Analysis of 1,000 cases of synthetic midurethral slings used for treatment of female urinary incontinence – a single-center experience

Dmitri Pushkar[1], George Kasyan[1], Michail Gvozdev[1], Roman Sosnowski[2]

[1]Department of Urology, Moscow State University of Medicine and Dentistry, Moscow, Russia
[2]Department of Urology M. Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland

KEY WORDS

TVT ◗ TVT-O ◗ tension-free tape ◗ stress urinary incontinence

ABSTRACT

Introduction. This study summarized our experience in the treatment of 1,081 women with stress urinary incontinence (SUI) using mid-urethral slings.

Material and methods. The study included 1,081 operated patients. Pure SUI was diagnosed in 77.80% (841) of the patients; another 18.68% (202) had mixed symptoms. The remaining 3.52% (38) suffered from recurrent SUI. Group 1 included the SUI patients treated with TVT. Group 2 – SUI managed with TVT-O. In Group 3, mixed urinary incontinent (MUI) patients were treated with TVT-O.

Results. Retropubic TVT was used in 273 patients (25.25%) and TVT-O in 740 (68.45%). Other slings were used in 68 patients (6.3%). Mean follow-up for the groups was 50.1, 31.1, and 32.6 months respectively. For objective evaluation of cure rate we used the cough stress test. Subjective efficacy was studied via a visual analog scale. The complication rate in each group of the patients was used as a secondary end point. A negative cough test was found in 85.58% of patients in Group 1. For the TVT-O group, the objective cure rate was 84.36%. Intra-operative complications for TVT and TVT-O were not related to age, BMI, or parity. Bladder perforation and pelvic hematoma developed more frequently in the TVT group. There is a higher risk of vaginal perforation for TVT-O. The objective and subjective cure rates for MUI patients were 86.15% and 87.69% respectively.

Conclusions. TVT and TVT-O are equally effective and safe methods of treatment for women suffering from SUI and MUI.

INTRODUCTION

Surgical treatment for stress urinary incontinence (SUI) rapidly evolved during the last decades. In 1993, DeLancy first suggested that a suburethral fascial defect might be responsible for female urinary incontinence [1]. Soon after that, Ulmsten and colleagues introduced the retropubic tension-free vaginal tape (TVT) procedure for treatment of female SUI. In 2001, Delorme proposed a new technique, the TOT procedure, in which the tape is passed through the obturator foramina. De Leval modified this approach by inserting the tape the "inside-out" way, known as the TVT-O procedure [2, 3, 4].

At present, the retropubic TVT procedure is accepted worldwide as a standard surgery for women suffering SUI. The transobturator approach, however, has become more popular these days due to a similar cure rate with relatively less complications [5, 6]. However, most of the studies have a limited number of patients and follow-up periods [7]. The treatment of the patients with mixed urinary incontinence (MUI) remains a challenge for specialists. There are more controversial opinions on this issue.

This study summarized our experience with the treatment of 1,081 patients with tension-free tapes. We aimed to evaluate and compare the efficacy and safety of retropubic and transobturator tapes for the management of female SUI. Long-term comparative data was researched and collected for these patients. Additionally, we analyzed our results of the surgical treatment of patients suffering from MUI with prevalence of the stress component.

MATERIALS AND METHODS

Patients

From 2001 to 2008, 1,081 women with SUI were operated in the Urology Department of MSMSU.

Their detailed history was taken and physical exam performed together with a urine culture, cough stress test, and Bonney test before surgery. Pure SUI was diagnosed in 77.80% (841) of the patients; another 18.68% (202 patients) presented urinary incontinence with mixed symptoms and the remaining 3.52% (38) suffered from recurrent SUI and had a history of at least one unsuccessful attempt with surgical treatment.

The treatment option was chosen for the patients according to the routine method used in our department at the time when the patients were admitted and treated. Retropubic TVT (Gynecare) procedures were used in 273 patients (25.25%). In 740 cases, transobtorator TVT-O (Gynecare) tapes were utilized for the treatment of SUI (68.45%). Other patients were operated with transobturator MONARC (28 pts, 2.59%) or Obtape (40, 3.70%) slings (Fig. 1).

