



# Assessment of the long-term outcome of TVT procedure for stress urinary incontinence in a female population: results at 17 years' follow-up

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## Abstract

**Introduction and hypothesis** To assess the outcome of the tension-free vaginal tape (TVT) procedure in female patients with urodynamic stress urinary incontinence at 17 years follow-up.

**Methods** We carried out a prospective study at the 2nd Department of Obstetrics and Gynecology, Aretaieio Hospital, University of Athens, Greece. Patients who had undergone a TVT procedure 17 years ago. The follow-up assessment included gynecological examination, urinalysis, cough stress test in the lithotomy and/or upright position, filling and voiding cystometry, and uroflow. Also, all patients were required to complete the Patient Satisfaction Questionnaire (PSQ).

**Results** Out of the 61 initial patients, 56 were available for follow-up. Objective cure rate was 83.9% (47/56) at 17 years follow-up. Subjective cure rate was 78.6% (44/56), subjective improvement was 8.9%, and failure rate was 12.5%. Frequency was present in 39.3% of patients, overactive bladder symptoms were present in 30.3% of patients and urge urinary incontinence was reported by 12.5% of patients. Difficulty emptying the bladder was reported by 10 patients (17.8%) and recurrent urinary tract infection was seen in 3.5% of patients. There was one case of TVT erosion to the vaginal mucosa, which was managed conservatively.

**Conclusions** The TVT procedure for the management of stress urinary incontinence in women maintains its efficacy in the long term, having an objective cure rate of 83.9% and a subjective cure rate of 78.6% at 17 years' follow-up, with a very low complications rate.

**Keywords** TVT · Long term · Stress incontinence · Tension-free tape · Outcome · Results

## Introduction

Stress urinary incontinence symptoms affect women's private, social, sexual, and professional life, and may alter their psychological status. These symptoms have been reported in epidemiological studies by approximately one third of the female population [1, 2]. The tension-free vaginal tape (TVT) procedure was introduced in 1996 as a minimally invasive anti-incontinence procedure for the management of stress

urinary incontinence (SUI) [3, 4]. Short-term results have showed the high efficacy and safety of the procedure [4–8]. In 2001, the trans-obturator technique (outside-in) was described by Delorme [9] and 2 years later the transobturator technique (inside-out) was published by De Leval [10] in an effort to make the surgical approach to treating SUI easier by combining the very high effectiveness of the retropubic mid-urethral sling, with reduced complication rates.

Despite the wide use of trans-obturator slings during the last decade, the TVT procedure retains its position in the surgical treatment of stress urinary incontinence and it does have satisfactory results for the treatment of recurrent SUI [5, 7]. Although very rare, bladder perforation and bleeding due to damage of the pelvic vessels are the most significant surgical complications of this procedure, and postoperative mesh erosion, dyspareunia, groin pain, and voiding dysfunction have been reported.

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The long-term efficacy of the TVT procedure at 5- and 7-year follow-up has been studied in a variety of studies [11–15], whereas clinical outcomes for a period of more than 10 years have started appearing in the literature in the last decade [16–20]. Only two studies have been published in which the follow-up period was more than 15 years [21, 22].

Objective cure rates in published studies with a follow-up period of more than 10 years vary from 82.5% [18] to 91.3% [20].

In the present study we present our experience in relation to the long-term efficacy of the TVT procedure in the management of women with urodynamic stress urinary incontinence at 17 years' follow-up.

## Materials and methods

The aim of this prospective study was to assess the outcome of the TVT procedure in patients who had undergone the TVT procedure for the management of urodynamic stress urinary incontinence 17 years ago. All the patients included had been submitted at follow-up at 5 and 7 years postoperatively and the results had been previously published [11]. Out of the initial 61 patients available at 7 years follow-up [11], 56 patients were available for follow-up at 17 years. Diagnosis of urodynamic stress urinary incontinence (USUI) and detrusor overactivity was based on the findings of urodynamic investigation. All patients had pure USUI with stage I prolapse or less of the anterior compartment according to the pelvic organ prolapse quantification system (POP-Q system) [23] for inclusion in the study.

Baseline exclusion criteria were urodynamic findings of detrusor overactivity, previous operation in the genital tract or maximum urethral closure pressure of less than 20 cmH<sub>2</sub>O, prolapse of the anterior compartment greater than stage I [23], or prolapse of the middle or posterior compartment requiring management. TVT tape adjustment was performed intraoperatively using the cough stress test at a bladder capacity of 300–350 ml. The Hospital's Ethics Committee approval was obtained and all patients had signed a preoperative informed consent for the TVT operation. The Declaration of Helsinki was followed in this study. The TVT procedure product group (Gynecare/Ethicon/Johnson and Johnson, Greece) was adhered to as has been previously

described [3, 4]. Also, all operations had been performed by the same experienced urogynecologist. The follow-up assessment at 17 years included a gynecological examination, urinalysis, a cough stress test in the lithotomy and/or upright position, filling and voiding cystometry, and uroflow. Also, all patients were required to complete the Patient Satisfaction Questionnaire (PSQ) [11].

