

Efficacy of the trans-obturator and retropubic mid-urethral slings for stress urinary incontinence

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Abstract

Background: The aim of our study was to report the extended long-term results of the use of tension-free vaginal tape (TVT) and trans-obturator tape (TOT) for the treatment of female urinary stress incontinence (SUI) at the Division of Gynaecology and Obstetrics / UMC Ljubljana. There are few data on this topic in the literature. Our aim was to find out whether and how the procedure improved the patients' quality of life and for how long, whether the patients had complications after the procedure, and how this type of procedure affected the long-term results.

Methods: A retrospective clinical trial comparing the use of TVT and TOT was carried out from January to August 2017 and included all the patients operated on at the Division of Gynaecology and Obstetrics / UMC Ljubljana with TVT or TOT procedure for stress or mixed urinary incontinence (UI) associated with urethral hyper mobility (the stress component was clinically predominant). The exclusion criteria were more than 10 years from procedure, age more than 80 years in 2016, previous anti-incontinence surgery and/or pelvic organ prolapse more than stage I on POP-q in any vaginal compartment. After inclusion and exclusion criteria, 1104 patients were sent quality-of-life questionnaires (PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, ICIQ-UI Short Form (Slovenian)) with questions about the diagnosis, procedures, complications, reoperations, post-operative results, and satisfaction with the procedure. Till August 2017 (6 months after sending) we received 466 questionnaires (42.2 % response rate). After 225 questionnaires were excluded due to incomplete data, 241 questionnaires were analysed.

Results: In the analysed group of patients (N = 241), 189 (78 %) had TOT and 52 (22 %) had TVT. Our retrospective study has confirmed that the efficacy and safety of TOT and TVT in the surgical treatment of SUI are comparable. The TOT and TVT groups did not differ significantly from each other in PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, and ICIQ-UI Short Form or in postoperative complication rate. Repeat surgery was needed in 25/189 (13.2 %) TOT patients and 12/52 (23.1 %) TVT patients; $p = 0.082$. Urinary retention appeared in 18/189 (9.5 %) TOT patients and 7/52 (13.5 %) TVT patients; $p = 0.411$. Mesh erosion/inflammation appeared in 12/189 (6.3 %) TOT patients and 2/52 (3.8 %) TVT patients; $p = 0.495$.

Conclusion: We can conclude that the efficacy and safety of TOT and TVT in the surgical treatment of SUI are comparable. The choice of the technique should be based on the relative pros and cons of techniques and the surgeon's experience.

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1 Introduction

Several surgical modalities and a number of different surgical techniques using tension-free vaginal tapes (TVT) are available for the treatment of stress urinary incontinence (SUI) today. The TVT procedure for the treatment of SUI was first described by Ulmstein in 1998 (1) and it soon became the most popular procedure worldwide for the treatment of SUI (2). Its high success rate ranges from 94 % to 95 % (3,4), but may be associated with complications, such as injury to the bladder, urethra, bowel or major blood vessels. Transient postoperative urinary retention may occur in 8–17 % of patients and 5–15 % patients may have postoperative urinary urgency (8,7). In order to avoid the complications associated with the retropubic approach, Delorme (8) introduced a transobturator sling procedure. Placing the sling tension-free through the obturator muscles improves the weak pelvic fascial musculature and avoids blind passage of a needle in the retropubic space and the groin, thereby reducing the risk of injury to the bladder, bowel and great vessels.

In his study, Delorme reported a high success rate for the transobturator approach, a low rate of perioperative complications and no bladder perforation (8). Similar results were achieved in a large-scale study by Krauth et al (9). One year after the operation, 85.5 % of the women reported satisfaction with the results and only 1.5 % complained of urinary retention and urinary emergency.

