

Long-term effectiveness of Tension-Free Vaginal Tape (TVT) procedure – twelve years after surgery

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Summary Background. Urinary incontinence is defined as any involuntary loss of urine. The TVT (Tension-Free Vaginal Tape) operation is a treatment for stress urinary incontinence introduced in Poland in the year 2000. There are few studies evaluating the long-term effectiveness of TVT in Polish women.

Objectives. To evaluate the long-term effectiveness of TVT in the treatment of stress urinary incontinence in women.

Material and methods. 40 women operated on in the period 1999–2004 were recalled 12.6 ± 1.2 years after TVT for a follow-up study. 85 vs 15% of women were operated on due to primary vs recurrent stress incontinence, respectively. 20 vs 80% of the patients had mixed vs pure stress urinary incontinence, respectively. The effectiveness of TVT operations was assessed objectively on the basis of a cough test, and subjectively on improvement after treatment according to the patients' answers (yes/no), PGI-I, PSQ and VAS („0” was the total absence of improvement after surgery, „100” – total improvement).

Results. The cough test was negative in 85% of cases. Subjectively, 85% of women declared improvement after TVT. Based on PGI-I – 77.5% of them maintained improvement after surgery. Based on PSQ – 70% of the women assessed control of urinary incontinence after surgery as better, 72.5% were satisfied with the results of the operation, and 77.5% of them would recommend TVT to other women. Based on VAS, total improvement was noted by 12.5% of women, 60% of women rated improvement “50–99”, and total lack of improvement was noted by 20% of the women.

Conclusions. TVT seems to be an effective form of treatment for urinary incontinence in women 12 years after surgery.

Key words: urinary incontinence, mid-urethral sling, TVT, effectiveness.

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Background

Urinary incontinence is a common condition among women of all ages [1]. Urinary incontinence is defined as any involuntary loss of urine [2]. Urinary symptoms affect different women in different ways and have variable influence on their physical, psychological, social, domestic and interpersonal lifestyle [1]. Among the most common types of urinary incontinence in women there are stress, urge and mixed (urge and stress) incontinence. Stress incontinence is the involuntary loss of urine with an increase in intra-abdominal pressure such as coughing, laughing, physical exercising, sneezing or sexual intercourse [3]. Urge incontinence is defined as involuntary loss of urine preceded by a sudden urge to void [1]. Symptoms of stress urinary incontinence increase with age and parity. Stress urinary incontinence is diagnosed with 0.5–20% of multiparae, and 15–60% of multiparae are affected by this condition [3]. Pregnancy itself, mode of delivery, oxytocin and prostaglandin use for induction of labour, and type of anaesthesia during the delivery have an impact on urinary incontinence [4]. The prevalence of urinary incontinence is nearly 4 times higher after vaginal delivery than after caesarean section (16.6% vs 4.3%) [5]. Urinary incontinence is associated with induction of labour with prostaglandins (OR = 1.74) [6]. Epidural analgesia during delivery is also a significant factor for later stress urinary incontinence surgery (OR = 0.82) [7]. Vaginal delivery has been strongly associated with a need of surgery for

stress incontinence in the future [4]. Persson et al. [8] analysed a group of 10,074 women who underwent surgery for stress urinary incontinence. The risk increases with the parity – from OR = 3.57 after one delivery to OR = 7.14 after more than 3 deliveries [8]. Obesity has been shown to be a risk factor for stress incontinence [1]. There are data to suggest that chronic constipation may lead to urinary incontinence [1].

The symptoms of urinary incontinence radically impair psychological, somatic, and social functioning. Women's emotional state is affected, leading to a lowered quality of life [9].

