

New surgical technique for the treatment of urinary incontinence in Clinic of Obstetrics and Gynecology of Kaunas University of Medicine

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Key words: *female urinary stress incontinence, mixed incontinence, surgical tension-free vaginal tape technique, prolene tape, cystocele, minimal invasive surgery.*

Summary. *There are various surgical methods for the treatment of female urinary stress incontinence.*

The aim of this study was to evaluate the effectiveness of tension-free vaginal tape (TVT) operation based on a three-year clinical experience and the possibility of its use in the outpatient settings.

Materials and methods. The patients were examined according to a standardized protocol for urinary incontinence and were operated on according to the original "Gynecare TVT" protocol. A total of 57 women were operated on and followed up during the study period (02/25/2000–12/31/2002). The average age was 52 years. Out of them 31 (54.4%) women were after menopause and 56 (97.9%) gave birth. Nine women had operations in their medical histories: five had hysterectomies and the other four were operated on because of urinary incontinence. Besides, five women were operated due to mixed urinary incontinence. Among the operated women, 6 had local anesthesia, 13 had epidural, and 38 had lumbar anesthesia. The average time of the operation was 22.3 minutes. The mean hospital stay was 4.4 days. Five patients were hospitalized for one day. Besides TVT operation, eight patients had anterior colporrhaphy, two patients had posterior colporrhaphy, and two patients had "mesh" application for cystocele treatment.

Results. One woman had stress urinary incontinence symptoms after operation (the effectiveness of operation was 98.2%). The main complications were: perforation of the urinary bladder was present in 1 (1.8%) patient and infection of urinary tract – in 4 (7.0%) patients.

Conclusion. TVT operation is a minimal invasive, fast, safe and very effective surgical procedure for the treatment of urinary stress incontinence, which has to be implemented in Lithuania as a routine outpatient procedure.

Introduction

Female urinary incontinence is a social, hygienic, and psychological problem that especially affects women and causes disablement.

The main factors that influence urinary incontinence are age, pregnancies and childbirths, menopause, obesity, urinary tract diseases, recognition disorder, hysterectomies, work character. It was noticed that women having cystocele or genital prolapse sometimes hold the urine well, and women in whom the position of genitalia is normal often suffer from urinary incontinence.

Mostly urinary incontinence occurs during physical load because of increased intraabdominal pressure and, consequently, increased mobility of cervico-urethral

segment and urethral dysfunction. These are the main indications for surgical treatment.

Diagnostics is based on gynecological and urological anamnesis, urination diary of the patient, examination, objective and bimanual analysis, cough, Valsalva, Bonney, Q-tip (cotton swab), stress, pad tests, and urodynamic examination (urethrocystometry, uroflowmetry, and videourodynamics) in case of mixed urinary incontinence when preparing for operative treatment.

More than 200 surgical techniques are used in the world for the treatment of female stress urinary incontinence. Until 1970, the main surgical method of treatment was anterior colporrhaphy. For last 20 years, this operation has been criticized for a high number of

relapses. Better outcomes are observed when retropubic surgical procedures are applied. Anterior colporrhaphy is effective for the treatment of vaginal wall prolapse if the problem of urinary incontinence does not exist. In the opinion of American Association of Urologists, anterior colporrhaphy is the least effective from four categories of operations (anterior colporrhaphy, suburethral sling, colposuspensions, and long-needle sling) for long-term treatment (1). Cochrane database provides comparative data: the results of eight studies showed that by applying anterior colporrhaphy for the treatment of urinary incontinence, failure rate within the first year was 29% and after 1 year – 41%, and while performing abdominal colposuspension, these numbers were 14% and 17%, respectively (2). Suprapubic colposuspension or urethrosuspension is much more effective than vaginal operations (3).

In this paper, most attention has been directed to a new technique, tension-free vaginal tape (TVT) operation, that was done for the first time in Lithuania and the Baltic states on February 25, 2000, in assistance of Dr. T. T. Penttinen (Finland). TVT operation is very effective and minimally invasive; it is widely used in the world for the treatment of female stress urinary incontinence. In 1995, a new surgical correction of urinary incontinence, TVT operation, was performed on a woman with stress urinary incontinence at Uppsala University Hospital by Prof. U. Ulmsten (4).

The aim of the study was to evaluate the results, effectiveness, and complications of TVT operation and to estimate the correlation between risk factors of urinary incontinence and postoperative complications.