There is limited literature that presents the results of stress urinary incontinence treatment or compares different surgical approaches (10–14). This study was undertaken to assess the efficacy of treating stress urinary incontinence with the placement of tension-free

vaginal tape used at the Department of Gynaecology and Obstetrics, University Medical Centre Ljubljana. The aims of the study were to determine a) whether, how, and for how long this procedure improved the quality of life of the patients, b) whether the patients suffered any postoperative complications and if they did, what the complications were like, and c) how the choice of surgical approach affected the outcome.

This retrospective study compared transboturator (TOT) and retropubic (TVT) procedures using tension-free vaginal tapes for the treatment of SUI in terms of their success rate and intra- and postoperative complication rates. In addition, objective and subjective (patient-perceived) outcomes are presented.

2 Materials and methods

This retrospective study conducted at the Department of Gynaecology and Obstetrics, University Medical Centre Ljubljana in January 2017 included female patients with stress or mixed (with the predominant stress component) urinary incontinence associated with urethral hypermobility, who were treated by tension-free transobturator tape (TOT) and tension-free vaginal tape (TVT) procedures.

Patients who had undergone surgery more than 10 years earlier and patients older than 80 years in 2016 were excluded from the study. The patients who remained in the study were thus supposed to be able to remember the operation and the postoperative course, and could duly complete the questionnaire. We also excluded patients who had had a previous operation for urinary incontinence and patients with pelvic organ prolapse Stage 1 or greater according to

POP-Q classification (15) in any of the vaginal compartments. By August 2017 (six months after mailing) we had received 466 questionnaires (response rate 42.2 %), of which 225 (48 %) were excluded from further consideration in the study because they were inadequately filled out. Thus a total of 241 participants (questionnaires) were available for analysis (Table 1).

Preoperative patient evaluation included detailed history taking and clinical, neurological and urogynaecological examinations. All patients underwent cough test and Valsalva maneuvers with a maximally full bladder. The tests were repeated after the operation. The severity of urinary incontinence was classified according to the International Continence Society (ICS) guidelines.

Prior to surgery the patients completed a 3-day voiding diary and had static pelvic ultrasound imaging. Patients with the diagnosis of overactive bladder syndrome were given appropriate drug therapy (anticholinergics, betamimetics).

Standard surgical techniques described by Ulmsten (TVT, GYNECARE; Ethicon, Somerville, NJ, USA) and Delorme were used (1,8). TOT procedure was performed using the GYNECARE TVT ABBREVO® system with the same mesh design as laser cut mesh used in the obturator system for the repair of pelvic organ prolapse. The suture passed through the sling tip is removed after the procedure (16). It is comparable to TOT slings in terms of fixation strength in the obturator membrane. It uses less mesh but provides the same tension-free support (16).

For the TVT approach GYNECARE TVT EXACT® system was used. It has a rigid 3-mm diameter trocar shaft designed to maintain control during passage while reducing penetration force. The trocar curvature and tip radius are designed so that the trocar maintains contact with the posterior aspect of the pubic bone (18).

The patients were operated on under local anaesthesia. After the procedure residual urine volume was measured. Patients with a postvoid residual urine volume greater than 50 % were recommended to perform intermittent self-catheterisation until the next residual urine measurement in one week's time.

After considering all inclusion and exclusion criteria, written information about the study and a consent form were mailed to 1,104 participants. The informed consent was signed by all participants. They were sent appropriate quality-of-life questionnaires (PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6,

Table 1: Data of participants who returned completely filled out questionnaires (N = 241).