Inclusion and exclusion criteria for study groups

In order to fulfill the study's goals we implemented restriction criteria for comparable group formation. Group 1 included the patients with pure SUI treated with retropubic TVT (Gynecare). Exclusion criteria were MUI and recurrent SUI. Group 2 included primary patients suffering from SUI who were operated with TVT-O (Gynecare). The patients with MUI who were treated with transobturator tape were assigned to Group 3. The number of patients with MUI operated with retropubic TVT was not enough (38 women) for proper statistical analysis, which is why they were not included in the study. The principles of the Groups' formation and patients' flow are presented in Figure 2.

Table 1. Characteristics of patients in Groups 1 and 2

	Group 1 (TVT) n = 207	Group 2 (TVT-O) n = 570	Test	p-value
Age (years)	54.14 ±9.31	55.33 ±8.97	t-test	0.105
BMI	25.33 ±2.89	26.51 ±4.42	t-test var. est.	0.000
Parity 0/1/2/3 %	28/102/58/19 13.52/49.28/28.02/9.18	69/289/157/55 12.11/50.70/27.54/9.65	χ^2-test	0.949
Pregnancy <4/4/5/>5 %	58/31/52/66 28.02/14.98/25.12/31.88	175/79/134/182 30.70/13.86/23.51/31.93	χ^2-test	0.882
Post-menopause % no/yes	64/143 30.92/69.08	141/429 24.74/75.26	Yates corrected χ^2-test	0.102

Table 2. Objective and subjective cure rates for retropubic and transobturator slings within one month after surgery

	Group 1 (TVT)	Group 2 (TVT-O)	Test	p-value
Objective cure rate				
	N = 187	N = 531		
Cough test negative/positive %	162/25 86.63/13.37	455/76 85.69/14.31	Yates corrected χ^2-test	0.844
Subjective cure rate				
	N = 166 (88.8% of pts completed VAS)	N = 488 (91.9% of pts completed VAS)		
Not satisfied with surgery %	11/155 6.63/93.37	31/457 6.35/93.65	Yates corrected χ^2-test	0.953
Satisfied %	64/102 38.55/61.45	189/299 38.73/61.27	Yates corrected χ^2-test	0.958
Very satisfied %	91/75 54.82/45.18	268/220 54.92/45.08	Yates corrected χ^2-test	0.946

Study end points

For objective evaluation of treatment efficacy we used the cough stress test. The subjective efficacy rate was evaluated by patients' satisfaction with surgery, which was expressed via a visual analog scale (VAS). The complication rate in each group of the patients was used as a secondary end point in this study.

Surgical techniques

The TVT procedures were carried out as originally described by Ulmsten [2]. The inside-out transobturator surgical technique (TVT-O) was used as first described by de Leval [4]. The procedures were performed by five surgeons with different levels of experience in vaginal surgery. Most of the procedures were carried out under spinal anesthesia (987/1081, 91.3%). Anterior and posterior colporrhaphy and vaginal hysterectomy were performed simultaneously

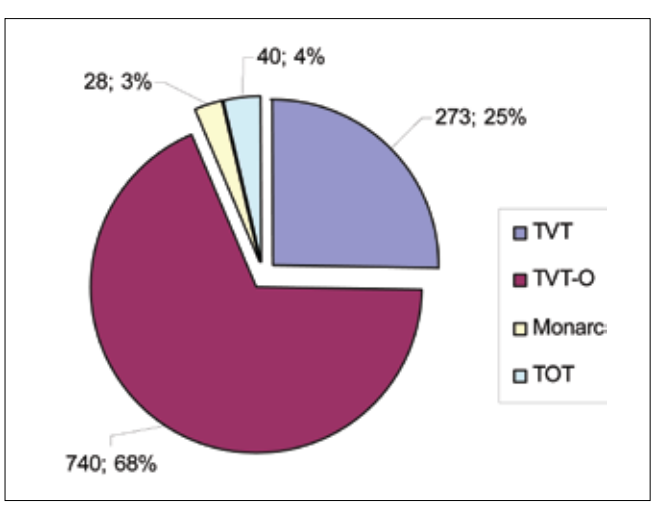

Fig. 1. Distribution of tapes among the patients.

