

Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up

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Abstract The objective of the study was to obtain a prospective assessment of the efficacy and the complications associated with the use of tension-free vaginal tape (TVT) for the management of urodynamic stress incontinence at 5- and 7-year follow-up. Sixty-five female patients with stage I cystocele or less who have been operated with TVT procedure for management of urodynamic stress incontinence have been included in the study. At 5-year follow-up, the objective cure rate was 83% and failure rate 9.4%. At 7-year follow-up, the objective cure rate was 80% and the failure rate 13.5%. De novo detrusor overactivity was seen in 9.4% and 11.4% of patients at 5- and 7-year follow-up, respectively. TVT operation is an effective and safe minimally invasive procedure for the management of urodynamic stress incontinence in women without significant cystocele in the long-term follow-up. The 10- and 20-year results are awaited.

Keywords Efficacy · Long term · Results · Stress incontinence · TVT · Urinary incontinence

Introduction

The tension-free vaginal tape (TVT) is a relatively new procedure that has been designed for the surgical management of stress urinary incontinence in women. It has been introduced since 1995 [1] and has achieved worldwide popularity since then. The short-term results of the proce-

dure have been encouraging [2] and are comparable to the Burch colposuspension, which is considered the most successful operation for stress urinary incontinence in women available to date. In addition, it is characterized by less operative time, significantly less surgical complications and postoperative voiding dysfunction, less hospitalization time, and faster recovery [3, 4]. During the last few years, the long-term results of TVT procedure started appearing in the literature [5], but there are limited data yet. In this study, we present our experience in relation to long-term efficacy of TVT procedure for the management of stress urinary incontinence in women.

Materials and methods

Seventy consecutive patients have been included in this study. It was estimated that, for a type I error-alpha 0.10 and a type II error-beta 0.10 (power of the study 90%) and an 82% success rate for TVT at 5 years follow-up, null hypothesis value to detect a success rate of 65% requires a sample size of at least 54 patients.

This prospective study took place in the 2nd Department of Obstetrics and Gynecology of the University of Athens. All patients were asked via telephone call to come for follow-up and underwent postoperative urodynamic assessment.

All patients had a full history taken and a complete gynecological examination performed at initial visit, and frequency–volume charts were completed for 2–4 days. Preoperative urodynamic investigations included filling and voiding cystometry, uroflow, and 1-h pad test. Stratification of severity of stress incontinence was based on the classification of pad weight gain suggested by the 5th Report of the International Continence Society, Bristol, 1987. Mild to moderate urine loss was observed in 31.4% of patients,

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severe loss in 45.8%, and very severe loss in 22.8% of patients. Patient assessment at 5-year follow-up included gynecological examination, filling and voiding cystometry, uroflow, and 1-h pad test, and at 7 years follow-up included filling and voiding cystometry, uroflow, and a simple patient satisfaction questionnaire. Urodynamic stress incontinence diagnosis was based on the findings of urodynamic investigation. Diagnosis of detrusor overactivity was based on cystometric findings. All patients had USI with stage I prolapse or less of the anterior compartment according to the International Continence Society classification (ICSC). Patients with urodynamic findings of detrusor overactivity, previous operation in the genital tract or maximum urethral closure pressure of less than 20 cmH₂O, prolapse of the anterior compartment greater than stage I according to ICSC, or prolapse of the middle or posterior compartment requiring management were excluded from the study. All patients were operated on with epidural anesthesia. All patients signed an informed consent, and approval of the hospital ethical committee was obtained. The outcome of the operation was assessed both subjectively and objectively. Objective assessment was based on the findings of cough stress test by asking the patient to cough with the bladder filled with 400–450 ml of normal saline or filled up to maximum cystometric capacity. At 5-year follow-up, objective cure was considered as the absence of urine leaking during cough test in lithotomy or upright position and a pad test weight of <1 g, and improvement as the reduction of urine loss to less than 50% of urine loss they experienced before the operation. This was based on the findings of the 1-h pad test. Subjective cure was defined as no loss of urine with exercise, coughing, or weight lifting and improvement as a subjectively significant reduction of the leaking episodes, expressed by patients' satisfaction. At 7-year follow-up, objective cure was considered as the absence of urine leaking during cough test in lithotomy and upright position. In subjective cure, improvement and failure were assessed with the use of a simple questionnaire that patients answered during their examination ("Appendix"). Statistical analysis was performed for variables following normal distribution with the Student's *t* test for independent samples and for variables not following normal distribution with the Mann–Whitney test for independent samples. A *p*<0.05 was considered statistically significant. The software used for statistical analysis was Medcalc version 7.6.0.0.

