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

Dmitri Pushkar1, George Kasyan1, Michail Gvozdev1, Roman Sosnowski2

1Department of Urology, Moscow State University of Medicine and Dentistry, Moscow, Russia
2Department 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 incontinence (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, transobturator 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.
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.

Table 1. Characteristics of patients in Groups 1 and 2

|                      | Group 1 (TVT) | Group 2 (TVT-O) | 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 | 60/289/157/55   | χ²-test    | 0.949   |
| Pregnancy <4/4/5/>5 %| 85.69/13.37  | 85.69/14.31     | χ²-test    | 0.882   |
| Post-menopause % no/yes | 64/143 | 141/429 | Yates corrected | χ²-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 % | 86.63/13.37 | 85.69/14.31     | Yates corrected | χ²-test | 0.844 |
| Subjective cure rate | N = 166 (88.8% of pts completed VAS) | N = 488 (91.9% of pts completed VAS) | Yates corrected | χ²-test | 0.953 |
| Not satisfied with surgery % | 63.63/36.37 | 63.5/36.45      | Yates corrected | χ²-test | 0.958 |
| Satisfied %          | 64/102       | 189/299         | Yates corrected | χ²-test | 0.946 |
| Very satisfied %     | 91/76        | 268/220         | Yates corrected | χ²-test |         |

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.

Table 1. Characteristics of patients in Groups 1 and 2

|                      | Group 1 (TVT) | Group 2 (TVT-O) | 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 | 60/289/157/55   | χ²-test    | 0.949   |
| Pregnancy <4/4/5/>5 %| 85.69/13.37  | 85.69/14.31     | χ²-test    | 0.882   |
| Post-menopause % no/yes | 64/143 | 141/429 | Yates corrected | χ²-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 % | 86.63/13.37 | 85.69/14.31     | Yates corrected | χ²-test | 0.844 |
| Subjective cure rate | N = 166 (88.8% of pts completed VAS) | N = 488 (91.9% of pts completed VAS) | Yates corrected | χ²-test | 0.953 |
| Not satisfied with surgery % | 63.63/36.37 | 63.5/36.45      | Yates corrected | χ²-test | 0.958 |
| Satisfied %          | 64/102       | 189/299         | Yates corrected | χ²-test | 0.946 |
| Very satisfied %     | 91/76        | 268/220         | Yates corrected | χ²-test |         |
Table 3. Evaluation of efficacy among the patients available for both short- and long-term follow-up

|                          | Group 1 (TVT) | Group 2 (TVT-O) | 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 % | 9/85 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 | Fisher exact test, two-tailed | 0.868   |
| Cough test negative/positive % | 89/15 85.58/14.42 | 178/33 84.36/15.64 | Fisher exact test, two-tailed | 0.117   |
| Not satisfied with surgery % | 7/84 6.73/93.27  | 30/181 14.22/85.78 | Fisher exact test, two-tailed | 0.117   |
| 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) | Group 2 (TVT-O) | Test                      | p-value |
|--------------------------|---------------|-----------------|---------------------------|---------|
| **Hematoma**             |               |                 | Yates corrected χ²-test   | 0.000   |
| %                       | 17/170 9.09     | 8/529 1.48      |                           |         |
| Post-void residual urine >100 cc |   |                 | Yates corrected χ²-test   | 0.114   |
| %                       | 11/176 5.88    | 16/521 2.98     |                           |         |
| Bladder trauma           |               |                 | Yates corrected χ²-test   | 0.000   |
| %                       | 10/177 5.35    | 3/534 0.56      |                           |         |
| Vaginal laceration       |               |                 | Yates corrected χ²-test   | 0.044   |
| %                       | 0/187 0.00     | 15/522 3.79     |                           |         |
| Tape extrusion           |               |                 | Yates corrected χ²-test   | 0.420   |
| %                       | 1/186 0.53     | 8/529 1.489    |                           |         |
| De novo OAB             |               |                 | Yates corrected χ²-test   | 0.151   |
| %                       | 15/172 8.02    | 26/511 4.84     |                           |         |
| De novo urge incontinence|               |                 | Yates corrected χ²-test   | 0.790   |
| %                       | 4/183 2.14     | 8/529 1.49     |                           |         |
| Recurrence               |               |                 | Yates corrected χ²-test   | 0.336   |
| %                       | 16/171 8.56    | 33/504 6.15     |                           |         |
| Tape section             |               |                 | Yates corrected χ²-test   | 0.142   |
| %                       | 4/183 2.14     | 3/534 0.56     |                           |         |
| Postoperative pain       |               |                 | Yates corrected χ²-test   | 0.823   |
| %                       | 4/183 2.14     | 11/526 0.58    |                           |         |
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
Characteristics of patients and complication rate