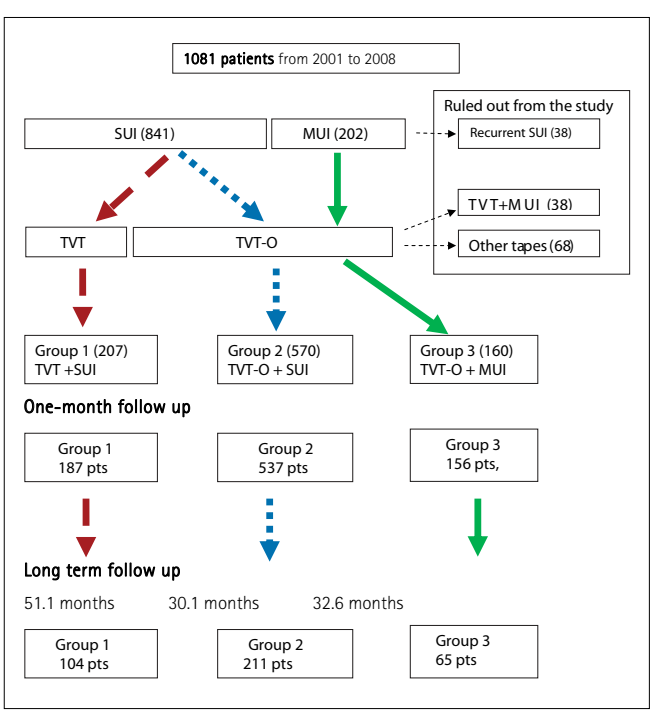

Fig. 2. Group formation and patients' flow through the study.

Table 3. Evaluation of efficacy among the patients available for both short- and long-term follow-up

	Group 1 (TVT) N = 104	Group 2 (TVT-O) N = 211	Test	p-value
Short-term follow-up (one month)				
Cough test negative/positive %	89/15 85.58/14.42	203/8 96.21/3.79	Fisher exact test, two-tailed	0.002
Not satisfied with surgery %	9/95 8.69/91.31	28/183 13.27/86.73	Fisher exact test, two-tailed	1.000
Satisfied %	41/63 39.42/60.58	77/134 36.49/63.51	Fisher exact test, two-tailed	0.623
Very satisfied %	54/50 51.92/48.08	106/105 50.24/49.76	Fisher exact test, two-tailed	0.811
Long-term follow-up				
Mean follow-up time	51.1 ±7.6 months	30.1 ±3.0 months		
Cough test negative/positive %	89/15 85.58/14.42	178/33 84.36/15.64	Fisher exact test, two-tailed	0.868
Not satisfied with surgery %	7/94 6.73/93.27	30/181 14.22/85.78	Fisher exact test, two-tailed	0.091
Satisfied %	52/52 50.00/50.00	85/126 40.28/59.72	Fisher exact test, two-tailed	0.117
Very satisfied %	45/59 43.27/56.73	96/115 45.50/54.50	Fisher exact test, two-tailed	0.720

Table 4. Intra- and postoperative complications after TVT and TVT-O

	Group 1 (TVT) N = 187	Group 2 (TVT-O) N = 537	Test	p-value
Hematoma	17/170	8/529	Yates corrected χ^2-test	0.000
%	9.09	1.48		
Post-void residual urine >100 cc	11/176	16/521	Yates corrected χ^2-test	0.114
%	5.88	2.98		
Bladder trauma	10/177	3/534	Yates corrected χ^2-test	0.000
%	5.35	0.56		
Vaginal laceration	0/187	15/522	Yates corrected χ^2-test	0.044
%	0.00	3.79		
Tape extrusion	1/186	8/529	Yates corrected χ^2-test	0.420
%	0.53	1.489		
***De novo* OAB**	15/172	26/511	Yates corrected χ^2-test	0.151
%	8.02	4.84		
***De novo* urge incontinence**	4/183	8/529	Yates corrected χ^2-test	0.790
%	2.14	1.49		
Recurrence	16/171	33/504	Yates corrected χ^2-test	0.336
%	8.56	6.15		
Tape section	4/183	3/534	Yates corrected χ^2-test	0.142
%	2.14	0.56		
Postoperative pain	4/183	11/526	Yates corrected χ^2-test	0.823