Material and methods

Before operation, gynecological and urological anamnesis was collected, gynecological and urinary examination, cough, Valsalva, Bonney, and stress tests were performed. Women were examined at 2, 6, 12, and 24 months after the operation. Women having stress urinary incontinence of grade I, II, III (according to Ingelman-Sundberg-Stamey classification) or mixed urinary incontinence with cystocele of grade I, II, III, who agreed to buy a single TVT set, were included in the study.

During the study period (02/25/2000–12/31/2002), 57 women were operated on according to original TVT operation protocol. The results of operation were evaluated according to the criteria accepted: very good – urine is held, no imperative urination or dysuria; good – urine is held, slight imperative urination, no dysuria; average – urine is held, imperative urination with

minimal urinary outflow, slight dysuria; bad – urine is not held, imperative urination, dysuria, a woman wears pads (5).

Protocol of TVT operation

Indications for the operation:

1. Stress urinary incontinence (grade I, II, III) with increased mobility of urethra and congenital sphincter dysfunction.
2. Mixed urinary incontinence.

Conditions: genital prolapse of I, II, III.

Contraindications:

1. Pregnancy.
2. Childhood, adolescence.
3. Pregnancy planned in the future.
4. Genital prolapse of IV, V.

TVT equipment:

- *Single-use “Gynecare TVT” apparatus.*
- *Multiple-use intubator.*
- *Stiff-catheter guide of multiple-use “Gynecare TVT.”*

Results and discussion

A total of 57 patients were enrolled in the study. The mean age of women was 53.2 years (95% confidence interval (CI) 50.1–56.4 years). The youngest patient was 31 years old, oldest – 82 years old. The contingent was homogeneous comparing these women according to the number of childbirths (average number of deliveries was 1.96 (95% CI 1.74–2.19)). Thirty-one patients were in the period of menopause. Mean duration of urinary incontinence was 6.5 years (95% CI 4.7–8.3). TVT operation was performed in seven obese women (BMI>30). Five women before the operation suffered from symptoms of irritable urinary bladder (in case of mixed incontinence). Besides, three women had previous total laparotomic hysterectomy, one – subtotal hysterectomy, and one – vaginal hysterectomy. Four women had a previous operation for urinary incontinence: two women were operated on in Kelly way, one – in open Burch way, and one – in Stoeckel way (Table 1).

Operated women were examined after 2, 6, 12, and 24 months. Table 2 shows the results of operations performed at our clinic. In average, the effectiveness of the operation is rather high (98.2%): after two months, the results of the operation were evaluated as very good and good (Table 3).

Our data are very similar to the data presented in foreign literature. L. M. Partoll reported a 94%

Table 1. Characteristics of patients operated on at the Clinic of Obstetrics and Gynecology in 2000-2002 (n=57)

Parameter	Mean (95% CI)	Range	n (%)
Age (years)	53.2 (50.1–56.4)	31–82	
Number of childbirths	1.96 (1.74–2.19)	0–5	
Duration of menopause (from 1 to 28 years)	10.3 (6.9–13.6)	1–30	31 (54.4)
Obesity (BMI>30)			7 (12.3)
Symptoms of irritable urinary bladder in case of mixed incontinence			5 (8.8)
Duration of urinary incontinence (years)	6.5 (4.7–8.3)	1–28	
Previous hysterectomy			5 (8.8)
Previous surgery for urinary incontinence			4 (7.0)
Follow-up duration (months)	22.9 (19.6–26.2)	2.1–48	

Table 2. Data on TVT operation at the Clinics of Obstetrics and Gynecology

Parameter	Mean (95% CI)	Range	n (%)
Effectiveness of operation	98.2 proc.		
Duration of operation (min)	22.3 (20.8–23.7)	15–40	
Duration of hospital stay (days)	4.4 (3.5–5.2)	1–14	
Anesthesia:			
local			6 (10.5)
epidural			13 (22.8)
lumbar			38 (66.7)
Drainage of urinary bladder:			
intermittent catheterization			9 (15.8)

Table 3. Results of TVT operation during follow-up (data of the Clinics of Obstetrics and Gynecology in Kaunas University of Medicine)

Results	After 2 months n (%)	After 6 months n (%)	After 12 months n (%)	After 24 months n (%)
Very good	54 (94.7)	49 (87.5)	34 (72.3)	12 (63.2)
Good	2 (3.5)	6 (10.7)	12 (25.5)	6 (31.6)
Satisfactory	–	–	–	–
Bad	1 (1.8)	1 (1.8)	1 (2.1)	1 (5.3)
No information	–	1	10	38

effectiveness of TVT operation. The author operated on 37 women for stress urinary incontinence using TVT procedure (6).

