

# Effectiveness and Complications of TVT and TVT-O Operations in the Treatment of Female Stress Urinary Incontinence. Five Years Follow-Up Prospective Study

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## Research Article

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## Abstract

**The Aim of the Study:** To compare TVT (tension - free vaginal tape) and TVT-O (tension-free vaginal tape obturator) operations: results, complications, effectiveness after 5 years of follow-up.

**Material and Methods:** A single center nonblind, prospective study of women with SUI who were randomized to TVT and TVT-O from April 2005 to April 2013. Prospective study out of 394 patients, 114 were operated using TVT operation and 280 patients – TVT-O operation. There was no significant difference between groups concerning the age, BMI (body mass index), parity, menopausal status and prolapse (no patients had cystocele greater than stage II).

**Results:** Mean operative time was significantly shorter in the TVT-O group (18±4.6 min) compared with the TVT group (27±7.1 min). There were no significant differences in the effectiveness of both procedures after 5 years. Hospital stay was statistically significantly shorter in TVT-O group (1.2±0.5 days) than in TVT group (4.0±0.6 days). Significantly less complication were in TVT-O group.

**Conclusion:** TVT and TVT-O operations are equally effective for the surgical treatment of female stress urinary incontinence. TVT-O had a shorter operation time and a lower complication rate.

**Keywords:** Tension-Free Vaginal Tape; Tension-Free Vaginal Tape Obturator from Inside to Outside; Stress Urinary Incontinence; Female Urinary Incontinence; Surgical Treatment of Female Urinary Incontinence

**Abbreviations:** TVT: Tension Free Vaginal Tape; TVT-O- Tension Free Vaginal Tape-Obturator; SUI: Stress Urinary Incontinence.

## Introduction

Female stress urinary incontinence is a common problem which does not resolve by itself, therefore management of this disease has become an important issue for both-patients and doctors.

Female stress urinary incontinence can be treated either by conservative method and surgical procedure, but the results of conservative treatment may not meet our expectations during management of severe SUI. Surgical treatment may offer a better outcome [1].

The minimally invasive midurethral slings have radically affected the surgical treatment of female stress urinary incontinence. Firstly introduced by U. Ulmsten, the tension-free vaginal tape (TVT) technique has become the most common surgical treatment for stress urinary incontinence since 1995 [2]. This tension-free vaginal tape procedure, whereby a thin polypropylene mesh tape is placed directly under the mid-urethra, is as effective as the open colposuspension. It causes less morbidity and is cost effective when compared to the Burch colposuspension [3].

The minimal invasiveness of TVT operation and the long term objective success rate have established TVT as a gold standard for SUI treatment [4]. 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 [5].

Since now, more than 700 articles about TVT have been published and about 1.500.000 TVT procedures have been performed worldwide. A new surgical technique that uses polypropylene tape with newly designed specific surgical instruments called a transobturator vaginal tape from inside to outside or tension-free vaginal tape obturator from inside to outside (TVT-O) was first proposed in 2003 [6]. De Leval J. described a technique in which the tape was passed through the obturator foramen from the inside to the outside (TVT-O). The use of the newly designed surgical instruments can prevent damage to the urethra and bladder [6]. In TVT-O, the use of the guide is strongly recommended. This device is inserted into obturator foramen rather than into retropubic space [7].

Although many reports have confirmed excellent cure rates for TVT, the complications associated with blindly entering the retropubic space have still put a great limitation on this procedure [8]. When transobturator approaches modified from the TVT such as TOT and TVT-O were proposed, much attention and interest have been generated in the transobturator suburethral tape because of their satisfying outcomes and lower complication rates at short-term follow-up. The reported success rate of transobturator tape varied from 80% to over 90% accordingly to different types of material used and different durations of follow-up [9].

Although TVT and TVT-O procedures are equally effective in the treatment of female stress urinary incontinence, TVT-O seems to be safer than the classic TVT [10-12]. Since July 2008, more than 35 clinical papers, including ten randomized trials and two national registries, have been published on the outcome of the TVT-O surgery. The results of these studies have confirmed that the TVT-O procedure is safe and as efficient as the TVT procedure, at least in the short-to-medium term [13]. This prospective study was performed to compare the TVT procedure concerning the effectiveness, safety and simplicity with the TVT-O procedure.

## Material and Methods

A single center (by one surgeon) nonblind, prospective study of women with SUI who were treated using TVT and TVT-O surgical treatment methods from April 2005 to April 2013. TVT procedure was administered to 125 patients and TVT-O procedure to 299 patients. Operated patients were invited for follow up after 2 months, 6 months and 1, 2, 3, 4, 5 years. Eleven patients from TVT and 19 from TVT-O group were lost for follow up at 5 years, so data of 114 TVT group and 280 of TVT-O group study subjects was included into the final analysis.