Stress urinary incontinence is mainly treated surgically. Surgical treatment of stress urinary incontinence has been used for almost a century. More than one hundred operations for urinary incontinence have been described. Plastic surgery of the anterior vaginal wall was one of the most popular procedures. The procedure has lost its popularity due to the relatively high rate of recurrence of the condition, which proved that its long-term efficiency amounted to 67–82% [3]. Afterwards, the Burch colposuspension was the most popular surgical procedure for the treatment of stress urinary incontinence until the team led by Professor Ulf Ulmsten introduced a new minimally invasive, ambulatory, standardized surgical procedure named Tension-Free Vaginal Tape (TVT) in Europe at the end of 1997 and in the USA at the end of 1998 [10]. The introduction of a mid-urethral retropubic sling like the TVT (Tension-Free Vaginal Tape) procedure has meant a significant step forward in the surgical treatment



of stress urinary incontinence in women, mainly due to the low invasiveness and high postoperative efficacy [11]. Although the TVT procedure is minimally invasive, it is not free of complications. The most severe intra-operative complication is bladder or urethra perforation. The most common complications of sling procedures are: overactive bladder (OAB), voiding difficulties, urinary retention, pain, tape erosion and treatment failure [12].

Although in Poland the first such operations were performed around 2000, there has not been any long-term observation until now.

Objectives

The aim of the study was to evaluate the long-term (12-year) effectiveness of TVT in the treatment of stress urinary incontinence in women.

Material and methods

The assessment was performed within an average period of 12.6 ± 1.2 years after TVT. Between the years 1999 and 2004, 240 women were operated on due to stress urinary incontinence by TVT in the 2nd Department of Obstetrics and Gynecology of the Medical University of Warsaw. Each patient was examined before the operation gynaecologically and underwent a cough test in the lithotomy or standing position. All the operated on women had a positive cough and Bonney's tests before surgery. Before and after the operation, the patients filled in a diary of micturition and a special urinary incontinence questionnaire. Prior to surgery, all patients had both general and culture urine analysis. They were operated on only in the presence of a sterile culture of urine. 85% of the women were operated on due to primary stress incontinence and 15% due to the recurring type. 20% of the operated on women had mixed (stress and urge) incontinence, and 80% had a pure urinary incontinence pattern. The average age of the women at the time of the treatment was 59 ± 10.09 years, while the control group was 71.9 ± 10.09 years ($p = 1.8$). The BMI was 26.4 ± 3.96 before and 27.3 ± 4.39 after surgery ($p = 0.3$). A group of 150 women were contacted in 2015. Forty of those were referred for a series of follow-up visits, and after the signed informed consent had been obtained the patients were included in the study. After the operation each patient was examined gynaecologically and underwent a cough test in the lithotomy or standing position.

Data	Before surgery	After surgery
Age [years]	59.0 ± 10.09	71.9 ± 10.09
BMI [kg/m ²]	26.4 ± 3.96	27.2 ± 4.39
POPQ		
grade 0	100%	82%
grade 1	0	8%
grade 2	0	10%
primary stress incontinence	85%	
recurrent stress incontinence	15%	
measurements	interview, diary of micturition, urinary incontinence questionnaire, gynaecological examination, cough test	
	urinalysis	PGI-I, PSQ4, VAS

Objectively, the effectiveness of TVT operations was assessed on the basis of a cough test in the gynaecological and standing position. A positive test in at least one of the positions mentioned above accounted for ineffective treatment. Subjective improvement after treatment according to patients was assessed by answering the question "Do you feel any improvement after the

treatment?". The Patient Global Impression of Improvement (PGI-I), the Patient Satisfaction Questionnaire (PSQ), and the 0–100% visual satisfaction scale (Visual Analogue Scale – VAS) were used also to assess patient satisfaction (Table 1). The study received the positive opinion of the Ethics Commission.

Statistical analyses section

The normal distribution of the data was checked using the Statgraphics Centurion Static Program Version XVII-X64. The data were reported as average values with standard deviation. The test of independence was calculated using the chi-square test ($p < 0.05$ was considered statistically significant).

Results

The cough test was negative in 85% of the women and positive in 15% of the women operated on with TVT (Table 2).