Table 5.1. Characteristics of patients and complication rate in Group 1

	Intraoperative complications (n = 31)	No complications (n = 176)	Test	p-value
Age	53.35 ±9.02	54.27 ±9.38	t-test	0.614
BMI	26.23 ±4.67	25.18 ±2.41	t-test var. est	0.238
Parity number (patients' number, %)				
0, yes/no %	4/27 12.90/87.10	24/152 13.64/86.36	Fisher exact test, two-tailed	1.000
1, yes/no %	18/13 58.06/41.94	84/92 47.73/52.27	Fisher exact test, two-tailed	0.333
2, yes/no %	5/26 16.13/83.87	53/123 30.11/69.89	Fisher exact test, two-tailed	0.132
≥3 yes/no %	4/27 12.90/87.10	15/161 8.52/91.48	Fisher exact test, two-tailed	0.497

Table 5.2. Characteristics of patients and complication rate in Group 2

	Intraoperative complications (n = 83)	No complications (n = 487)	Test	p-value
Age	54.60 ±8.69	55.45 ±9.02	t-test	0.425
BMI	26.60 ±3.95	26.49 ±4.50	t-test var. est	0.838
Parity number (patient number, %)				
0 yes/no %	13/70 15.66/84.34	56/431 11.50/88.50	Yates corrected χ^2-test	0.372
1 yes/no %	36/47 43.37/56.63	253/234 51.95/48.05	Yates corrected χ^2-test	0.185
2 yes/no %	23/60 27.71/72.29	134/353 27.52/72.48	Yates corrected χ^2-test	0.924
≥3 yes/no %	11/72 13.25/86.75	44/443 9.03/90.97	Yates corrected χ^2-test	0.316

if indicated in symptomatic women with pelvic organ prolapsed, which included 11.19% (121/1081) of patients.

Measurements and follow up visits

Data about the type of sling procedure, associated surgery, and intra- and postoperative complications were collected. Intraoperative and postoperative complications were searched for. In case of urgencies, urinary tract infections were ruled out by urine culture test.

All patients were routinely invited for clinical examination within one month after surgery by the operating surgeon. Beginning in June of 2008, the studied patients were contacted again via post mail or phone call and they were invited for additional follow-up visits at their convenience. During both follow-up visits, patients underwent physical and vaginal examination with consequent cough stress test, uroflowmetry, and post-void residual urine. The patients were asked to express their satisfaction with anti-incontinence surgery via the VAS. Five degrees of VAS were utilized (1 – very unsatisfied, 2 – unsatisfied, 3 – satisfied, 4 – very satisfied, and 5 – excellent). For statistical analysis these data were grouped in three categories: unsatisfied (1-2), satisfied with surgery (marked 3), and very satisfied (4-5).

Statistical analysis

In order to compare the safety and effectiveness of transobturator and retropubic tension-free tapes for the treatment of SUI in female patients it is necessary to determine minimal sample size for proper statistical analysis.

The success rate of 90% for tension-free tape was used. It was decided that a 20% difference in the success rate between TVT versus TVT-O would be clinically significant. Therefore, to detect a 20% difference with an alpha value of 0.05 and power of 80%, at least 72 subjects were required in each group. Student's t test was used for continuous variables. Chi-square and Fisher exact tests were applied for proportions to compare results.

RESULTS

Anthropometric data of patients included in Groups 1 and 2 are shown in Table 1. There were no significant differences in patient characteristics such as age, menopause, parity, and number of pregnancies between the two groups (Table 1). Body mass index for patients in Group 2 was significantly higher than in Group 1 ($p = 0.000019$).

Comparison of retropubic (TVT) and transobturator (TVT-O) approaches for management of female SUI. Objective and subjective cure rates at 1 month after surgery

Within one month after surgery, the cough test results were available for 187 patients of the 207 (90.33%) in Group 1. In Group 2, within one month after surgery, 531 women visited the clinic for follow-up and passed the cough test (93.15%). Table 2 presents the comparative data for Groups 1 and 2. There was no significant difference in satisfaction with surgery rate for patients treated with retropubic or transobturator tapes ($p < 0.000$). The vast majority of

Table 6. Predictive value of cough test

	Negative cough test – more than 12-months after surgery	Positive cough – more than 12 months-after surgery	p-value for Fisher exact test, two-tailed
Negative cough test within 1 month after surgery	318 pts (90.86%)	32 pts (9.14%)	0.000
Positive cough test within 1 month after surgery	4 pts (14.81%)	23 pts (85.19%)	

