Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence

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Key words: *tension-free vaginal tape, tension-free vaginal tape obturator from inside to outside; stress incontinence; female urinary incontinence; surgical treatment of female urinary incontinence.*

Summary. *The objective of this study was to compare TVT (tension-free vaginal tape) and TVT-O (tension-free vaginal tape obturator from inside to outside) procedures for the female surgical treatment of stress urinary incontinence: results, complications, and effectiveness after 1 year.*

Material and methods. A prospective randomized study was carried out. The patients were followed up for 12 months. A total of 114 patients were operated on using TVT procedure and 150 patients – TVT-O procedure. There was no significant difference in age, body mass index, parity, menopausal status, and prolapse (no patients had cystocele greater than stage II) comparing both groups.

Results. The mean time in surgery was significantly shorter in the TVT-O group (19±5.6 min) as compared with the TVT group (27±7.1 min). No differences in the effectiveness of both procedures were found: TVT – 94.6% and TVT-O – 94.6% after one year, respectively. Hospital stay was significantly shorter in the TVT-O group (1.5±0.5 days) than in the TVT group (4.0±1.6 days). Significantly fewer complications were observed in the TVT-O group.

Conclusion. TVT and TVT-O operations are equally effective for the surgical treatment of female stress urinary incontinence. TVT-O group had shorter time in surgery and showed a lower rate of complications.

Introduction

Since 1995, the tension-free vaginal tape (TVT) technique has been the most commonly used surgical treatment for stress urinary incontinence (1). A new surgical technique that uses polypropylene tape with the new designed specific surgical instruments called transobturator vaginal tape from inside to outside or tension-free vaginal tape obturator from inside to outside (TVT-O) was described for the first time in 2003 (2).

When comparing the TVT and TVT-O procedures, both of them are equally effective in the treatment of female stress urinary incontinence, but the TVT-O procedure seems to be safer than the classic TVT procedure (3–5).

This study was performed to compare prospectively the TVT procedure with the TVT-O procedure regarding the effectiveness, safety, and simplicity.

Material and methods

A total of 114 patients were subjected to TVT procedure and 150 patients to TVT-O procedure. All these patients were followed up for 12 months.

Inclusion criteria were as follows: women with stress urinary incontinence and patient's agreement to buy a TVT or TVT-O set (there is no compensation from territorial patients funds in Lithuania).

Exclusion criteria were as follows: urogenitale prolapse greater than stage II, urinary retention, overactive bladder and mental disease.

All patients had a typical medical history of stress incontinence. The degree of incontinence was 2–3 according to the Ingelman-Sundberg scale.

Number of births, obesity, menopause, urinary incontinence period, past history of hysterectomy and incontinence operations of all patients were estimated.

All patients underwent gynecological examination. A stress provocation test was carried out in the supine and standing positions with a comfortably filled bladder (300 mL) before and after operation.

Urodynamic evaluations were performed for 40% of patients (for 44 patients from the TVT group and

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62 patients from in the TVT-O group) in the accordance with criteria established by the International Continence Society (ICS) (6). The degree of vaginal defects was evaluated using the pelvic organ prolapse quantification (POP-Q) system (7).

Cystoscopy and cough test were routinely performed only in the TVT group. Antibiotic prophylaxis was applied for all patients during surgery.

Foley catheter was left for 12 hours in the TVT group and for 6 hours in the TVT-O group after operation. Surgical procedures (TVT and TVT-O) were performed by the same surgeon (R.A.) using the standardized Gynecare protocol.

Results were estimated according to the following criteria:

- Excellent – no signs of stress incontinence, imperative urination, or dysuria.
- Good – no signs of stress incontinence, very mild imperative urination, no disuria.
- Moderate – no signs of stress incontinence, imperative urination with minimal leakage, very mild dysuria.
- Bad – stress incontinence, imperative urination, dysuria, a woman uses inlays.

The statistical analysis was performed using Student's test and χ^2 test, and *P* value of <0.05 was considered as statistically significant.

Results

All patients (114 patients in the TVT group and 150 patients in the TVT-O group) were assessed for eligibility. They agreed to buy a single set for operation, met the inclusion criteria, and signed informed consent. All patients were operated on at the Department of Obstetrics and Gynecology, Hospital of Kaunas University of Medicine (by the same surgeon).

Patients' characteristics are shown in Table 1. Comparing both groups, there were no significant changes in age, body mass index, menopausal status, and prolapse stage (no patients had cystocele greater than stage II). In addition, no difference was observed in the duration of stress urinary incontinence (Table 1).