Parameter	No. of patients(N)	Percent (%)
Type of incontinence		
Stress	154	64
Stress incontinence associated with urge component	87	36
Surgical technique		
transobturator (TOT)	189	78
retropubic (TVT)	52	22
Previous gynaecological operations		
None	173	72
Total abdominal hysterectomy	31	13
Vaginal hysterectomy with vaginal plastic	26	11
Other (Burch's, Wertheim's, Stamey's) procedures	11	4

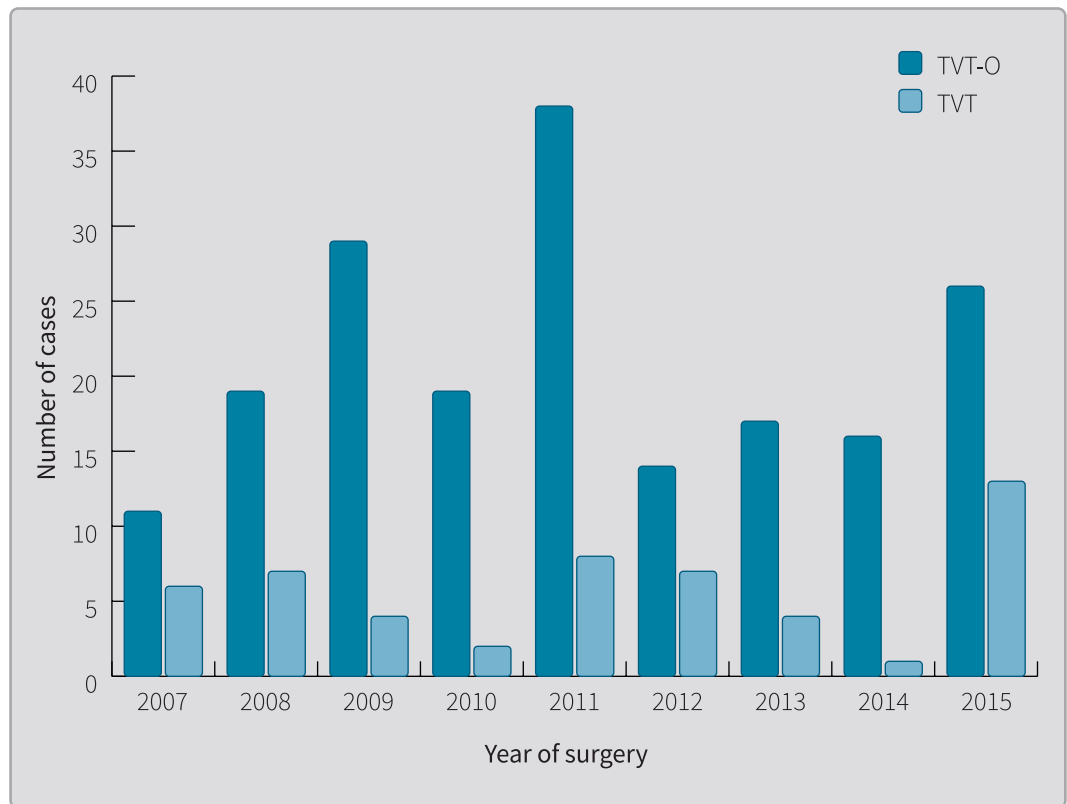


Figure 1: The distribution of TVT-O (TOT) and TVT procedures over time.

IIQ-7, ICIQ-UI Short Form (in Slovene)) and questions asking about their diagnosis, procedures, complications, reoperations, treatment results and satisfaction with the procedure. Data on body weight and height, previous gynaecological procedures, type of the procedure, date of birth, year of surgery, level of education, job at the time of the study, number of vaginal deliveries and cesarean sections prior to the procedure, rate of previous gynaecological operations, previous conservative treatment of urinary incontinence, menopausal status and intra- and postoperative complications were retrieved also from the Department of Gynaecology and Obstetrics database and patient medical records.

By August 2017 (six months after mailing the questionnaires) we had received 466 completed questionnaires (response rate 42.2%), of which 225 (48%) were

excluded from further consideration in the study because of missing data.

Ordinal categorical variables were analysed with the Mann-Whitney U test. For a comparison of other categorical variables either the chi-square test or the Fisher's exact test was used, as appropriate. The Student's t-test was used to compare continuous variables. A p value < 0.05 was regarded as statistically significant. All data were analysed using IBM SPSS Statistics, Version 24 (IBM Corp, Armonk, NY).