Table 7. Patients' comparative characteristics of Groups 2 and 3

	Group 2 n = 570	Group 3 n = 160	Test	p-value
Age (years)	55.33 ±8.97	54.91 ±8.52	t-test	0.594
BMI	26.51 ±4.42	27.05 ±4.60	t-test	0.177
Parity 0/1/2/3 %	69/289/157/55 12.11/50.70/27.54/9.65	35/77/38/10 21.88/48.13/23.75/6.23	χ^2-test	0.013
Pregnancy <4/4/5/>5 %	175/79/134/182 30.70/13.86/23.51/31.93	42/40/31/47 26.25/25.00/19.38/29.38	χ^2-test	0.009
Post-menopause no/yes %	141/429 24.74/75.26	50/110 31.25/68.75	Yates corrected χ^2-test	0.120

the patients in both groups were satisfied or very satisfied with surgery.

Objective and subjective cure rates at long term follow-up

Mean follow-up time in Group 1 and 2 was 51.1 ±7.6 months and 30.1 ±3.0 months. For analysis of long-term follow-up (at least 12 months) we chose patients who previously underwent early follow-up visits. For correct application of statistical methods it was decided to take into account the patients for whom both cough test and VAS results were available. It finally summarized into 104 patients from Group 1 (50.24%) and 211 (37.01%) from Group 2. Additionally, a significant decrease in the number of patients from Group 2 was due to the fact that some of these patients had a follow-up time of less than 12 months. In Table 3 we presented early and long-term results among these patients.

Although early cough test results showed dominance of the TVT-O sling, longer follow-up revealed no significant difference in both objective and subjective cure rates (Table 3). A negative cough test in TVT patients was found in 85.58% of patients (89/104). The same parameter for TVT-O patients was 84.36% (178/211). Only 8.69% of patients of Group 1 and 13.27% in Group 2 were not satisfied with surgery (p = 0.091).

Complication rate in Group 1 and 2

The complications are reported in Table 4. Bladder injuries occurred more often when the retropubic technique was used (5.35% *vs.* 0.56%, p = 0.000). All bladder perforations were confirmed by cystoscopy and managed conservatively. Besides that, vaginal wall lacerations arose more often when transobturator tape was inserted (0% *vs.* 3.79%, p = 0.044). Other complication rates were similar for TVT and TVT-O procedures.

Characteristics of patients and complication rate

We hypothesized that the complication rate in both groups might be related to age of the patients, their BMI, or obstetric history. For that purpose we have compared subsequent data of patients who developed intra-operative and early postoperative complications in Groups 1 and 2 with those patients who did not. The data are presented in Tables 5.1 and 5.2.

The intraoperative complication rate for both retropubic and transobturator tension-free vaginal tapes was not related to patients age, BMI, or parity. Although patients in Group 2 (TVT-O) had a higher BMI; statistical analysis among this group showed that there is no statistically significant difference on BMI for patients who developed intraoperative complications and those who did not (p = 0.838).

Predictive value of cough test performed within one month after surgery

The cough stress test is the one of the most widely used tools for subjective evaluation of efficacy of anti-incontinence surgery. However, there is still no consensus on the minimum follow-up period for which this test might be valid.

The cough test results of patients at short- and long-term follow-ups were compared. Respectively, the data of 377 women operated with TVT or TVT-O, and with at least 12-months follow-up, were analyzed.

We found that 90.86% of patients who had a negative cough test in the first month after surgery remained dry on the cough test during their long-term follow-up. Our study also showed that 85.19% of the patients who leaked urine during the cough test in the first month after surgery still had a positive cough long after the surgery. Only 14.81% of women with initially unsuccessful cough test results showed improvement later on (see Table 6). Statistical analysis proved that the results of the one-month cough test for female patients treated with tension-free tape might remain the same for a long while with high probability (p = 0.000).