Results

Of the 70 patients, five were lost at 5-year follow-up (three patients could not be located and two patients could not come for follow-up because they were living far away from

the clinic). At 7-year follow-up, four additional patients were excluded because two of them had died from natural causes and two were living in a nursing home and could not attend for follow-up. The patients' characteristics are shown in Table 1. The objective cure rate was 83% at 5-years and 80% at 7-year follow-up. In the objective cure rate at 5- and 7-year follow-up, the patients having pure urge urinary incontinence have been included because they have been considered treated from their initial problem that was pure stress urinary incontinence. Total success rate, improvement, and failure rates at 5- and 7-year follow-up are presented in Tables 2 and 3. Cystocele grade II or higher was seen in 9.2% of patients at 5-year follow-up and in 12.5% at 7-year follow-up.

At 5-year follow-up, de novo detrusor overactivity was seen in 8% (5/65) of patients and urgency in 12.3% (8/65) of patients. Out of the five patients with detrusor overactivity, one patient had mixed incontinence and four patients had urge urinary incontinence (6.5%). Three out of five patients complained of dysuria, but they had postvoid residual volume (PVR) of urine of less than 100 ml and peak flow rates (PFRs) of 17.8, 13.4, and 13.8 ml/s, respectively.

At 7-year follow-up, de novo detrusor overactivity was seen in 11.4% (7/61) of patients and urgency in 19.6% (12/61). Out of seven patients with detrusor overactivity, two patients had mixed incontinence and five patients had urge urinary incontinence. Four out of seven patients complained of dysuria, and two of them had 80 and 60 ml PVR and 13.4 and 13.8 ml/s PFR, respectively, while the rest of the patients had PFR>15 ml/s and PVR<100 ml (Table 4). At 5-year follow-up, the median age of patients with bladder overactivity was 72 (range 55–78), and at 7-year follow-up the median age was 72 (range 57–80). At 7-year follow-up, overall subjective dysuria was 14.7% (9/61), but PVR was normal (median 5 ml, range 0–60 ml), and PFR median was 16.2 ml/s (range 13.4–24 ml/s). Recurrent lower urinary tract infection was seen in 3.2% of patients (2/61), but they had no complaints of dysuria or incontinence.

We had one case of TVT tape erosion developed at 29 months postoperatively which was treated by cutting the TVT tape edges which were projecting through the vaginal

Table 1 Patients' characteristics at 7-year follow-up

	Values (N=61)
Age (years)	58.1±10.4
Parity	2±1.1
BMI	26.8±2.3
Menopausal	70.4%

BMI Body mass index

Table 2 Outcome of surgery at 5-year follow-up

	Values	Percentage
Objective		
Cure	54/65	83
Improvement	5/65	7.6
Failure		
Mixed incontinence	1/65	1.5
USUI	5/65	7.6
Subjective		
Cured	55/65	84.6
Improved	3/65	4.6
Failed	7/65	10.7

USUI Urodynamic stress urinary incontinence

mucosa. The rest of the patients had no evidence of tape erosion at 7-year follow-up.

Discussion

The introduction of TVT procedure for the management of stress urinary incontinence in women was based on the integral theory. According to such theory, the female urethra is closed at the level of the midurethra and not at the bladder neck. Lack of support of the midurethra from the pubourethral ligaments and from the suburethral anterior vaginal wall and defective function and insertion of pubococcygeal muscles predisposes one to stress urinary incontinence [6, 7]. The purpose of the TVT procedure is to reinforce the midurethral support, and it uses a polypropylene mesh tape that is inserted beneath and around the midurethra [8].