The study was approved by the Medical Ethics Committee of the Republic of Slovenia on 22 Nov. 2016 (Decision No.0120-565/2016-2). All the research participants received detailed information about the study and signed a written consent form for participation in the study. All the operating surgeons

had adequate experience with both surgical techniques.

3 Results

After considering inclusion and exclusion criteria we mailed questionnaires to 1,104 patients eligible for the study. By August 2017 (six months after mailing) we had received 466 completed questionnaires (response rate 42.2 %); 225 questionnaires (48 %) were incompletely filled out and were excluded from further consideration. Thus a total of 241 duly completed questionnaires were available for analysis.

We first assessed the sample representativeness. No statistically significant difference was found between responders and non-responders in terms of the type of the procedure, date of birth, date of operation, age in 2016, education level, occupation, number of vaginal deliveries and cesarean sections prior to the procedure, rate of previous gynaecological operations, previous conservative treatment of urinary incontinence, menopausal status, type of anaesthesia and intra- and postoperative complications ($p > 0.15$).

The average age of participants was 56.2 years (SD 9.7).

Figure 1 displays the distribution of TVT-O (TOT) and TVT procedures over time.

Among the participants who returned incomplete questionnaires ($N = 241$), 189 (78 %) underwent the TOT procedure and 52 (22 %) had the retropubic TVT operation. The operating surgeons based their choice between the procedures on the perceived relative advantages and disadvantages of the techniques, and, to a great extent, on their experience with the procedures. TOT and TVT groups showed comparable data. They did not differ significantly in their body weight

at the time of surgery ($p = 0.533$), body weight at the time of filling out the questionnaire ($p = 0.118$), body height ($p = 0.427$) age or time elapsed from surgery (5.8 yrs: 5.9 yrs; $p = 0.665$). There was no significant difference between TOT and TVT groups in their answers to the question »Did your mother had bladder control problems?« ($p = 0.957$). The graph showed that TOT-O (TOT) and TVT procedures were distributed randomly over time, showing no definite trend.

Responses to structured questionnaires (PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, ICIQ-UI Short Form (in Slovene)) and to individual additional questions are analysed in Table 2 and Table 3.

4 Discussion

This retrospective study showed that TOT is as safe and effective as TVT in the treatment of female SUI (Table 2 and Table 3).

Analysis of responses obtained by the validated structured questionnaires (PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, ICIQ-UI Short Form (in Slovene)) revealed no statistically significant differences between TOT and TVT groups. Participants of the two groups did not differ significantly in their responses to the questions » How much urine do you lose now?« ($p = 0.792$) and » Do you leak urine when the bladder is half full and you cough?« ($p = 0.781$).

Regression models were used to determine possible effects of time elapsed from surgery on surgical outcomes. As there was no association of time from surgery and present urinary status, these data were not presented in detail.

The groups did not differ significantly in the rate of complication either (Table 3). Reoperation was required in 25 of the