As it is shown in Table 2, there were no differences in the effectiveness of both procedures (TVT – 94.6%, TVT-O – 94.6%). The mean time in surgery was significantly shorter in the TVT-O group (19±5.6 min) as compared with the TVT group (27±7.1 min). Hospital stay was significantly shorter in the TVT-O group (1.5±0.5 days) than in TVT group (4.0±1.6 days). Bladder drainage was significantly rare in the TVT-O group as compared with the TVT group (3.3% and 15.8%, respectively).

The main type of anesthesia in the TVT group was lumbar (83.3%) and in TVT-O group – intravenous (85.3%).

As it is shown in Table 3, the results of operations in both groups were similar. They were as follows: bad results were documented in 3 cases in the TVT group and 3 cases in the TVT-O group; moderate, 3 cases in the TVT group and 5 cases in the TVT-O; good, 11 cases in the TVT group and 25 cases in the TVT-O; and excellent, 97 cases in the TVT group and 117 cases in the TVT-O.

As it is shown in Table 4, significantly fewer comp-

Table 1. **Characteristics of the patients**

Characteristic	TVT (n=114)	TVT-O (n=150)	*P*
Age, years, mean±SD	51±10.1	49±9.5	NS
POP Q system, n: stage 1	26	31	NS
stage 2	22	29	NS
Follow-up period, months	12	12	NS
BMI, kg/m^2	27.9±4.0	28.2±3.8	NS
Number of births	2.6±1.1	2.5±1.2	NS
Birth weight >3500 g	49±1.2	51±1.3	NS
Menopause (1–30 years)	48	47	NS
Obesity (BMI>30)	14	16	NS
Irritated bladder symptoms, n	6	5	NS
Urinary incontinence period, years	6.5±3.1	7.5±2.4	NS
Hysterectomy in the past, n	15	21	NS
Operated incontinence in the past, n	16	18	NS

Table 2. **Data of TVT and TVT-O procedures**

Parameter	TVT (n=114)	TVT-O (n=150)	*P*
Effectiveness of procedure, %	94.6	94.6	NS
Duration of procedure, min	27±7.1	19±5.6	<0.05
Hospital stay, days	4.0±1.6	1.5±0.5	<0.05
Anesthesia, n (%)			
Epidural	13 (11.4)	0	–
Local	2 (1.8)	0	–
Lumbar	95 (83.3)	22 (14.7)	–
Intravenous	4 (3.5)	128 (85.3)	–
Bladder drainage, n (%)			
Interrupted catheterization	18 (15.8)	5 (3.3)	<0.05

Table 3. **Follow-up results of TVT and TVT-O procedures**

Results (after 1 year)	TVT n (%) (n=114)	TVT-O n (%) (n=150)
Excellent	97 (85.1)	117 (78)
Good	11 (9.7)	25 (16.7)
Moderate	3 (2.6)	5 (3.3)
Bad	3 (2.6)	3 (2)

lications were in the TVT-O group. Suprapubic hematoma occurred in 0.9% of the patients in the TVT group, and 1 case of bladder perforation was observed in the TVT group. The prevalence of postoperative urinary retention was significantly higher in the TVT group than in the TVT-O group (15.8% and 3.3%, respectively). There was no significant difference in such complications as occurrence of symptoms of irritated bladder. Infection of urinary tract in the TVT group was observed in 4.4% of the patients and in the TVT-O group – 0.7%.

Discussion

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

There was a significant difference in the mean time in surgery, which was much longer for the TVT procedure than for the TVT-O procedure due to the fact that intraoperative cystoscopy was necessary in the TVT group (8). The duration of hospital stay was statistically significant longer in the TVT group as compared to the TVT-O group (4.0±1.6 days versus 1.5±0.5 days).

The results are not in agreement with the findings of other authors (9), where the majority of patients were discharged from the hospital on the first postoperative day.

Effectiveness of the procedure was 94.6% in the TVT group and 94.6% in the TVT-O group. These results are in agreement with the findings of other authors who reported effectiveness ranging from 84% to 95% (10–14).