The data are presented in Tables 5.1 and 5.2. The complications are reported in Table 4. Bladder injuries occurred more often when the retropubic technique was used (5.35% vs. 5.56%, 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.

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. 5.56%, 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

Table 6. Predictive value of cough test

| Negative cough test within 1 month after surgery | Positive cough – more than 12 months after surgery | p-value for Fisher exact test, two-tailed |
|-----------------------------------------------|-----------------------------------------------|------------------------------------------|
| 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

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. 5.56%, 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.
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. These 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 was similar in Groups 2 and 3 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 84.30% 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.
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

---

**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 |
|------------------------|----------------|----------------|------|--------|
| Cough test negative | 455/76         | 141/13         | Yates corrected χ²-test | 0.076 |
| N = 488 (available patients) | 85.69/14.31 | 91.56/8.44 |
| Not satisfied with surgery | 31/457         | 11/128         | Yates corrected χ²-test | 0.648 |
| % | 6.35/93.65 | 7.91/92.09 |
| Satisfied | 189/299         | 45/94          | Yates corrected χ²-test | 0.205 |
| % | 38.73/61.27 | 32.37/67.63 |
| Very satisfied | 268/220 | 83/56 | Yates corrected χ²-test | 0.364 |
| % | 54.92/45.08 | 59.71/40.29 |

**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 |
|------------------------|----------------|----------------|------|--------|
| Cough test negative | 203/8         | 64/1           | Fisher exact test, two-tailed | 0.690 |
| N = 201 (available patients) | 96.21/3.79 | 98.46/1.54 |
| Not satisfied with surgery | 28/283         | 10/55          | Fisher exact test, two-tailed | 0.171 |
| % | 13.77/86.23 | 15.38/84.62 |
| Satisfied | 77/134         | 16/49          | Fisher exact test, two-tailed | 0.098 |
| % | 36.49/63.51 | 24.62/75.38 |
| Very satisfied | 106/105        | 39/26          | Fisher exact test, two-tailed | 0.258 |
| % | 50.24/49.76 | 60.00/40.00 |

| Mean follow-up time | 30.1 ±3.0 months | 32.6 ±8.6 months | Fisher exact test, two-tailed | 0.845 |
| Cough test negative | 178/33 | 56/9 | 86.15/13.85 | 0.838 |
| % | 84.36/15.64 | 86.15/13.85 |
| Not satisfied with surgery | 30/181 | 8/57 | Fisher exact test, two-tailed | 0.385 |
| % | 14.22/85.78 | 12.31/87.69 |
| Satisfied | 85/126 | 22/43 | Fisher exact test, two-tailed | 0.258 |
| % | 40.28/59.72 | 33.85/66.15 |
| Very satisfied | 96/115 | 35/30 | Fisher exact test, two-tailed | 0.136 |
| % | 45.50/54.50 | 53.85/46.15 |
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 (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 frequently when the retropubic approach was used.

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 intraoperative 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 = 0.000), 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.