The number of patients to be studied was established using PASS (Power Analysis and Sample Size programme). The statistical power of the research was found to be 0.8. Inclusion criteria: women with genuine stress urinary incontinence who agree to buy single use TVT or TVT-O equipment by themselves and signed informed consent form confirming their willingness to participate in the study.

Exclusion criteria: urogenital prolapse greater than stage III (pelvic organ prolapse quantification system- POP-Q classification), urinary retention, overactive bladder and psychiatric disease. All patients had typical medical

history of stress incontinence. The degree of the incontinence was 2 – 3 according to the Ingelman-Sundberg scale.

Number of births, obesity, menopause, urinary incontinence period, hysterectomy in the past and incontinence operations in the past of all patients were estimated. A gynecological examination was performed for all patients before the procedure and during the follow-up period, including palpation of prolene tapes. A stress provocation test was performed in the supine and standing positions with a comfortably filled bladder (300 ml) before and post operation.

Urodynamic evaluations were performed for 40% of patients (in TVT group n = 44, in TVT-O group - n = 112) in accordance with the criteria established by the International Continence Society (ICS) [14].

The degree of vaginal defects was evaluated using POP-Q system [15].

Cystoscopy and cough test were routinely carried out only in TVT group. Surgical antibiotic prophylaxis was performed for all operations. Foley catheter was left for 12 hours in TVT group and for 4 hours in the TVT-O group after operation.

Surgical procedures (TVT and TVT-O) were performed by the same surgeon, using the standardized Gynecare protocol. GYNECARE TVT Retropubic System is a retropubic mid-urethral sling used for the treatment of female stress urinary incontinence. The needle curvature and tip radius is designed to maintain contact with the posterior aspect of pubic bone during passage.

TVT-O procedure starts at a precise mid-urethral point and continues away from critical structures utilizing a

safety-winged guide for accurate introduction and passage of the device, allowing for minimal dissection.

Results after 5 years were estimated according to the following criteria:

- Excellent- no signs of stress incontinence, no imperative urination, no dysuria.
- Good- no signs of stress incontinence, very mild imperative urination, no dysuria.
- Medium- no signs of stress incontinence, imperative urination with minimal leakage, very mild dysuria.
- Bad- stress incontinence, imperative urination, dysuria, woman uses inlays [16].

This scale was validated in Lithuania to evaluate the efficacy of surgical treatment of SUI [16]

During 5 years we have lost for follow up 11 patients from TVT group and 19 from TVT-O group. Calculation was performed using SPSS-20 for Windows and statistical analysis was performed using Student's test and chi-square test, Pearson's correlation coefficient and  $p < 0.05$  was considered as statistically significant. The study was approved by the Ethic Committee of the university hospital, approval number BEC-MF-306. No financial support was received from any company for the execution of this study.

## Results

Characteristics of 114 study subjects from TVT group and 280 from TVT-O group are compared in the Table 1. There were no significant differences between the two groups concerning the age, BMI, hormone replace therapy use, and duration of stress urinary incontinence (Table 1). But there were significant differences in menopause duration and birth weight of newborn  $>3500$ g between the study groups.

Patient characteristics	TVT n=114	TVT-O n=280	p
Age, year	51±10.1	49±9.5	0.421
Follow up period (months)	12 (10.5%)	12 (4.2%)	0.104
BMI, kg/m <sup>2</sup>	27.9±4.0	28.2±3.8	0.523
Number of births	2.6±1.1	2.5±1.2	0.259
Birth weight >3500 g	49 (43.0%)	61 (21.8%)	<0.001
Menopause (1 – 30 years)	48 (42.1%)	57 (20.4%)	<0.001
Obesity (BMI > 30)	14 (12.3%)	36 (12.8%)	0.394
Hormone replace therapy use	7 (6.1%)	9 (3.2%)	0.081
Urinary incontinence period, year	6.5±3.1	7.5±2.4	0.322
Hysterectomy in the past	15 (13.2%)	37 (13.1%)	0.861
Operated incontinence in the past	16 (14.0%)	35 (12.5%)	0.294

**Table 1:** Patient characteristics.

As shown in the Table 2, mean operative time was significantly shorter in TVT-O group (18±4.6 min.) compared with TVT group (27±7.1 min.). Hospital stay was significantly shorter in TVT-O group (1.2±0.5 days)

than in TVT group (4.0±0.6 days). There was significantly less cases of bladder drainage in the TVT-O group (2.5%) if compare with TVT group (15.8%).

