Original article

Is there any difference? A prospective, multicenter, randomized, single blinded clinical trial, comparing TVT with TVT-O (POLTOS study) in management of stress urinary incontinence. Short-term outcomes

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Abstract: *Objective:* to compare effectiveness and safety of tension-free vaginal tape (TVT) and tension-free obturator tape (TVT-O) in surgical treatment of stress urinary incontinence (SUI). *Materials and Methods:* A prospective, multicenter, randomized, single blinded trial. 51 patients were screened and 35 patients were randomly allocated to either TVT (n=19) or TVT-O (n=16) group. *Results:* At 6 months' follow-up, we demonstrated that TVT and TVT-O seems to be equally effective in surgical treatment of SUI. For estimated objective efficacy, pad and cough tests were performed. There were no statistical differences between two procedures. There were no statistical differences between two groups when comparing early (postoperative) and late complications. Average operation time was shorter for TVT-O group, with statistical significance difference between two procedures. *Conclusion:* There appears to be equal efficacy of TVT and TVT-O in surgical treatment of female SUI.

Key words: Transobturator tapes; Short term follow-up; Stress urinary incontinence; Suburethral tape.

INTRODUCTION

Stress urinary incontinence (SUI) is defined as involuntary loss of urine associated with activities increasing intraabdominal pressure, such as coughing, laughing, sneezing or performing the Valsalva maneuver,[1] affecting up to 65% of women aged 45-49.[2]

Many surgical approaches for SUI treatment have been suggested, with different level of success. Until the mid-1990s the gold standard was Burch colposuspension.[3] Currently, mid-urethral sling procedures are considered to be the first line of surgical treatment for the SUI. The tension-free vaginal tape (TVT) procedure was first described by Ulmsten in 1996[4] and is known to be associated with a cure rate between 80 and 90%.[5] Although TVT is a technique considered minimally invasive there are numerous publications on its complications including: bladder perforations (3.8-6.5%), bleeding (1.9-2.7%), mesh erosion (0.9%), and bowel perforations (0.3%).[6,7] To minimize these complications in 2001 Delorme described a method of placing a synthetic polypropylene mesh via transobturator route from the outside to the inside with cured rate almost 90%.[8] In 2003 de Leval described a technique, in which the tape is passed through the obturator foramen from the inside to the outside, called tension-free obturator tape TVT-O.[9]

These transobturator approaches, seem to be safer for the patient, because they decrease the risk of bladder and/or bowel injury and postoperative hemorrhage. Several randomized, controlled trials in the literature compared TVT with TVT-O and other methods of surgical SUI treatment. There are also two meta-analyses[10,11] but there can be some problems with drawing evident conclusions from them, such as methodology or inclusion criteria of the trials that where included. In contrast to those trials, this trial was designed as a single blinded trial, where a patient did not know which procedure is undertaken, which helped us avoid bias. This prospective randomized single blinded trial was designed to compare the use of TVT and TVT-O in surgical treatment of stress urinary incontinence in terms of subjective evaluation of SUI symptoms regression, regression of ailments corresponding with SUI and subjective assessment of health condition after operation. Additionally, the trial included estimation of differences in objective demission of SUI symptoms measured by pad test and cough test, evaluation of quality of life after operation, differences in time of procedure, complications and time of hospitalization.

PATIENTS AND METHODS

Between October 2006 and October 2009, after approval from local ethics committee (06/2006), Caucasian women with SUI symptoms, who were not surgically treated before, were invited to participate in the study. Fifty-one women were screened by 3 centers in Warsaw. All patients gave verbal and written consent. Inclusion criteria included: women aged 40 - 80, SUI confirmed with 1-hour pad-weighing test and positive results of urodynamic tests, maximum bladder volume over 300 ml, patients without urinary tract infection. Exclusion criteria were: BMI over 33 kg/m^2, pathology in the reproductive organ or in lower pelvis which should be qualified for surgical treatment, bladder pathology, hysterectomy with or without salpingectomy in the past, neurological urinary incontinence, overactive bladder, hypotony of detrusor muscle or any form of mixed incontinence, pregnancy, radiotherapy of pelvis in the past, hypersensitivity to anesthetic drugs, post voiding volume >150ml, pelvic organ prolapse, myocardial infarction or hemorrhagic or ischemic stroke within past 6 months prior to randomization, auto immunologic disorders, cancer disease, family of investigator.