The outcome of the operation at 17 years was assessed both subjectively and objectively.

The surgeon who had performed the operations did not participate in the team that conducted the follow-up. Objective cure was defined as the absence of any urine leakage with the cough stress test that was performed during filling cystometry and at a bladder volume between 200 and 350 ml in supine and/or upright position. Subjective cure was defined as no loss of urine during an increase in intra-abdominal pressure (coughing, weight-lifting, sneezing, etc.) as it was experienced and stated by the patient. Subjective improvement was defined as a subjectively significant reduction of urine-leaking episodes, as it was experienced and expressed by the patients. Subjective failure was defined as the absence of improvement or cure in urine-leaking episodes as it was experienced and stated by the patients. Subjective assessment was completed by patients using the PSQ questionnaire.

## Results

Out of the 61 initial patients 5 could not attend for follow-up. Three had passed away from natural causes and 2 could not be located through telephone calls. Characteristics of the 56 women who were submitted to follow-up (FLU) are shown in Table 1. Objective cure rate was 83.9% (47/56) at 17 years follow-up (Table 2). All patients who were continent at 7 years' follow-up remained continent at 17 years' follow-up. Subjective cure rate was 78.6% (44 out of 56), subjective improvement was 8.9% (5 out of 56), and failure rate was 12.5% (7 out of 56). None of the failed patients had a repeat surgery for their stress urinary incontinence. Surgery outcomes at 17 years' follow-up are summarized in Table 3.

Two patients had undergone anterior colporrhaphy for cystocele grade II at 10 and 12 years post-TVT procedure respectively. These patients were continent at 7 years' follow-up and remained continent at 17 years' follow-up.

**Table 1** Urodynamic investigation findings preoperatively and at 17 years' follow-up

	Preoperatively	17 years' follow-up	<i>p</i>
Maximum flow rate (ml/s)	24.3 ± 3.3	17.0 ± 2.1	<0.01
First desire to void (ml)	101.5 ± 32.4	97.4 ± 33.2	>0.05
Maximum cystometric capacity (ml)	346.7 ± 59.6	354.8 ± 60.2	>0.05
Postvoid residual (ml)	13.4 ± 20.7	16.5 ± 21.3	>0.05

**Table 2** Objective cure rates at 5, 7, and 17 years' follow-up

	5 years (65/70)	7 years (61/65)	17 years (56/61)	<i>p</i>
Objectively cured (stress test), % ( <i>n/N</i> )	83 (54/65)	80.3(49/61)	83.9(47/56)	0.97* 0.81**
Objectively cured considering those patients lost to follow-up as failures, % ( <i>n/N</i> )	77.1(54/70)	75.4(49/65)	77.04 (47/61)	0.99* 0.86**
Objectively cured considering those patients lost to follow-up that maintain their last outcome, % ( <i>n/N</i> )	81.4(57/70)	78.5(51/65)	80.3(49/61)	0.98* 0.88**

\*Chi-squared test

\*\*Chi-squared test for trend

Two patients were diagnosed with recurrent urinary tract infection (3.5%). Adverse events and complications are summarized in Table 4. Cystocele grade II was seen in 10.7% (6 out of 56) and rectocele grade II in 3.5% (2 out of 56). Uterine prolapse grade III was seen in 1.7% (1 out of 56) of women. No patient had postvoid residual of urine more than 50 ml. Frequency was present in 39.3% of patients (22 out of 56), whereas overactive bladder (OAB) symptoms were reported by 30.3% of patients (17 out of 56) and urge urinary incontinence was present in 41.1% of these patients (7 out of 17). Also, the symptom of difficulty emptying the bladder was reported by 17.8% patients (10 out of 56). None of these patients had residual urine more than 50 ml and their uroflow was more than 15 ml/s. There was one case of TVT erosion (documented in the patient's file) fully developed at 29 months after the operation. Vaginally protruding edges of the tape had been cut several days after the tape erosion was diagnosed. No other case of erosion was noted during the follow-up period.

## Discussion

The introduction of the TVT procedure as a minimally invasive anti-incontinence procedure [3] has been a revolution in the management of SUI. The TVT procedure based on the concepts of the “integral theory” is based on the assumption

that the midurethral placement of the polypropylene mesh tape replicates the natural midurethral backboard, naturally composed of the pubourethral ligaments and of the effective function of the pubococcygeal muscles [24]. The management of SUI for many years had been based mainly on the use of Burch colposuspension and the pubovaginal sling [25, 26]. But, these procedures have been replaced to a significant degree by the TVT operation [27]. Furthermore, there are data supporting the notion that the retropubic approach is better in patients with low maximum urethral closure pressure (MUCP) than the transobturator approach if the MUCP is <30 cm [28]. At present, there are to our knowledge only two published studies on the outcome of the TVT procedure at 17 years' follow-up with a relatively small number of patients included; therefore, more research is needed on this topic to reinforce the existing data and provide support for future meta-analysis studies to be performed.