Table 2. Effectiveness of TVT operation in women with stress urinary incontinence 12 years after surgery (objective measurements)

Method		Number of patients	
		n	%
Cough test	negative	34	85
	positive	6	15

Subjectively (improvement after treatment according to patient's answer "Yes" or "No"), 83% of the women declared improvement after the TVT surgery. In a more detailed analysis based on the PGI-I questionnaire 77.5% of the patients claimed improvement after surgery, of which 30% vs 30% vs 17.5% assessed the change after treatment as much better, better and slightly better. 10% of the operated on women reported changes for the worse. Based on the PSQ questionnaire, 70% of the women in the study assessed control of urinary incontinence after surgery as better, 72.5% were satisfied with the results of the operation, and 77.5% of the patients would recommend this form of treatment to other women. On the basis of the VAS, total improvement was noted by 12.5% of women, 60% of women rated improvement "50–99", and total lack of improvement was noted by 20% of the examined women (Table 3).

Table 3. Effectiveness of TVT operation in women with urinary incontinence 12 years after surgery (subjective measurements)

Method		Number of patients	
		n	%
Improvement after treatment according to patients	yes	33	83
	no	7	17
Patient Global Impression of Improvement (PGI-I): overall impression of the patient – change from pre-operation	much better	12	30
	better	12	30
	a little better	7	17.5
	no change	5	12.5
	a little worse	1	2.5
	less	1	2.5
Patient Satisfaction Questionnaire (PSQ): control of urinary incontinence after surgery	much worse	2	5
	extremely well controlled	2	5
	well controlled	15	37.5
	slightly controlled	11	27.5
	no change	1	2.5
	slightly out of control	2	5
	poorly controlled	8	20
not controlled at all	1	2.5	

Table 3. Effectiveness of TVT operation in women with urinary incontinence 12 years after surgery (subjective measurements)

Method		Number of patients	
		n	%
Patient Satisfaction Questionnaire (PSQ): degree of satisfaction after the treatment for urinary incontinence	very satisfied	5	12.5
	satisfied	17	42.5
	a little satisfied	7	17.5
	no change	0	0
	a little dissatisfied	1	2.5
	very dissatisfied	2	5
Patient Satisfaction Questionnaire (PSQ): would the patients recommend a TVT operation to other people	would strongly recommend	13	32.5
	recommend	12	30
	would probably recommend	6	15
	probably would not recommend	3	7.5
	would not recommend	3	7.5
	would definitely not recommend	1	2.5
Visual Analogue Scale (VAS): patient impression	0 – total lack of improvement after surgery	8	20
	1–49	3	7.5
	50–99	24	60
	100 – total improvement	5	12.5

We observed the presence of such late postoperative complications as painful gynaecological examination (3/40), vaginal erosion (3/40), bladder erosion (1/40), overactive bladder (OAB) de novo (4/40), recurrent urinary tract infection (8/40).

We assessed control of urinary incontinence after surgery based on PSQ according of various factors. The lack of positive cough test ($p = 0.001$), the absence of painful gynaecological ex-

amination ($p = 0.011$), and bladder erosion ($p = 0.002$) had the greatest effect on improving urinary incontinence after surgery (Table 4).

Discussion

Urinary incontinence is defined by the International Continence Society as any uncontrolled urinary leak [2]. The incidence of this disease increases with age [2]. According to Polish studies, the incidence of incontinence in our operated on group of 59-year-old women is high and amounts to 76%. The most common form of urinary incontinence in this group is stress urinary incontinence [13]. The basic treatment for stress urinary incontinence is surgical procedures. More than 100 types of operation have been described, but since the last decade of the twentieth century, vaginal access has been most popular, with the placement of a polypropylene mesh under the central urethra. The mesh can be placed retropubically (e.g. TVT, I VS, SPARC), through the obturator foramen (e.g. Monarc, TVT-O), or exclusively from a single incision in the vagina (TVT-secure, MiniArc, Ajust) [14–16]. There are many studies evaluating the efficacy of TVT in the treatment of stress incontinence, also in comparison with other operations mentioned above. However, most of these studies assess the effectiveness of surgery after 1–7 years of follow-up. There are only a few studies analyzing the effectiveness of this method more than 10 years after the operation.