REFERENCES
1. DeLancey J: Anatomy and biomechanics of genital prolapse. Clin Obstet Gynecol 1993; 36:897-909.
2. Ulmsten U, Henriksson L, Johnson P, Varhos G: An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996; 7:81-86.
3. Delorme E: La bandelette trans-obturatrice: un procedé miniinvasif de traitement de l’incontinence urinaire de la femme. Prog Urol 2001; 11:656-659.
4. De Leval J: Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur Urol 2003; 44 (6):724-730.
5. Sung WJ, Schleinitz MD, et al: Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and metaanalysis. Am J Obstet Gynecol 2007; 197 (1):3-11.
6. Watregny D, Reul Q, Mathantu B: Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: Interim results of a prospective study after a 1-year minimum followup. J Urol 2006; 175:2191-2195.
7. Latthe PM, Foon R, Toozs H: Transobturator and retropubic tape procedures in stress urinary incontinence: A systematic review and meta-analysis of effectiveness and complications. BJOG 2007; 114:522-531.
8. Novara G, Ficarra V, Boscolo-Berto R, et al: Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. Eur Urol 2007; 52:683-779.
9. Watregny D, Gaspar Y, Reul Q: TVT-O for the treatment of female stress urinary incontinence: Results of a prospective study after a 3-year minimum follow-up. Eur Urol 2008; 53:401-408.
10. Nilsson CG, Palva K, Rezapour M, Falconer C: Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J 2008; 19:1034-1047.
11. Meschia M, Bertozzi R, Pifarotti P, et al: Peri operative morbidity and early results of a randomized trial comparing TVT and TVT- O. Int Urogynecol J Pelvic Floor Dysfunct 2007; 18:1257-1261.
12. Darai E, Frobert J-L, Grisard-Anaf M, et al: Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicentre study comparing the retropubic and transobturator routes. Eur Urol 2007; 51: 795-802.

13. David-Montefiore E, Frobert J-L, Grisard-Anaf M, et al: Peri-operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomised multicentre study comparing the retropubic and transobturator routes. Eur Urol 2006; 49: 133-138.

14. Ryu KH, Shin JS, Du JK, et al: Randomized trial of tension-free vaginal tape (TVT) vs. tension-free vaginal tape obturator (TVT-O) in the surgical treatment of stress urinary incontinence: comparison of operation related morbidity. Eur Urol Suppl 2005; 4 (3): 15 (abst. 50).

15. Laurikainen EH, Valpas A, Kilholma P, et al: A prospective randomized trial comparing TVT and TVT-O procedures for the treatment of SUI: immediate outcome and complications. Int Urogynecol J Pelvic Floor Dysfunct 2006; 17 (Suppl 2): S104 (abst. 77).

16. Daneshgari F, Kong W, Swartz M: Complications of mid urethral slings: Important outcomes for future clinical trials. J Urol 2008; 180: 1890-1897.

17. Tamussino K, Hanzal E, Kolle D, et al: Transobturator tapes for stress urinary incontinence: Results of the Austrian registry. Am J Obstet Gynecol 2007; 197: 634.e1

18. Abdel-Fattah M, Ramsay I, Pringle S: Lower urinary tract injuries after transobturator tape insertion by different routes: A large retrospective study. Br J Obstet Gynaecol 2006; 113: 1377-1381.

19. Novara G, Galleano A, Boscolo-Berto R, et al: Complication rates of tension free midurethral slings in the treatment of female stress urinary incontinence: A systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Eur Urol 2008; 53: 288-309.

20. Barry C, Lim YN, Muller R, et al: A multi-centre, randomized clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study. Int Urogynecol J Pelvic Floor Dysfunct 2008; 19: 171-178.

21. Meschia M, Bertolzi R, Pifarotti P, et al: Peri-operative morbidity and early results of a randomized trial comparing TVT and TVT-O. Int Urogynecol J Pelvic Floor Dysfunct 2007; 18: 1257-1261.

22. Waltregny D, de Leval J: The TVT-obturator surgical procedure for the treatment of female stress urinary incontinence: A clinical update. Int Urogynecol J 2009; 20: 337-348.

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