In reviewing rather many publications in the literature on surgical treatment of urinary incontinence, we would like to mention Nordic multicenter study where 90 women operated on using TVT procedure were included. The patients were followed up for 5 years. The effectiveness of the operation was 84.7% (n=72); 10.6% (n=9) of patients were significantly improved, and 4.7% (n=4) showed no improvement.

The authors did not present any information about remaining five patients. No signs of rejection of the tape material were observed during the study. Twenty-five women out of mentioned 90 patients were included into the study because of mixed type of urinary incontinence. Fourteen patients suffered from symptoms of irritable urinary bladder after the operation. The authors state that TVT operation justifies all hopes of surgeons, staying the most effective operative treatment for female urinary incontinence (7).

Similar conclusion has been reported by S. L. Stanton. He states that minimally invasive methods such as TVT procedure are more successful, and a patient tolerates this procedure well because of minimal pain, short hospitalization, a few complications and side effects. The effectiveness of the operation reached 88–96% (8).

The length of operation and inpatient treatment, method of anesthesia, and need of postoperative drainage of urinary bladder were compared with corresponding data from the Central TVT register of Austria (9). According to the data presented by Austrian urogynaecologic work group, mean duration of TVT operation was 30 minutes, mean length of inpatient treatment – 4 days, local anesthesia was applied in 46% of cases, regional – in 43% of cases. Intermittent catheterization is necessary for 20% of patients. It is possible to perform TVT operation under intravenous anesthesia. In the study by T. S. Lo *et al.*, 45 women aged 65–85 years were operated on under intravenous anesthesia with deep sedation. The mean duration of operation was 21 minute, the length of postoperative stay in inpatient department – 1–3 days. According to their data, the effectiveness of the operation was very high (91%) (10).

In 1998, a multicenter study including six Scandinavian centers, where 131 women were

operated on, was performed. All operations were performed under local anesthesia. Mean operation time was 28 min (range 19–41 min). Majority of patients (n=119, 91%) recovered, and 7% considerably improved; 90% of women were released from the hospital at the same day, others – the next day. Three patients needed indwelling catheter for 3 days. Complications were following: two women developed hematomas, and in one case perforation of the urinary bladder occurred (11).

Table 3 shows the postoperative results which were evaluated during follow-up. After 6 months, the percentage of patients experiencing excellent postoperative results decreased (87.6%) and experiencing good results – increased (10.7%). The percentage of patients experiencing bad results did not change (1.8%). After 12 months, the same tendencies were observed: the percentage of patients who had excellent results decreased (72.3%) and who had good results – increased (25.5%); therefore, postoperative results of the most of women did not change essentially – they were very good or good. Comparing the results after 2 months and 12 months, the frequency of bad results has slightly increased (0.3%).

A logistic regression analysis to predict the worsening of postoperative results showed that the

Table 4. Logistic regression analysis of risk factors for worsening of postoperative results (information of the Clinic of Obstetrics and Gynecology in Kaunas University of Medicine)

Variable	Exp(B)	95% CI	p
Duration of operation (min)	1.208	1.042–1.421	0.012
Age (years)	0.870	0.7538–1.0035	0.420
Duration of menopause (years)	1.163	0.9562–1.415	0.380
Number of childbirths	2.289	1.829–6.327	0.024
Duration of urinary incontinence (months)	1.002	0.852–1.177	0.380

Table 5. Correlation of various factors (information of the Clinic of Obstetrics and Gynecology in Kaunas University of Medicine)

Variable	Duration of operation	Postoperative urinary retention	Amount of childbirths	Age	Duration of menopause
Duration of treatment in inpatient department	–0.083	–0.025	–0.069	0.101	–0.030
Duration of operation		0.109	0.036	–0.012	–0.068
Postoperative urinary retention			0.148	0.494**	0.354**
Amount of childbirths				–0.024	–0.263*
Age					0.751**

*p<0.05. **p<0.01.

Table 6. Early complications of TVT operation (data of the Clinic of Obstetrics and Gynecology in Kaunas University of Medicine)

Complication	n (%)
No complications	35 (61.3)
Suprapubic hematoma	1 (1.8)
Hemorrhage from the wound in vagina	2 (3.5)
Perforation of urinary bladder	1 (1.8)
Postoperative urinary retention	9 (15.8)
Symptoms of irritable urinary bladder	5 (8.8)
Infection of urinary tract	4 (7.0)

number of childbirths and the duration of operation influenced poor postoperative results statistically significantly (Table 4). Every childbirth increased odds ratio (OR) for the worsening of postoperative results by 2.29 times ($p < 0.05$) and every minute of operation increased this OR by 1.21 times ($p < 0.05$); while, age, duration of menopause and urinary incontinence did not have any influence on worsening of very good results (Table 4).