Register parameters	TVT n=114	TVT-O n=280	p
Duration of procedure	27±7.1	18±4.6	<0.001
Hospital stay (days)	4.0±0.6	1.2±0.5	<0.001
Anesthesia: Epidural	13 (11.4%)	0	-
Local	2 (1.8%)	0	-
Lumbar	94 (82.5%)	22 (7.8%)	<0.001
Intravenous	4 (3.5%)	256 (91.4%)	<0.001
General	1 (0.08)	2 (0.07%)	0.837
Bladder drainage: - Interrupted catheterization	18 (15.8%)	7 (2.5%)	<0.001

**Table 2:** TVT and TVT-O procedure register data.

The main type of anaesthesia in TVT group was lumbar (83.3%) and in TVT-O group - intravenous (91.4%). Simultaneous operations - 37 in TVT group and

79 in TVT-O group - were performed during the surgery (Table 3).

Operation	TVT n=37	TVT-O n=79	p
Anterior colporrhaphy	25 (22.1%)	41 (14.6%)	0.141
Perineorrhaphy	5 (4.4%)	19 (6.8%)	0.264
Prolift anterior	2 (1.7%)	0	-
Vaginal hysterectomy	2 (1.7%)	4 (1.4%)	0.429
Hysteroscopy, D/C	2 (1.7%)	6 (2.1%)	0.381
Diatermoconisation of cervix	2 (1.7%)	4 (1.4%)	0.429
Excision of vulvar papilloma	1 (1.87%)	0	-
Excision of Bartholine cyst	1 (1.87%)	0	-
Laparoscopy	0	1 (0.3%)	-
Excision of lipomae perinei	0	1 (0.3%)	-
Biopsy of cervix uteri	0	1 (0.3%)	-
Labioplasty	0	1 (0.3%)	-
Colpoplasty-dilatation of vagina	0	1 (0.3%)	-

**Table 3:** Simultaneous operations combined with TVT and TVT-O operations.

The effectiveness of surgical SUI treatment was similar in both study groups. The excellent effectiveness was estimated in 78.0% cases of TVT group and in 84.6%

cases of TVT-O operations, and OR=1.55; 95% CI 1.41-1.71; p=0.012. Bad results were in 3 cases (2.6%) in TVT group and in 4 cases (1.4%) in TVT-O group (Table 4).

Results (after 5 years)	TVT n=114	TVT-O n=280	p
Excellent	89 (78.0%)	237 (84.6%)	0.037
Good	7 (6.1%)	15 (5.3%)	0.344
Medium	2 (1.7%)	5 (1.8%)	0.473
Bad	3 (2.6%)	4 (1.4%)	0.205
Lost patients	11 (9.6%)	19 (6.8%)	0.171

**Table 4:** Follow -up results of the TVT and TVT-O procedures.

As shown in Table 5, significantly less complication were in TVT-O group. Suprapubic hematoma occurred in 0.8% of cases in TVT group and 1 case of bladder perforation was in TVT group. Postoperative urinary retention was significantly higher in TVT group (15.8%) if compare to TVT-O group (2.5%). Leg/groin pain during the first postoperative week was observed in TVT-O

group (2.5%) only. There was no significant difference in such complications as symptoms of irritated bladder, but infection of urinary tract was statistically significant higher in TVT group. Vaginal erosions 6 months after the operation were observed in 2 (1.8%) cases in TVT group and 7 (2.5%) cases in TVT-O group.

Complications	TVT n=114	TVT-O n=280	p
No	81 (71.0%)	235 (93.3%)	<0.001
Suprapubic hematoma	1 (0.8%)	0	-
Wound bleeding in vagina	2 (1.8%)	3 (1.07%)	0.257
Bladder perforation	1 (0.8%)	2 (0.6%)	0.412
Postoperative urinary retention	18 (15.8%)	7 (2.5%)	<0.001
Symptoms of irritated bladder	6 (5.3%)	7 (2.5%)	0.167
Infection of urinary tract	5 (4.4%)	2(0.6%)	0.007
Temperature > 38°C	0	1 (0.3%)	-
Leg/groin pain	0	7 (2.5 %)	-
Vaginal erosion	2 (1.8%)	7 (2.5%)	0.337

**Table 5:** Postoperative complications.

## Discussion

The GYNACARE TVT Retropubic System has been used in over 2 million cases worldwide and studied for over 11 years. It is the proven mesh with the largest pore size, 350% greater elasticity and the lowest initial stiffness among the leading brands of mesh [17].

The GYNECARE TVT Obturator System includes the trusted mesh used in over 1.5 million patients, and in a 3 year prospective clinical trial demonstrated a 97% overall success rate [18].

In the present study no statistically significant differences were noted between the two groups concerning the age, parity, menopause status, duration of urinary incontinence and degree of prolapse.