Treatment of mixed urinary incontinence: Group 2 *vs.* Group 3

Patients' characteristics

We aimed to evaluate to efficacy of synthetic slings on patients with MUI. One hundred and sixty patients suffering from MUI with a dominant stress component were treated with the TVT-O procedure and were included in Group 3. Mean age of the patients was 54.91 ±8.52 years. The average BMI was 27.05. Most of the patients were post-menopausal (68.75%). For this part of the study we used Group 2 patients (SUI managed with TVT-O) as a control group. Patient characteristics are presented in Table 7.

Table 8.1. Intraoperative complications after TVT-O among patients with SUI (Group 2) and MUI (Group 3)

	Group 2 n = 570	Group 3 n = 160	Test	p-value
No complication/ Intraoperative no/yes %	487/83 85.44/14.56	138/22 86.25/13.75	Yates corrected 2-test	0.896
Hematoma %	19/551 3.33/96.67	4/156 2.50/97.50	Yates corrected 2-test	0.782
Post-void residual urine >100 cc %	16/554 2.81/97.19	5/155 3.13/96.87	Yates corrected 2-test	0.956
Bladder injury %	3/567 0.53/99.47	0/160 0.00/100.00	Yates corrected 2-test	0.826
Vaginal injury %	17/553 2.98/97.02	3/157 1.88/98.12	Yates corrected 2-test	0.628
Urethral injury %	0/570 0/100.00	1/159 0.63/99.37	Yates corrected 2-test	0.497
Postoperative pain %	28/542 4.91/95.09	9/151 5.63/94.37	Yates corrected 2-test	0.874

Table 8.2. Postoperative complications after TVT-O among patients with SUI (Group 2) and MUI (Group 3)

Postoperative complications	n = 537	n = 156	Test	p-value
0 no/yes %	454/83 84.54/15.46	133/23 85.26/14.74	Yates corrected χ^2-test	0.927
De novo OAB yes/no %	26/511 4.84/95.16	5/151 3.21/96.79	Yates corrected χ^2-test	0.515
De novo urge incontinence yes/no %	8/529 1.49/98.51	1/155 0.64/99.36	Yates corrected χ^2-test	0.673
Recurrence of incontinence yes/no %	33/504 6.15/93.85	13/143 8.33/91.67	Yates corrected χ^2-test	0.433
Tape extrusion yes/no %	2/535 0.37/99.63	0/23 0.00/100.00	Yates corrected χ^2-test	0.136
Sling incision yes/no %	3/534 0.56/99.44	0/23 0.00/100.00	Yates corrected χ^2-test	0.272
Postoperative pain yes/no %	11/526 2.05/97.95	4/152 2.56/97.44	Yates corrected χ^2-test	0.939

Efficacy and complication rate in Group 2 and 3

A negative cough test in MUI patients was found in 91.56% of patients (141/154). In SUI group it was 85.69% (455/531). Only 7.91% patients suffering MUI were not satisfied with surgery. There were no statistically significant differences in objective and subjective cure rates on short- and long-term follow-ups (Tables 9.1 & 9.2). The rate of surgical complications immediately after surgery and during the following 30 days was similar in Groups 2 and 3 (Tables 8.1 & 8.2).

DISCUSSION

Efficacy

TVTs are known to be very effective procedures for management of female SUI. Comparative studies including randomized control trials (RCTs), evaluating the efficacy of retropubic and transobturator tapes showed similar cure rates [21]. Latte et al. assessed 11 RCTs including 1,261 women for effectiveness and complications of retropubic *vs.* transobturator tapes [7]. The author found similar cure rates for both approaches. Another meta-analysis for mid-urethral slings published by Novara et al. was in accordance with that [8].

The long-term success rates for transobturator tapes were showing a cure rate of 88.4% and an improvement in 9.3% of the patients [9]. The transobturator tape therefore appears to be equivalent to retropubic TVT at short- and midterm follow-up [8]. Presently the longest 11-year data was published by Nilsson [10]. According to his work there is no notable decrease in cure rate of the TVT procedure over eleven years with an efficacy of 90.2%.

Comparative analysis of our study revealed no statistically significant difference for both objective and subjective cure rates in TVT and TVT-O groups. Our data were collected for the patients with mean 51.1 months follow-up after TVT. At this stage our patients showed a 85.58% objective cure and a 93.27% "satisfaction with surgery" rate. As for TVT-O, the average follow-up was 31.1 months and the cure rate reached 84.36% and 85.78% respectively.