A cough test is considered an objective test showing whether a given procedure improves continence. Its execution is not standardized. It is performed in a litotomy and/or standing position, with various bladder filling (up to 150 ml, 250 ml, 300 ml) or with „bladder filled“ [4, 6]. Other authors performed a cough test during a urodynamic examination of the bladder filled up to a volume of 400–450 ml [17]. In our study, the effectiveness of TVT operations was assessed on the basis of a cough test in both the gynaecological and standing position, with a „filled bladder“ feeling reported by the patient. A positive test in at least one of the listed items was proof of ineffective treatment. The cough

Table 4. Assessment of control of urinary incontinence after surgery based on PSQ according to the various factors

Control of urinary incontinence after surgery	extremely well controlled	well controlled	slightly controlled	no change	slightly out of control	not controlled at all	total	chi-square p
Factor								
Primary urinary incontinence	5	15	6	0	7	1	34	0.124
Secondary urinary incontinence	0	2	1	1	1	1	6	
Positive cough test after operation	0	0	0	1	4	1	6	0.001
Negative cough test after operation	6	17	7	0	3	1	34	
Painful gynaecological examination	0	0	0	0	3	0	3	0.011
Normal gynaecological examination	5	17	7	1	4	2	37	
Vaginal erosion	0	1	0	0	1	0	2	0.881
No vaginal erosion	5	16	7	1	7	2	38	
Bladder erosion	0	0	0	0	0	1	1	0.002
No bladder erosion	5	17	7	1	8	1	39	
OAB de novo	0	2	1	0	1	0	4	0.950
No OAB de novo	5	15	6	1	7	2	36	
Recurrent urinary tract infection	0	1	2	0	4	1	8	0.089
No recurrent urinary tract infection	5	16	5	1	4	1	32	

test was negative in 85% of the analyzed women. Similar results were observed by Olsson et al. in their work [18]. 11.5 years after the operation the cough test was negative in 83.7% of the women surveyed [18]. In the study by Nilsson et al. [19] the cough test was negative in 95.35 women but it was performed in the lithotomy position, and on average 141 months after the procedure. Our study was performed on average 151 months after surgery. In the above mentioned Nilsson et al. study, when the position during the cough test was changed, the results were slightly different – 90.2% of the women treated by TVT had a negative cough test in the standing position [19]. The lack of a positive cough test ($p = 0.001$) had the greatest effect on improving urinary incontinence after surgery in our study.

Liapis et al. [17] assessed objective efficacy on the basis of the pad test and standing cough test results. The one hour pad test was negative in 83% vs 80% of the operated on women 5- vs 7-years after operation, respectively [17]. Other objective methods of evaluating operations included a cough test during the gynaecological examination, which was also reported in our study.

The Patient urinary incontinence questionnaire, the Patient Global Impression of Improvement (PGI-I), the Patient Satisfaction Questionnaire (PSQ) and the 0–100% Visual Analogue Scale (VAS) show the subjective efficacy of the tested procedure. Other researchers have also used similar methods in evaluating patient satisfaction in long-term follow-up after TVT [18]. Olsson et al.

[18] used the same questionnaire assessing urinary symptoms which was applied pre-operatively along with the visual analogue scale. The rate of subjective cure was 77% 11.5 years after the operation [18]. In our study, the subjective improvement after the TVT procedure, depending on the method of assessment, reached the level of 85–70%, 12 years after the operation.

Adams-Piper et al. [20] checked twenty-six patients who underwent a singleton delivery after placement of a mid-urethral sling. There were no MUS-related pregnancy complications, and the vaginal route of delivery had no negative impact on urinary continence [20]. In our study none of the women delivered after the TVT operation. Due to the fact that this procedure is performed in the case of younger women, it is important to know the long-term effectiveness of this type of surgery.

Conclusions

1. Long-term follow-up of TVT seems to prove the effectiveness of treatment for urinary incontinence in women.
2. The objective effectiveness of TVT is 85% 12 years after surgery.
3. The subjective improvement after TVT, depending on the method of assessment, reaches the level of 83–70%.
4. It should be noted that no more than 1/3 of the women undergoing surgery were unsatisfied with its results.

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