In our study there was a significant statistical difference in the mean operative time, which was much longer in the TVT procedure than in TVT-O method, since in TVT group there was a need for intraoperative cystoscopy and cough test. With the exception of one randomized trial run by Laurikainen E, et al. [19], mean operative time was consistently and significantly shorter in the TVT-O than in the TVT technique, with differences ranging from 4 to 23 minutes [20-26]. Interestingly, in the trial by Laurikainen E, et al. [19], intraoperative cystoscopy was performed in all TVT-O procedures, while this was not the case in all TVT versus TVT-O;

comparative studies that found TVT-O were associated with a shorter operative time. Reasonably, it may be hypothesized that the differences in operative time between TVT and TVT-O surgeries were at least in part due to the routine use of intraoperative cystoscopy during TVT [13].

The duration of hospitalisation was statistically significant longer in TVT group (4.0±0.6 days), than in TVT-O group -1.2%±0.5 days. The main cause of that is 15.8 % of urinary retention cases in TVT group.

The results are not in agreement with other authors, where the majority of patients were discharged from the hospital on the first postoperative day [27].

The effectiveness of the procedure (excellent results) was in agreement with other authors with a range of cure rate from 84% to 95% [28-31]. Randomized clinical trials including 1.040 women in total and eight non-randomized studies compared the TVT-O and TVT procedures for the treatment of SUI [20,21,24-26,31-33]. Ross S et al. in one of the randomized controlled trials has got the following results: 76 women (81%) in the transobturator tape group were cured, compared with 67 (77%) in the TVT group after 12 month follow-up [34]. Serious adverse events and tape effectiveness did not differ between groups at 5 years [35].

All these studies, with follow-ups ranging from 6 to 24 months, showed similar SUI cure rates for the two types

of sling techniques. An objective cure rate of 90% was reported by Nilsson CG et al., when 69 women were studied for 11.5 years post-operatively [36]. In some studies we can also find data that TVT procedure is effective and safe for more than 10 years [37]. Excellent results in our study (after 5 years) were 78.0 percent after TVT and 84.6 percent after TVT-O operation and odds for excellent results after TVT-O operation -1.55 (95% CI 1.41-1.71; p=0.012).

Only a few studies, mainly non-randomized trials, suggested that the TVT-O procedure is associated with a significantly reduced incidence of perioperative complications as compared with the TVT technique [25,26,32]. In our study we received the same data. 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 [32]. Bladder perforation in our study was in 0.8% in TVT group and it is less than reported in the literature [5,29,38]. In TVT-O group there were no such complications. 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, while there are no reported cases of bladder injury when the "inside-out" approach is used [20,39].

Postoperative urinary retention was significantly higher in TVT group (15.8%), thus our data disagree with the literature [40]. Postoperative infection of urinary tract in TVT group was 4.4% and in TVT-O group - 0.6%. Early postoperative wound bleeding in TVT group was 1.8% and TVT-O-1.07%. One patient was treated surgically and four-conservatively.

6 patients in TVT and 7 patients in TVT-O group after 5 years had irritated bladder symptoms. In a meta-analysis assessing randomized trials comparing transobturator tapes (TOT and TVT-O) with the retropubic TVT tape, de novo frequency and urgency symptoms were equivalent [41].

Some differences in the outcomes and complications rate between our results and the other published studies might be related to some limitations in our study. All operations were performed by one surgeon, so, experience increased during the long inclusion into the study period.

Simultaneous operations, such as hysterectomy before or after the TVT procedure, might have a negative impact on the results of the TVT procedure [35]. In our study TVT

and TVT-O operations, combined with other operations, did not have any influence on complications, however, they prolonged the time of general operation and hospital stay.

We didn't calculate cost-effectiveness of both procedures, because the patients single use TVT and TVT-O instruments and tapes bought by them self. In our country patient funds didn't cover expenses. Other authors suggest that TOT operation could be cost-effective compared with TVT in the treatment of SUI [42].

TVT is a safe and effective surgical treatment of female stress urinary incontinence with a good effectiveness, but TVT is associated with various perioperative complications [4,31,43-46]. Several suburethral tape insertion procedures have been described such as tension-free trans-obturator tape (TOT) either from outside to inside or inside to outside [6,47]. One retrospective comparative study investigating retropubic and outside-in transobturator sling, demonstrated that these procedures are equally efficacious to treat female stress urinary incontinence with a cure rate of 90% versus 84% for TOT and TVT, respectively [11]. One theoretical advantage of the TVT-O is that the retropubic space is avoided reducing the risk of bladder, bowel or major vascular injury [6].

## Conclusion

TVT and TVT-O operations are very effective procedures for the cure of female stress urinary incontinence when evaluating effectiveness after 5 years of follow-up. However, TVT-O procedure leads to a shorter operation time, shorter hospital stay and lower complications rate.

## Authors' Contributions

RA - surgeon of all cases and general inspiratory of main idea of manuscript.  
BZ and PA - participated in the design and coordination of the manuscript, also helped to draft the manuscript and participated in patients' interrogatory before and after operation.  
RZ - performed the statistical analysis.  
All authors read and approved the final manuscript.

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