Fifty-one patients were primary screened, but 35 patients fulfilled inclusion criteria and were randomized 1:1 to undergo TVT or TVT-O procedure. The randomization was done through a web page secured with a 128-bit code.

In order to increase credibility of the trial, during the whole trial, patients were not informed which type of operation was performed. Due to the fact that TVT and TVT-O

procedure differs in technique and places of skin incisions, every patient had extra skin incisions for masking the type of procedure ("sham operation"). Each patient had 4 skin incisions in localization typical for needle introduced in TVT and TVT-O procedure. Finally 35 patients were randomized to either TVT (n=19) or TVT-O (n=16) group.

The surgical procedures have been described previously.[4,12] In the TVT group, cystoscopy was routinely performed. In both procedures the needles and woven polypropylene tape were Gynecere products (Gynecere Ethicon Inc., Somerville, NJ, USA). The procedures were conducted under spinal anesthesia.

The primary outcome measure was to estimate effectiveness of procedure by measuring subjective regression of SUI symptoms after TVT or TVT-O, before and after 3 and 6 months from operation. To estimate this outcome VAS was used, where zero means no urinary problems and 10 means unbearable urinary complaints. The patients were also asked for subjective estimation of ailments corresponding to SUI and subjective assessment of health condition before and after 3 and 6 months from operation.

The secondary outcome measure was to estimate differences in TVT or TVT-O procedures with regard to: effectiveness of procedure based on objective demission of SUI symptoms, evaluated by pad test before and after 6 months from operation and cough test after 3 and 6 months, evaluation of life quality after 3 and 6 months, differences in time of procedure, complications after each procedure and time of hospitalization.

To estimate life quality of the patients before and after operation, all patients filled in King's Health questionnaire (KHQ) and SF-36 questionnaire.[13,14] Because the KHQ was not translated into Polish in accordance with the principle of „cross-culture translation" and did not undergo appropriate validation under Polish conditions, fully validated SF-36 questionnaire was used, for extra estimation of life quality of patients.

Cough test was performed in recumbence and standing position. Pad test was performed according to ICS (International Continence Society) guidelines.

Operative data such as operative time, estimated intraoperative blood loss, operative complications and the time of hospitalization after procedure were recorded. Due to the fact that, there are different ways to define length of the procedure time in clinical trials, we made a distinction between surgical procedure time, defined as time from first incision till the last suture was made, and operation time, which was defined as time from patient's arrival at operating room to her transfer to the gynecological department. Statistical analysis was performed according to intention to threat (ITT). Analysis of results was performed based on primary and secondary outcome. The differences between both groups were tested. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) v. 10.0. Parameters with normal distribution were evaluated using Student's t-test and ANOVA Friedman test. Test U Manna-Whitney was used for the cases that did not have a normal distribution. Chi-squared test was used for evaluation of categorical data. The level of statistical significance was set at $p<0.05$.

RESULTS

There were no significant differences in age and body mass index between two groups. Four patients did not complete the follow up schedule and thus were excluded from the study, leaving a total of 15 patients in TVT and 16 patients in TVT-O group. One of them was lost in follow up and three had bladder perforation during TVT procedure and were excluded from the trial. After perforation, which was confirmed in cystoscopy, the tape was removed.

Effectiveness of each procedure was measured subjectively. To estimate this outcome VAS was used, and resulted in statistical improvement of SUI symptoms regression in both groups measured after 3 and 6 months (Figure1). However, there was no difference in VAS, comparing TVT vs. TVT-O groups. There was no difference in subjective ailments corresponding to SUI before the operation between two groups (p=0,564). We observed statistically significant reduction in subjective estimation of ailments corresponding to SUI after 3 and 6 moths from operation in TVT group and TVT-O group. However, the difference between both groups was statistically insignificant (p-value=0,956 and 0,873 respectively).