The efficacy of TVT procedure in the short term has been reassuring and very encouraging, and this is supported by several papers [2, 9, 10].

In the present study, the objective cure rate is 83%, the objective improvement is 7.8%, and the failure rate is 9.2% at 5-year follow-up, while there is no significant difference

Table 3 Outcome of surgery at 7-year follow-up

	Values	Percentage
Objective		
Cure	49/61	80
Improvement	4/61	6.5
Failure		
Mixed incontinence	2/61	3.2
USUI	6/61	9.8
Subjective		
Cured	48/61	78.7
Improved	5/61	8.1
Failed	8/61	13.1

USUI Urodynamic stress urinary incontinence

from the results of subjective assessment. These results are similar with the 84.7% [11] and 94.5% [12] for pure stress urinary incontinence that has been reported, and it is comparable with the 78% for pure stress urinary incontinence that has been published [13]. At 7-year follow-up, the objective cure rate is 80%, the objective improvement is 6.5%, and the failure rate is 13%. These findings are comparable with the 81.3% cure rate that has been reported by Nilsson et al. [14]. De novo detrusor overactivity was seen in 11.4% of patients, while in the Nilsson et al. series de novo urge symptoms were 6.3%. The presence of detrusor overactivity was not associated with significant obstructive findings from the lower urinary tract and could at least be partly attributed to the aging of the patients.

These findings support that TVT procedure maintains its very good short-term efficacy in the long term, and it is very satisfactory for the patients and the physicians. We had no significant intraoperative complications, and we had no patients with voiding difficulties in the long term. There was only one case of erosion of vaginal mucosa by TVT tape, which was treated by cutting the edges of the TVT tape, and the patient remained continent. Its clinical presentation was as a sharp foreign body in the vagina, making sexual intercourse for her husband painful. These results are comparable with the Burch colposuspension [15], while TVT procedure is much less invasive, with fast recovery time and low rate of complications. However, Burch colposuspension presents a time-dependent decline in its efficacy, having a surgical success decline to 62% at more than 10-year follow-up [16]; at 14 or more years of follow-up, subjective cure rate could be reduced to 44% [17]. It has to be seen in the near future if the use of TVT tape as prosthetic material and the fibrotic tissue that is developed around it could maintain their function in the long term, preventing stress urinary incontinence. The incidence of de novo urgency at 5-year follow-up was 12.3%, which is in agreement with the results published by Doo et al. [13] wherein they report 11.5% incidence of de novo urgency and urge incontinence, higher than the 6% incidence of de novo urgency reported by Chene et al. [12].

Table 4 Findings of filling and voiding cystometry at 5- and 7-year follow-up

	5 years (65 patients)	7 years (61 patients)	<i>p</i>
First desire (ml)	95.2±31.3	98.3±29.5	
Maximum cystometric capacity (ml)	363.2±60.7	362.4±57.7	NS
Maximal flow rate (ml/s)	16.7±1.8	16.6±2	NS
Postvoid residual (ml)	12.9±19.3	15.5±19.4	NS

NS No statistically significant difference

At 7-year follow-up, the incidence of de novo urgency was 19.6%, while other studies have reported an incidence of de novo urge symptoms at 6.3% [5]. The higher incidence of de novo urgency in the present study could be possibly attributed to the relatively smaller number of patients studied compared to that of other studies and to the aging of patients, which could contribute to a higher incidence of de novo urgency.

TVT procedure maintains a high efficacy at 5- and 7-year follow-up, which is comparable with the Burch colposuspension, but its efficacy at 10- and 20-year follow-up remains to be known. TVT procedure for the management of urodynamic stress incontinence appears to be a cost-effective technique at 5- and 7-year follow-up.

Conflicts of interest None.

Appendix

1. Do you feel cured from your stress urinary incontinence after the operation you had?
YES NO
2. Do you think that your incontinence has been improved after the operation you had?
YES NO
3. Do you think that you are about the same or worse after your operation for the management of your stress urinary incontinence
About the same YES NO
Worse YES NO

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