participants [26].

In 2007, Latthe et al. published a systematic review and meta-analysis of the effectiveness of transobturator and retropubic tape procedures. There were RCTs that compared TVT-O with TVT and trials that compared TOT with TVT [22]. When compared with TVT, the subjective cure of SUI was slightly worse in the TVT-O group (OR=0.69, 95% CI=0.42–1.14) and equivalent in the TOT group (OR=1.05, 95% CI=0.64–1.70), although neither were statistically significant. Also, a meta-analysis published by Sung et al., found no significant difference in the subjective continence rates between these procedures [29].

Our study revealed significant improvements in the incontinence-related QoL following both TVT and TVT-O. These data suggest an improvement in the QoL, and this is consistent with other studies [15, 30]. The strengths of this prospective randomized study are the use of standardized validated outcome measures, the use of a blinded clinical examiner for the follow-up evaluations, a low drop out rate, and the fact that 100% of the procedures were TVT or TVT-O without any concomitant additional surgery.

The results of the 1-year follow-up of this prospective randomized trial indicate that both procedures appear to be equally effective for the treatment of SUI. The theoretical advantage of TVT-O is that the retropubic space is not entered, thus the risk of bladder, bowel, or major vessel trauma is absent. In our population, both methods were associated with a low incidence of perioperative and early postoperative complications. Overall complication rates were also similar, with the exception of de novo urgency. The question remains to what extent it would be appropriate to routinely perform a stress test in slings with a transobturator trajectory.

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Conflicts of interest None.

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