We observed statistically significant improvement in subjective assessment of health condition in each group after 3

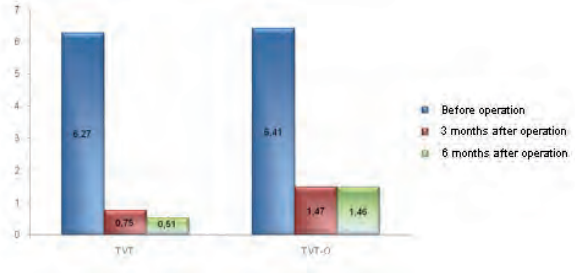

Figure 1. – Comparison of subjective effectiveness of both procedure, TVT and TVT-O, before, after 3 and 6 months from operation. For this purpose Visual Analogue Scale (VAS) was used.

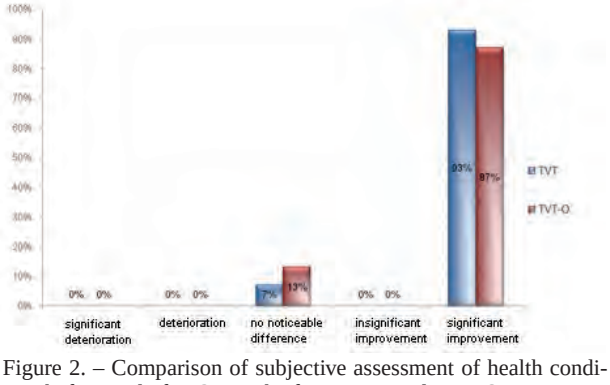

Figure 2. – Comparison of subjective assessment of health condition before and after 3 months from TVT and TVT-O operations. Significant improvement of health condition took place in 93% of women after TVT operation and in 87% TVT-O group.

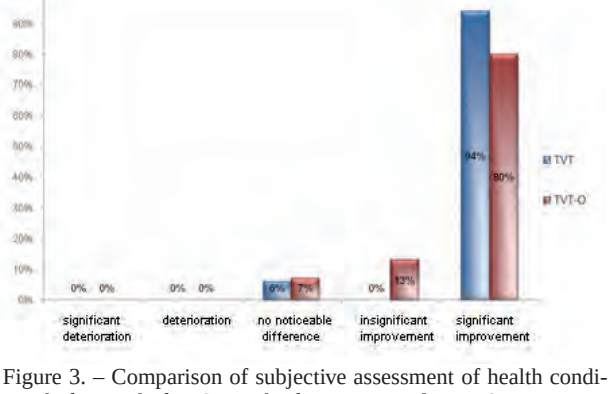

Figure 3. – Comparison of subjective assessment of health condition before and after 6 months from TVT and TVT-O operations. Significant improvement of health condition took place in 94% of women after TVT operation and in and in 80% TVT-O group.

and 6 months from operation (Figure 2, Figure 3). However, when we compared both groups, the difference was not statistically significant (p-value=0,95 and 0,37 respectively).

There were no statistical differences between two procedures after 3 and 6 months in the results of cough test in standing and recumbence position (after 3 months p value in standing position p=0,59, in recumbence position p=0,96; after 6 months p value in standing position p=0,26, in recumbence position p=0,51).

The pad test was performed before and after 6 months from operation and significant improvement was achieved. In the TVT group the test was negative in 94% patients after operation, and in TVT-O in 87% patients. The difference was statistically insignificant (p=0,51).

Both groups showed improvements in all aspects (Table 1, Table 2) in postoperative questionnaires, KHQ and SF-36. There were no significant differences in the quality of life (Table 1, Table 2) in both procedures.