Objective cure rate and cough test

Pad test and stress cough test are two of the most widely used tools for evaluation of treatment objective outcome [8]. Both of these methods have limitations in the matter of standardization. The stress cough test is widely accepted by physicians because of decreased time consumption when compared to the 24-hour pad-test, and because it might be a part of routine physical examination on follow up visits. Although coughing efforts of the patients are difficult to standardize, many authors used the cough test in randomized comparative studies

Table 9.1. Objective and subjective cure rates in Groups 2 and 3 within 1 month follow-up

Evaluation of efficacy	Group 2 N = 531	Group 3 N = 154	Test	p-value
Early follow up (1 month)				
Cough test negative No/yes %	455/76 85.69/14.31	141/13 91.56/8.44	Yates corrected χ^2-test	0.076
	N = 488 (available patients)	N= 139 (available patients)		
Not satisfied with surgery %	31/457 6.35/93.65	11/128 7.91/92.09	Yates corrected χ^2-test	0.648
Satisfied	189/299 38.73/61.27	45/94 32.37/67.63	Yates corrected χ^2-test	0.205
Very satisfied	268/220 54.92/45.08	83/56 59.71/40.29	Yates corrected χ^2-test	0.364

Table 9.2. Objective and subjective cure rates among the patients of Groups 2 and 3 available for both short term and long term follow up

Evaluation of efficacy	Group 2 N = 211	Group 3 N = 65	Test	p-value
Early follow-up (1 month)				
Cough test negative No/yes %	203/8 96.21/3.79	64/1 98.46/1.54	Fisher exact test, two-tailed	0.690
Not satisfied with surgery %	28/283 13.27/86.73	10/55 15.38/84.62	Fisher exact test, two-tailed	0.171
Satisfied %	77/134 36.49/63.51	16/49 24.62/75.38	Fisher exact test, two-tailed	0.098
Very satisfied %	106/105 50.24/49.76	39/26 60.00/40.00	Fisher exact test, two-tailed	
Long-term follow-up				
Mean follow-up time	30.1 ±3.0 months	32.6 ±8.6 months		
Cough test negative No/yes %	178/33 84.36/15.64	56/9 86.15/13.85	Fisher exact test, two-tailed	0.845
Not satisfied with surgery %	30/181 14.22/85.78	8/57 12.31/87.69	Fisher exact test, two-tailed	0.838
Satisfied %	85/126 40.28/59.72	22/43 33.85/66.15	Fisher exact test, two-tailed	0.385
Very satisfied %	96/115 45.50/54.50	35/30 53.85/46.15	Fisher exact test, two-tailed	0.258

of retropubic and transobturator tapes [11]. According to our statistical conclusions, the results of the cough test performed after one month will predict the long-term outcome with high probability (90.86%).

Subjective cure rate

There are several options for the evaluation of subjective outcome rate after treatment for SUI. Some authors used Urinary Distress Inventory [12,13] or other questionnaire such as I-QOL (Incontinence Quality of Life) [14]. Laurikainen et al. proved the visual analog scale (VAS) as an effective method for evaluating the subjective cure rate [15]. In our study we used VAS to study the satisfaction of the patients with anti-incontinence surgery.

The results of our study revealed that the patients satisfaction with surgery rate remains at a higher level and stays constant in time.

Intraoperative and postoperative complications

A recent review revealed the total reported complication rates ranging from 4.3% to 75.1% for TVT and from 10.5% to 31.3% for TVT-O [16]. Serious complications such as bowel injury, major vascular injury, and death can occur with the TVT [17].

Bladder perforations and hematomas

There is a statistically significant increased risk of bladder perforations and hematomas with TVT inserted via the retropubic route. In our study, hematoma was encountered in 9.09% (TVT) and 1.48% (TVT-O) of cases. The TVT-O scores heavily over the TVT in avoiding bladder perforations (0.56% *vs.* 5.35%, respectively).

Various multicenter RCT's [17,18] and systematic reviews [7, 19] show similar results [20, 21, 22]. A systematic review of Novara found that the occurrence of bladder perforations and pelvic hematoma were significantly less common in the patients treated by TVT-O [20]. Another review found that the odds for bladder injury (OR 0.13; 95% CI 0.06-0.27) were less for all transobturator tapes [7].