Table 2: Analysis of questionnaires

Please mark the letter that best describes the present state of your lower urinary tract (PGI-S):			
	TOT (N = 189)	TVT (N = 52)	p-value
a) normal	63 (33,3 %)	15 (28,8 %)	
b) mild problems	59 (31,2 %)	13 (25,0 %)	
c) moderate problems	35 (18,5 %)	17 (32,7 %)	
d) severe problems	21 (11,1 %)	6 (11,5 %)	p = 0,199
no data	11	1	
Please mark the letter that best describes the present state of your lower urinary tract as compared to the state before the therapy (PGI-I):			
	TOT	TVT	p-value
a) notably improved	73 (38,6 %)	21 (40,4 %)	
b) moderately improved	39 (20,6 %)	11 (21,2 %)	
c) slightly improved	34 (18,0 %)	7 (13,5 %)	
d) unchanged	14 (7,4 %)	6 (11,5 %)	
e) slightly worse	6 (3,2 %)	1 (1,9 %)	
f) moderately worse	9 (4,8 %)	3 (5,8 %)	
g) notably worse	5 (2,6 %)	2 (3,8 %)	p = 0,912
no data	9	1	
Sandvik Hunskaar severity index : How often do you experience urine leakage? (1.less than once a month; 2. one or several times a month ; 3.once or several times a week; 4.every day and/or night; How much urine do you lose each time? (1.a few drops or little; 2. more)			
	TOT	TVT	p-value
mild	119 (63,0 %)	27 (51,9 %)	
moderate	45 (3,8 %)	12 (23,1 %)	
severe	25 (13,2 %)	13 (25,0 %)	p = 0,078
	TOT	TVT	p-value
Urogenital distress inventory (UDI-6)	35,29	31,20	p = 0,292
Incontinence impact questionnaire (IIQ-7)	30,95	28,39	p = 0,595
International consultation on incontinence - short form (ICIQ-SF)	7,30	8,65	p = 0,145

How much urine do you lose now?			
	TOT	TVT	p-value
a) no leakage	45 (25,0 %)	13 (26,0 %)	
b) urine leakage triggered by severe coughing or straining	88 (48,9 %)	22 (44,0 %)	
c) urine leakage triggered by mild coughing or straining	17 (9,4 %)	4 (8,0 %)	
d) urine leakage not related to cough or strain	22 (12,2 %)	10 (20,0 %)	
d) constant urine leakage	8 (4,4 %)	1 (2,0 %)	p = 0,792
no data	9	2	

Do you leak urine when the bladder is half full and you cough?			
	TOT	TVT	p-value
yes	36,6 %	38,8 %	
no	63,4 %	61,2 %	p = 0,781

189 TOT patients (13.2 %) and in 12 of the 52 TVT patients (23.1 %); ($p = 0.082$). Urine leakage was reported by 18 of the 189 TOT patients (9.5 %) and by 7 of the 52 patients operated on by the TVT approach (13.5 %); ($p = 0.411$). Tape erosion into the vagina/ inflammation occurred in 12 of the 189 TOT patients (6.3 %) and in 2 of the 52 patients in the TVT group (3.8 %); ($p = 0.496$).

The majority of participants reported no pain related to the procedure. The TOT and the TVT group did not differ significantly in their postoperative sequelae rates (Table 3).

4.1 Tape erosion into the vagina

Vaginal tape erosion occurred in 6.3 % of patients undergoing TOT (95 % CI = 2.03 % - 10.8 %) as compared to 3.8 % of patients operated on by TVT (95 % CI = 0.5 % - 13.2 %). Vaginal tape erosion rate reported in other studies is 3.8 % to 15 % (20,21). The incidence of this complication depends on the type of the synthetic mesh, as well as on the operating surgeon's experience and the type of

the approach used (22). There are several possible causes of vaginal tape erosion: rubbing between the mesh and vaginal mucosa, mesh tension, which could cause an increased inflammatory reaction, subclinical infection of the mesh and poor wound healing; compromised vascularity and consequent ischaemia in the underlying tissue to the mesh. Pore size in monofilament mesh is very important, too. Multifilament mesh, woven materials, and silicone-coated materials are associated with higher risk of tape erosion into the vagina (21,23,24).

The advantage of this study was that in both groups of patients a mesh made of polypropylene was used. TOT was performed using GYNECARE TVT ABBREVO®, while GYNECARE TVT EXACT® was used for the TVT approach. Thereby we avoided bias due to the use of different mesh materials, reported in some other investigations (22). Rechberger et al. (25), who compared the impact of monofilament and multifilament mesh used for the same type of surgery, found that the only intergroup difference was in the rate of postopera-