For evaluating associations between various symptoms and risk factors, correlation coefficients were determined (Table 5). The moderate correlation was determined between age and postoperative urinary retention.

We report all complications, even the slightest, that occurred in our examined group because it caused longer hospitalization of the patients. In world literature, authors present only major complications of TVT operation such as perforation of the urinary bladder or urinary tract infection (3). In our study (Table 6), these complications were observed only in five cases (8.8%). Authors of the other countries indicate a 2–6% rate of similar complications (3).

A group of American researchers that have examined the technique of TVT operation, outcome, and complications reports that it is a unique procedure for treatment of stress urinary incontinence. Mesh tape of prolene that raises the middle part of urethra to physiological position effectively cures stress urinary incontinence. The foreign body is well tolerated, and the procedure is more effective than other corrective operations for urinary incontinence (12).

In our clinic, more than half (61.3%) of patients developed no complications during the operation and after it. In one case suprapubic hematoma was observed that resorbed itself in early postoperative period when applying procedures of physiotherapy, in two cases (3.5%) hemorrhage from the wound was observed: in one patient – at the first day after the operation, in another – on the 7th day when the patient was already at home. The hemorrhage in the latter patient was stopped, and no operative interventions were needed. Perforation of the urinary bladder occurred in one case (1.8%), possibly because of atypical anatomy of the urinary bladder sticking the second needle into Retzius' cavity. However, the urinary bladder was only pricked, the needle was taken out, and the operation was finished. After the operation while performing cystoscopy, a small lesion in one place of the cavity was detected. This patient had a permanent catheter inserted for 7 days. The most frequent complication – postoperative urinary retention – occurred in 9 (15.8%) of women. This index exceeds the values presented in the literature possibly because of non-adequate strain of prolene tape (13).

The symptoms of irritable urinary bladder during early postoperative period occurred in 8.8% ($n=5$) of cases; however, this was influenced by analogical preoperative symptoms observed in 8.8% ($n=5$) of cases of mixed urinary incontinence. Urinary tract

Table 7. Association between complications and risk factors (information of the Clinic of Obstetrics and Gynecology in Kaunas University of Medicine)

Complication	Risk factor			
	Age (</≥50 years)	Childbirth (yes/no)	Menopause (yes/no)	Duration of urinary incontinence (</≥10 years)
Hemorrhage from vaginal wound	1/1	1/–	–/–	1/–
Suprapubic hematoma	–/1	1/–	1/–	1/–
Postoperative urinary retention	1/9	1/1	1/1	1/1
Symptoms of irritable urinary bladder	–/5	1/1	1/–	–/1
Infection of urinary tract	1/3	1/1	1/1	1/1

Table 8. Logistic regression analysis of risk factors for complications (information of the Clinic of Obstetrics and Gynecology in Kaunas University of Medicine)

Variable	Exp(B)	95% CI	p
Age	1.004	0.922–1.095	0.920
Duration of menopause	1.091	0.960–1.240	0.180
Number of childbirths	0.659	0.279–1.555	0.341
Duration of urinary incontinence	1.143	1.008–1.296	0.038

Table 9. Operations combined with TVT (n=12) (information of the Clinic of Obstetrics and Gynecology in Kaunas University of Medicine)

Operative procedure	n (%)	n=57 (%)
Anterior colporrhaphy	8 (66.6)	14.1
Prolene mesh application for liquidating the cystocele	2 (16.7)	3.5
Posterior colporrhaphy (colpoperineoplasty)	2 (16.7)	3.5

infection was found in 4 (7%) cases. These complications were observed two times more frequently as compared to the data presented in the literature; however, it is difficult to compare these indices because the world literature provides the data from multicenter studies where much more patients were enrolled (14).

After presenting the complications, their association with risk factors was evaluated. The strongest association was determined when evaluating the age and postoperative urinary retention – the latter increased with age (Table 7). A logistic regression analysis of risk factors for complication showed that the number of childbirths did not influence the frequency of complications, and other indices, especially the duration of urinary incontinence, were related to complications (Table 8).