There were no statistical differences between two groups in perioperative complications and late complications, however there were 3 cases of bladder perforation in TVT group (18%) (Table 3)

The average procedure time was shorter in TVT-O group (12,4 min (SD=3,52) vs. 47,75 min (SD=42,89)) and the difference was statistically significant (p<0,001). Also average operation time was shorter for TVT-O group (39,25 min (SD=10,19) vs. 71,35 min (SD=48,73)) with statistical significance difference between two procedures (p=0,001).

There was no statistical difference between two groups in the time of hospitalization (p=0,578). Average hospitalization time in TVT group was 2,41 days (SD=1,37), for TVT-O group it was 2 days per each patient (SD=0.0).

DISCUSSION

This prospective, multicenter, randomized single blinded trial was designed to compare the use of TVT and TVT-O in surgical treatment of stress urinary incontinence. At 6 months' follow up, we demonstrated that TVT and TVT-O seem to be equally effective in SUI surgical treatment, which is consistent with results of others trials,[15] but not all of them,[16] in which TVT operation was more efficient than TVT-O or TOT in treating SUI. Effectiveness, which was measured in our trial subjectively and objectively, did not differ between both groups. Subjective evaluation was the primary outcome and resulted in improvement of SUI symptoms regression in both groups measured after 3 and 6 months. Objective effectiveness was also estimated after 3 and 6 moths by pad and cough tests and resulted in improvement of SUI symptoms regression. The differences were insignificant between both groups. When we asked patients for subjective estimation of ailments corresponding to SUI and subjective assessment of health condition before and after 3 and 6 months from operation, we found improvement in both aspects in TVT and TVT-O group, but we did not find differences between them. Noteworthy, none of the patients in both groups reported deterioration of general health after 6 months of the operation. When we compare both procedures, there were no differences in each domain of KHQ or SF-36 questionnaire in the quality of life.

We think, as the others, that advantage in TVT-O operation is that retropubic space is avoided, which reduces the risk of bladder, bowel or major vascular injury or perfusion. Although many reports confirmed excellent cure rates for TVT, the complications associated with blindly entering the retropubic space, might be limitation of this procedure.[17] With TVT-O procedure many of these problems are avoided. Several recent studies have demonstrated that the incidence of perioperative and short-term postoperative complications associated with the TVT-O procedure is low.[18] On the other hand, what is also critical, retropubic TVT procedure required less operative time and results in shorter hospitalization time, with significantly less postoperative pain and faster return to regular daily activities than the traditional Burch colposuspension.[19] In our trial, bladder perfusion occurred in 3 TVT patients' (18%). None of these complications occurred in TVT-O group. However, bladder perforation usually has no long-term adverse consequences.[20] Despite that, we did not notice any differences in early and late complications between the two groups.

Probably, due to the fact that cystoscopy was necessary to verify bladder injury during TVT procedure, the operation

TABLE 1. – Scores of each domain of the King's health questionnaire before and after 3 and 6 months follow-up in TVT and TVT-O groups. Statistical improvement was achieved in a TVT-O group in all domains of KHQ after 3 and 6 months from operation. In a TVT group statistical improvement was achieved in almost all domains of KHQ after 3 months (except general health perception (p=0,110) but in all domains of KHQ after 6 months from operation time.