Vaginal wall lacerations and pain

Vaginal injuries, thigh and groin pain occur more frequently with the transobturator approach because of the passage of tape beneath

the pubic bone and an exit in the groin. According to Meschia, groin pain resolved in most cases within one month after surgery [12]. Other authors found no significant difference related to either technique [19]. We did not find any difference in postoperative pain rate related to surgical approach. Indeed there is a significantly higher risk of vaginal perforation, mostly on the lateral fornix, when the transobturator sling is inserted (0.00% *vs.* 3.79%, p = 0.044).

Tape extrusion

Tape extrusions usually occur in the early post-operative period. Unrecognized vaginal perforations or lacerations occurring during transobturator tape insertion may lead to subsequent extrusion. Although, the occurrence of vaginal wall injury during TVT-O was found to be very low, the transobturator route predisposes to a higher rate of vaginal lacerations when compared with the retropubic route, which is possibly the reason for the slightly higher rate of mesh extrusion with this approach. It is necessary to note that vaginal wall erosions over the tapes are relatively benign and may often be managed with the application of local estrogens.

Obstructive symptoms

The voiding dysfunction is expectedly higher in the TVT group as the sling might be more obstructive when compared to the TVT-O, which has less obstructive hammock effect. Residual urine volume more than 100 mL on the second day after surgery occurred in 5.88% of patients in the TVT group and 2.98% (p = 0.114) of patients in the TVT-O group, which is consistent with other reports [11].

De novo urgency symptoms

The results of our study reported that *de novo* urgency incontinence and *de novo* overactive bladder were found in 2.14% and 8.02 % in the TVT group and in 1.49% and 4.84% in the TVT-O group, respectively. It has been proposed that the prevalence of symptoms with voiding dysfunction after tape procedures is reduced with time.

BMI and complication rate

Increased BMI is a well-known factor for the development of SUI in females. One may suppose that overweight patients are not ideal candidates for minimally invasive surgery causing a higher intra operative complication rate. In our study the patients in Group 2 (TVT-O) had a higher BMI; statistical analysis among this group showed that there is no statistically significant difference in BMI for patients who developed intra operative complications and those who did not.

CONCLUSION

In summary of our study the following conclusions could be stated:

- TVT *vs.* TVT-O: short-term results
  - 85.58% of the patients operated with TVT have had negative cough test within one month after surgery. Among the patients operated with TVT-O the negative cough test rate reached 96.21%. This difference was statistically significant (p = 0.002), but disappeared on long-term follow-up.
  - Within one month after surgery 91.31% of patients managed with TVT were satisfied or very satisfied with anti-incontinence treatment. Similar result for TVT-O group reached 86.73% (p = 1.0).
- TVT *vs.* TVT-O: long-term results
  - After 51.1 ±7.6 months follow up negative cough test was found in 85.58% of TVT patients.
  - Within 30.1 ±3.0 months follow up for TVT-O group objective cure rated measured as negative cough test was 84.36%.
  - Comparative analysis showed no significant difference in objective cure rate for TVT and TVT-O (p = 0.868).
  - 93.27% and 85.78% of patients respectively were satisfied either very satisfied with results of treatment. Although more patients were satisfied with TVT procedure, this difference was not statistically significant (p = 0.091).
  - Intra-operative complication rate for both retropubic and transobturator slings was not related to patients' age, BMI, or parity.
  - While patients in Group 2 (TVT-O) had higher BMI, statistical analysis among this group showed that there is no significant difference in BMI for patients who developed intraoperative complications and those who did not.
  - Bladder perforation and pelvic hematoma developed more frequently when the retropubic approach was used.
  - Transobturator tension-free tape implication was associated with higher occurrence of vaginal wall injuries.
  - The results of one-month cough test may be a reliable prognostic factor and may remain the same long while with high probability (p = 0.000).
  - Mixed urinary incontinence with predominance of the stress component may be treated with TVT-O. The objective and subjective cure rates within 32.6 ±8.6 months were 86.15% and 87.69% respectively, which is comparable to results of patients with SUI treated with similar sling.

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Correspondence
Dmitry Y. Pushkar
Department of Urology of MSMSU
21, Vucheticha Street
127206 Moscow, Russia
phone: +7 095 611 31 29
pushkar@co.ru