Operations combined with TVT (or simultaneous operations) are presented in Table 9. Anterior colporrhaphy was performed in 8 (14.1%) cases aiming to remove the cystocele. In two cases (3.5%), prolene mesh was used, and in two cases (3.5%), posterior colporrhaphy was performed because of rectocele. These combinations of operations had no influence on outcome or complications of TVT operation, only the duration of operation (10–20 minutes) and the length of hospital stay increased (2–3 days).

According to literature data in the world, it is established that the most effective treatment for stress urinary incontinence is TVT operation, laparoscopic and laparotomic Burch operations (3, 13, 15). However, the economical advantage due to more rapid patient's

recovery, smaller amount of blood lost, shorter bed stays, and lower labor input is greatest when performing the TVT operation. At this time, minimally invasive and effective techniques for the treatment of stress urinary incontinence are looked for in the world. TVT operation is most like that – a patient receives the maximum benefit. The only one disadvantage of TVT operation in our country is that Territorial Patient Fund does not compensate the operation, and patients have to buy the expensive set for the operation by themselves.

Conclusions

1. TVT operation is a very effective procedure for the treatment of female stress urinary incontinence and mixed incontinence.
2. The number of childbirths is related to poor postoperative results after 12 months.
3. Early major postoperative complications after TVT operations occurred in 8.8% of cases.
4. Postoperative urinary retention is related to older age.
5. Duration of urinary incontinence in the anamnesis is connected with complications of TVT operation.
6. Operations combined with TVT did not have any influence on complications; however, they prolonged the duration of operation and bed stay.
7. TVT operation is a minimum invasive, safe, and very effective surgical procedure which has to be implemented in Lithuania as a routine outpatient procedure for the treatment of stress urinary incontinence and mixed incontinence.

Naujos šlapimo nelaikymo chirurginės korekcijos analizė Kauno medicinos universiteto Akušerijos ir ginekologijos klinikoje

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Raktažodžiai: šlapimo nelaikymas, sukeltas įtampos, mišrus šlapimo nelaikymas, proleno kilpa, vezikocelė, minimaliai invazinė chirurgija.

Santrauka. Šlapimo nelaikymas fizinio krūvio metu gydomas įvairiais chirurginiais būdais.

Tyrimo tikslas. Remiantis beveik trejų metų klinikine patirtimi, įvertinti TVT (angl. tension-free vaginal tape) operacijos efektyvumą ir galimybę ją daryti ambulatorinėmis sąlygomis.

Tyrimo metodas ir tiriamųjų kontingentas. Ligonės iširtos vadovaujantis standartizuotu moterų šlapimo nelaikymo tyrimo protokolu ir operuotos pagal originalų „Gynecare TVT“ operacijos protokolą. Tiriamuoju laikotarpiu (2000 02 25–2002 12 31) operuotos ir stebėtos 57 moterys. Jų amžiaus pasikliautinis intervalas svyravo nuo 50,1 iki 56,4 metų. Menopauzė konstatuota 31 (54,4 proc.) moteriai, gimdžiusios – 56 moterys. Anksčiau operuotos devynios moterys: gimda pašalinta penkioms, keturios moterys jau buvo operuotos dėl šlapimo nelaikymo. Dėl mišraus šlapimo nelaikymo operuotos penkios moterys. Vietinė analgezija taikyta darant 6 operacijas, epidurinė – 13, lumbinė – 38 moterims. Vidutinė operacijos trukmė – 22,3 minutės. Vidutinė gydymo stacionare trukmė – 4,4 dienos. Penkios ligonės gydytos vieną dieną. Daliai ligonių TVT operacija daryta derinant ją su priekine makšties plastika (n=8), užpakaline makšties plastika (n=2), „Mesho“ aplikacija cistocelei pašalinti (n=2).

Rezultatai. Po operacijos fizinio krūvio metu šlapimas nesilaikė tik vienai moteriai (operacijos efektyvumas – 98,2 proc.). Komplikacijos. Pagrindinės komplikacijos: šlapimo pūslės plyšimas – 1 (1,8 proc.), šlapimo takų infekcija – 4 (7,0 proc.) ligonėms.

Išvada. TVT operacija yra minimaliai invazinė, greita, saugi ir labai efektyvi chirurginė procedūra, jei fizinio krūvio metu nesilaiko šlapimas, ir šią procedūrą būtina įdiegti klinikinėje praktikoje kaip įprastą ambulatorinėmis sąlygomis atliekamą operaciją (vienos dienos stacionare).

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