KHQ Domain	Preoperative score (mean (SD))			Three months postoperative score (mean (SD))			Six months postoperative score (mean (SD))		
	TVT	TVT-O	p-value	TVT	TVT-O	p-value	TVT	TVT-O	p-value
General health perception	37,5 (15,5)	32,4 (17,1)	0,314	26,7 (25,8)	14,1 (15,7)	0,129	13,9 (15,4)	20 (16,9)	0,287
Incontinence impact	75,9 (22,3)	82,4 (31,4)	0,186	22,2 (37,1)	31,3 (37,5)	0,413	18,5 (30,7)	17,8 (30,5)	0,965
Role limitations	63,9 (23,7)	68,6 (31,7)	0,417	13,3 (21,1)	17,7 (29,5)	0,886	10,2 (19,1)	13,3 (23,7)	0,721
Physical limitations	76,9 (24,3)	82,4 (33,1)	0,355	26,7 (15,2)	32,3 (28,8)	0,948	24,1 (18,3)	28,9 (25,6)	0,731
Social limitations	42,5 (30,2)	39,9 (32,4)	0,767	0,9 (3,1)	11,8 (21,6)	0,101	0 (0)	4,8 (12)	0,057
Personal relationships	36,7 (29,7)	39,2 (38,6)	0,969	2,6 (9,2)	6,7 (17,6)	0,384	1,2 (4,5)	11,1 (24,1)	0,275
Emotions	56,8 (24,7)	50,3 (32,9)	0,453	8,7 (12,5)	19,4 (31,3)	0,814	6,8 (17,1)	12,6 (22,6)	0,419
Sleep/energy	46,3 (24)	37,3 (23,2)	0,263	10,7 (14)	13,5 (20,4)	0,944	9,3 (14,3)	10,7 (14)	0,692
Severity measures	69,9 (12,8)	67,7 (26,5)	0,903	25 (26,9)	25,5 (28,8)	0,936	25,6 (25,3)	27,4 (31,3)	0,965

Table 2. – Scores of each domain of the SF-36 questionnaire before and after 3 and 6 months follow-up in TVT and TVT-O groups. Statistical improvement was achieved in a TVT-O group only in physical functioning (p=0,003) and PCS (p=0,024). After 6 months statistical improvement was also achieved in a physical limitations (p=0,012) and social functioning (p=0,026). In TVT group, questionnaire performed after 3 months, reveal that statistical improvement was not achieved only in general health domain (p=0,224) and pain feeling (p=0,182). After 6 months from operation there were no changes in SF-36 questionnaires statistical analysis (p=0.328 and p=0,170 respectively for general health and pain feeling).

SF-36 Domain	Preoperative score (mean (SD))			Three months postoperative score (mean (SD))			Six months postoperative score (mean (SD))		
	TVT	TVT-O	p-value	TVT	TVT-O	p-value	TVT	TVT-O	p-value
Physical functioning	49,2 (19,6)	52,1 (27,8)	0,529	88,4 (14)	82,6 (25,1)	0,722	89,4 (18,4)	79,1 (26,8)	0,123
Physical limitations	47,2 (45,3)	58,8 (43,2)	0,488	87,5 (28,9)	79,4 (38,8)	0,487	94,4 (18,3)	92,6 (24,6)	0,929
Pain feeling	71,5 (27)	73,5 (29,5)	0,685	82,8 (21,6)	81,2 (27,9)	0,892	87,8 (25,7)	83,8 (26,3)	0,470
General health	60 (17,4)	61,6 (25,1)	0,466	67,1 (16,7)	69,7 (25,3)	0,368	70 (18,3)	68,4 (25,1)	0,850
Vitality	51,8 (14,1)	57,1 (25,1)	0,226	71,8 (13,5)	68,2 (27,3)	0,905	69,7 (14)	69,4 (29,3)	0,511
Social limitations	61,8 (20,8)	64 (34,5)	0,484	92,2 (11,1)	77,2 (27,7)	0,122	91 (16,5)	86 (25,3)	0,579
Emotional limitations	70,4 (39,4)	64,7 (44,8)	0, 854	93,8 (25)	74,5 (43,3)	0,096	92,6 (24,4)	88,2 (28,7)	0,587
Sanity	56,2 (18,9)	62,8 (27)	0,132	72 (16,9)	71,8 (26,1)	0,591	77,2 (14)	71,3 (26,5)	0,641
MCS	59,9 (17,4)	62,1 (29,7)	0,270	81,9 (11,8)	72,9 (28,4)	0,889	82,4 (13,7)	78,7 (25)	0,863
PCS	57 (17,3)	60,7 (26,1)	0,343	80,4 (15,5)	78,2 (26,5)	0,450	85,4 (16,8)	81 (23,8)	0,406

Table 3. – Peri- and postoperative complications (although cystoscopy was not used for TVT-O group, we have assumed that no bladder perforation occurred in TVT-O group, because we recorded no signs suggesting this complication (p=0,39 when comparing two groups)). There were no symptoms suggesting vaginal, bladder or urethral erosion. There were no bowel, nerves or major vessels injuries. To sum up, perforation of the bladder, urinary retention and hematoma appear to be bore often after TVT operation, but with no statistical difference between both groups.