In the present study, the objective cure rate was 83.9%. The subjective cure rate was 78.6% with 8.9% improvement rate and 12.5% failure rate. These findings are comparable with the outcome of another study with a similar follow-up period, showing an objective cure rate of 91.3% and a subjective cure rate 80% [21]. Furthermore, the findings of the study are comparable with those of two recently published studies at 13 years' follow-up with an objective cure rate of 90.9% and a subjective cure rate of 85.5% [19, 20]. The published results

**Table 3** Subjective cure rates at 5, 7, and 17 years' follow-up

	5 years (65/70)	7 years (61/65)	17 years (56/61)	<i>p</i>
Subjectively cured, % ( <i>n/N</i> )	84.6 (55/65)	78.7 (48/61)	78.6 (44/56)	0.95* 0.75**
Subjectively cured considering those patients lost to follow-up as failures, % ( <i>n/N</i> )	78 (55/70)	73.8 (48/65)	72.1 (44/61)	0.94* 0.73**
Subjectively cured considering those patients lost to follow-up that maintain their last outcome, % ( <i>n/N</i> )	82.8 (58/70)	76.9 (50/65)	75 (46/61)	0.97* 0.82**

\*Chi-squared test

\*\*Chi-squared test for trend

**Table 4** Clavien–Dindo classification of long-term complications up to 17 years' follow-up ( $N = 56$ )

Complication	% $n$	Action
Clavien grade I		
Difficulty emptying the bladder	17.8 (10/56)	Observation
Clavien grade II		
OAB symptoms	30.3 (17/56)	Antimuscarinics/ $\beta$ 3 agonists
Recurrent UTI	3.5 (2/36)	Antibiotic therapy $\pm$ prophylaxis
Clavien grade IIIa		
Tape exposure	1 (1.7)	Cutting of the projecting edges of tape into the vagina and local estrogens.

OAB overactive bladder, UTI Urinary tract infection

of the TVT procedure with a follow-up period of 10–11.5 years' support the notion that this procedure could maintain its efficacy for up to 17 years [16–18, 29].

Overactive bladder symptoms in these patients had an incidence at 17 years post-TVT procedure of 30.3%. OAB symptoms at 17 years' follow-up are significantly more frequent than the reported incidence of 18% [20] or 14.9% [29] at 10 years' follow-up. But, it is comparable with the incidence of OAB symptoms of 32.6% reported by Braga et al. [22] at 17 years' post-TVT procedure. This increase in the incidence of the de novo development of OAB symptoms could be attributed to the increased patient's age [22]. Difficulty emptying the bladder was reported by 10 patients (17.8%). None of these patients had residual urine of more than 50 ml and their urine flow at follow-up was more than 15 ml/s. This finding is supported by the incidence of voiding difficulties of 26.7% at 10 years' follow-up without objective findings to support the presence of obstruction [29] and a possible explanation could be local changes in sensation secondary to menopause. There was only one case of mesh erosion (1 out of 57); thus, the rate of this complication (1.75%) was considered very low and reassuring, taking into account the already published data [21, 23, 29, 30], but meta-analyses are a useful method of studying less common events in the literature. There were no cases of dyspareunia, pain at the site of the tape insertion, and partner pain during intercourse. Also, there were no cases requiring tape removal. Recurrent lower urine tract infection was found in 3.5% (2 out of 57). Limitation of the study could be the relatively small number of patients at follow-up mainly in relation to complications concerning tape erosion, but this could be surmounted with the use of meta-analysis studies to increase the number of patients. Furthermore, a limitation of the study could be the lack of bladder diary data and the use of only one validated questionnaire.

The findings of the present study support the notion that the TVT procedure provides a very satisfactory cure rate that is maintained at 17 years' follow-up with a very low complication rate. Therefore, the TVT procedure is an operation that has been in clinical practice for more than 20 years now, and it

appears that it has passed the test of time at least at 17 years' follow-up.

In conclusion, the TVT procedure for the management of SUI in women with pure SUI and no significant cystocele (less than or equal to grade 1) has an objective cure rate of 83.9% and a subjective cure rate of 78.6% at 17 years' follow-up, with a very low complication rate. It requires very good theoretical and practical training and experience of the operator for patient selection, a proper surgical technique, and the correct management of possible complications if they occur.

## Compliance with ethical standards

**Conflicts of interest** None.

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