Table 4. **Postoperative complications**

Complication	TVT, n (%) (n=114)	TVT-O, n (%) (n=150)	*P*
No complications	81 (71.0)	135 (90.0)	<0.05
Suprapubic hematoma	1 (0.9)	0	NS
Wound bleeding in vagina	2 (1.8)	3 (2)	NS
Bladder perforation	1 (0.9)	0	NS
Postoperative urinary retention	18 (15.8)	5 (3.3)	<0.05
Symptoms of irritated bladder	6 (5.3)	5 (3.3)	NS
Infection of urinary tract	5 (4.4)	1 (0.7)	NS
Fever >38˚C	0	1 (0.7)	NS

Bladder perforation in our study occurred in 0.9% of the patients in the TVT group and its occurrence is more rare than that reported in the literature (10, 15, 16).

The prevalence of postoperative urinary retention was significantly higher in the TVT group (15.8%); therefore, our data disagree with that one in the literature (17).

Postoperative infection of urinary tract occurred 4.4% of the patients in the TVT group and 0.7% in the TVT-O group (less likely than reported in the literature) (16).

The prevalence of wound bleeding in the TVT group was 1.8% and in the TVT-O – 2.0%. One patient was treated surgically and four patients received conservative treatment.

Duration of the TVT-O operation was shorter than that of the TVT, because in the TVT-O procedure, there was no need to perform cough test and cystoscopy.

The TVT procedure is more safe and effective surgical treatment of female stress urinary incontinence showing good effectiveness (18–22), but the TVT procedure is associated with various perioperative complications (23–26).

Several suburethral tape insertion procedures such as tension-free transobturator tape (TOT) either from outside to inside or inside to outside have been described (2, 26, 27). One retrospective comparative study investigating retropubic and outside-in transobturator sling demonstrated that these procedures were equally efficacious to treat female stress urinary incontinence with a cure rate of 90% and 84% for TOT and TVT, respectively (3).

Conclusions

1. The results of 12-month follow-up showed that TVT and TVT-O operations were very effective procedures while treating female stress incontinence.
2. TVT-O procedure had a shorter time in surgery and hospital stay.
3. The TVT-O group showed a lower complication rate than the TVT group.

Laisvai traukiama makšties ir obturacinė kilpa (moterų fizinio krūvio šlapimo nelaikymo chirurginių gydymo metodų palyginimas)

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Raktažodžiai: laisvai traukiama makšties kilpa, transobturacinė makšties kilpa (iš vidaus į išorę), fizinio krūvio šlapimo nelaikymas, moterų šlapimo nelaikymas, chirurginis moterų šlapimo nelaikymo gydymas.

Santrauka. *Tyrimo tikslas.* Palyginti moterų fizinio krūvio šlapimo nelaikymo chirurginio gydymo metodų: laisvai traukiamos makšties kilpos ir obturacinės kilpos rezultatus, komplikacijas, gydymo veiksmingumą vienų metų laikotarpiu.

Medžiaga ir metodai. Atliktas perspektyvusis tyrimas. 114 pacienčių operuota naudojant laisvai traukiamos kilpos metodą ir 150 pacienčių – laisvai traukiamos obturacinės kilpos metodą. Vertinant amžių, KMI, gimdymų skaičių, menopauzės laiką ir makšties slinkimo stadiją (nebuvo pacienčių, kurioms būtų didesnė nei antra priekinės makšties sienelės slinkimo stadija). Tarp grupių statistiškai reikšmingo skirtumo nerasta.

Rezultatai. Vidutinė operacijos trukmė, naudojant laisvai traukiamos obturacinės kilpos metodą, buvo trumpesnė (19±5,6 min.) lyginant su pacienčių grupe (27±7,1 min.), kai naudotas laisvai traukiamos makšties kilpos metodas. Nebuvo statistiškai reikšmingo skirtumo tarp šių operacijų efektyvumo: 94,6 ir 94,6 proc., atitinkamai. Po operacijų, kurių metu naudotas laisvai traukiamos obturacinės kilpos metodas, statistiškai reikšmingai trumpesnė hospitalizacijos trukmė – 1,5±0,5 dienos, o operacijų, kurių metu naudotas laisvai traukiamos makšties kilpos metodas – 4,0±1,6 dienos. Statistiškai reikšmingai mažiau komplikacijų konstatuota operacijai naudojant laisvai traukiamos obturacinės kilpos metodą.

Išvados. Naudojant abu metodus operacijos yra vienodai efektyvios chirurginiu būdu gydant moterų fizinio krūvio šlapimo nelaikymą, operacijos, naudojant laisvai traukiamos obturacinės kilpos metodą, trunka trumpiau ir sukelia mažiau komplikacijų.

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