	Perioperative complications			Postoperative complications after3 months			Postoperative complications after 6 months		
	TVT	TVT-O	p-value	TVT	TVT-O	p-value	TVT	TVT-O	p-value
Infection (other than urinary tract infection)	0(0%)	1(6%)	0,76	1(7%)	0(0%)	0,74	0(0%)	1(7%)	0,75
Bladder perforation	3(18%)	0(0%)	0,39	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Urinary retention	1(6%)	0(0%)	0,76	2(15%)	0(0%)	0,49	1(6%)	0(0%)	0,77
Hematoma	2(12%)	0(0%)	0,56	3(21%)	0(0%)	0,33	3(19%)	0(0%)	0,37
Pain	0(0%)	2(13%)	0,54	6(46%)	4(27%)	0,38	2(13%)	1(7%)	0,78
Bleeding	3(18%)	0(0%)	0,4	3(21%)	5(33%)	0,59	0(0%)	0(0%)	1

and procedure times were longer, which is related to results of others.[21]

Till today there is only one meta-analysis in literature, which compares TVT and TVT-O procedures.[10] For this analysis 15 RCTs that compared both procedures were included. When direct comparison was made, subjective and objective cure rate did not differ between both groups (OR 1.06, 95% CI 0,85-1.33 and for objective cure rate OR 1.03, 95% CI 0.77-1.39). When patients with only SUI were analyzed, subjective cure rate in 8 trials reached OR 1.03 (95% CI 0.81-1.31). The TVT-O had fever complications of bladder injury but more groin pain and de novo urgency than TVT. The primary outcome in most trials was 'cured' and this was measured and reported in various ways. Most, but not all studies reported on subjective cure rates and only some defined objective cure rate. Advantage of our study is that we analyzed both of them using appropriate methods (VAS for objective cure rate and pad or cough test for objective cure rate) to estimate effectiveness of each operative method.

There are some strengths and limitations of our study. Based on published data, our study is the first single blinded trial comparing TVT vs. TVT-O. The one study comparing surgical techniques in SUI treatment, TVT-O vs. TOTARIS[22] started as single blinded but ended because of an ethical issue. This is one of few trials so far that compares both subjective and objective effectiveness of TVT or TVT-O in surgical treatment of SUI.

Another advantage of our study is wide and very restrictive inclusion criteria, which also resulted in small number of patient in each group and is primary limitation of this study. A recently published randomized study, demonstrated that patients with severe SUI had significantly better outcome after TVT compared to TVT-O, suggesting that severity of SUI is an parameter that can influence the results of

sling operations.[23] Additionally, patients with previous surgery for SUI or pelvic reconstruction may carry a higher risk of postoperative urine retention or procedure failure, when they are treated with TVT or TVT-O procedure.[24] As mentioned before, in our trial, only pure-SUI patients, confirmed in urodynamic exam, were recruited. It was very important, because in one study it was found, that patients with SUI had a persistent cure rate of 85% from 2 to 8 years after TVT surgery, whereas the cure rate of patients with mixed urinary incontinence steadily declined to 30% from 4 to 8 years after surgery.[25]

Long-term follow up is required and is under way to ascertain long-term validity of our results. Adequate randomization, concealment and low patient withdrawal are also without fail strengths of this trail.

To conclude, this prospective randomized single blinded study shows no significant difference in the early and late operative complications, objective and patient-reported success rate between TVT and TVT-O procedures in SUI surgical treatment at 6 months follow up. On the other hand 18% of operating patients from TVT group had bladder perforation, even that it was not statistical different between both procedures, it makes a difference for a patient. Undoubtedly, TVT-O had shorter operation and procedure time for no need of routine cystoscopy.

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