Table 3: Complications and satisfaction

Postoperative complications			
	TOT (N (%; 95 % CI))	TVT (N (%; 95 % CI))	p-value
tape erosion into the vagina	12 (6,3 %; 2,03 % – 10,8 %)	2 (3,8 %; 0,5 % – 13,2 %)	p = 0,495
inflammation	12 (6,3 %; 2,03 % – 10,8 %)	2 (3,8 %; 0,5 % – 13,2 %)	p = 0,495
difficulty fully emptying the bladder	18 (9,5 %; 5,7 % – 14,6 %)	7 (13,5 %; 5,6 % – 25,8 %)	p = 0,411
reoperation required	25 (13,2 %; 8,7 % – 18,9 %)	12 (23,1 %; 11,6 % – 34,5 %)	p = 0,082
no complications	118 (62,4 %)	29 (55,8 %)	p = 0,384
Sequelae of surgery			
	TOT	TVT	p-value
thigh pain	17 (9,0 %)	3 (5,8 %)	p = 0,456
groin pain	23 (12,2 %)	3 (5,8 %)	p = 0,189
abdominal pain	19 (10,1 %)	2 (3,8 %)	p = 0,161
no problems	118 (62,4 %)	39 (75,0 %)	p = 0,093
Were you satisfied with the procedure?			
	TOT	TVT	p-value
yes	161 (86,6 %)	41 (80,4 %)	
no	25 (13,4 %)	10 (19,6 %)	p = 0,271
no response	3	1	
Would you have the surgery again?			
	TOT	TVT	p-value
yes	163 (89,1 %)	37 (75,5 %)	
no	20 (10,9 %)	12 (24,5 %)	
no response	6	3	p = 0,014
Would you recommend this procedure to your friend?			
	TOT	TVT	p-value
yes	167 (90,8 %)	39 (81,3 %)	
no	17 (9,2 %)	9 (18,8 %)	p = 0,063
no response	5	4	

tive urine retention, whereas the success rates were equal.

Local excision, antiseptic irrigation and vaginal wall reclosure in synthetic mesh erosion may not be sufficient and

complete tape removal is often necessary. Many of these patents require reoperation to restore continence (26). Erosion and secondary infection of mesh materi-

al may develop as late as 18 or more years after the procedure (27).

The limitations of this study include: shortage of data on success rate obtained by objective evaluation methods (cystometry), and a retrospective study design. Success rate could be objectively evaluated by the results of urodynamic and cystometric measurements, but patient satisfaction with final outcome depends on a number of other subjective factors. The level of patient satisfaction with surgery and perceived success can be assessed with questionnaires, which have added value over objective evaluation methods: the main goal for the patient and the doctor is satisfaction with the procedure rather than mere improved cystometric and urodynamic parameters.

4.2 Voiding disorders

Urinary retention is one of the most common complications of retropubic surgery (17–50 %) (28,29). In their study, de Tayrac et al (6) reported that urinary retention developed in 13 % of their patients undergoing TOT and in 25.8 % of TVT patients. Similarly, in our study urinary retention occurred in 9.5 % of TOT

patients (95 % CI = 5.7–14.6 %) and in 13.5 % of patients operated on by the TVT approach (95 % CI = 5.6–25.8 %). There was no statistically significant intergroup difference in the incidence of urinary retention ($p = 0.411$). Similar results were documented by Zullo et al. (19). Morey et al. (30) reported a higher urinary retention rate after TOT, yet most of urinary problems resolved spontaneously within a few weeks.

Satisfaction with the procedure was reported by 86.6 % of TOT patients versus 80.4 % of TVT patients, yet the difference was not statistically significant ($p = 0.271$). A significantly higher percentage of TOT patients compared to TVT patients responded that they would have the operation again (89.1 %) ($p = 0.014$), and that they would recommend the procedure to their friends (90.8 %) ($p = 0.063$).

In conclusion, TOT and TVT for the treatment of SUI in female patients have comparable safety and success rates. The choice between the two procedures should take into account relative advantages and disadvantages of these two options. The operating surgeon's experience is another important factor contributing to the success of the procedure.

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