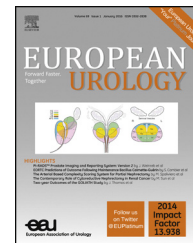


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## Incontinence

# Tension-free Vaginal Tape–Obturator for Treatment of Pure Urodynamic Stress Urinary Incontinence: Efficacy and Adverse Effects at 10-year Follow-up

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### Article info

#### Article history:

Accepted August 23, 2016

#### Associate Editor:

Christian Gratzke

#### Keywords:

Long-term follow-up  
Sling  
Stress urinary incontinence  
Tension-free vaginal tape–  
obturator  
TVT-O  
Urinary incontinence

### Abstract

**Background:** Inside-out transobturator tape (tension-free vaginal tape–obturator [TVT-O]) is currently one of the most effective and popular procedures for the surgical treatment of female stress urinary incontinence (SUI). However, data reporting long-term outcomes are lacking.

**Objective:** To assess the efficacy and safety of TVT-O 10 yr after implantation for the treatment of female pure SUI.

**Design, setting, and participants:** A multicenter, prospective study was conducted in five tertiary referral centers in three countries. All consecutive women with urodynamically proven pure SUI treated by TVT-O were included. Patients with mixed incontinence and/or anatomic evidence of pelvic organ prolapse were excluded.

**Intervention:** TVT-O implantation.

**Outcome measurements and statistical analysis:** Data regarding subjective outcomes (International Consultation on Incontinence Questionnaire–Short Form, Patient Global Impression of Improvement, and patient satisfaction scores), objective cure (stress test) rates, and adverse events were collected during follow-up. Univariable analysis was performed to investigate outcomes.

**Results and limitations:** One hundred sixty-eight women had TVT-O implantation. At 10-yr follow-up, 160 patients (95%) were available for the evaluation. We did not find any significant change of the surgical outcomes during this time. At 10 yr after surgery, 155 of 160 patients (97%) declared themselves cured ( $p = 0.7$ ). Similarly, at 10-yr evaluation, 148 of 160 patients (92%) were objectively cured. No significant deterioration of objective cure rates was observed over time ( $p = 0.4$ ). The history of failure of previous anti-incontinence procedures (hazard ratio: 5.34; 95% CI, 2.61–11.9;  $p = 0.009$ ) was the only predictor of recurrence of SUI. The onset of de novo overactive bladder was reported by 23 of 160 patients (14%) at 10-yr follow-up. No other late complications were reported.

**Conclusions:** The 10-yr results of this study showed that TVT-O is a highly effective and safe option for the treatment of SUI.

**Patient summary:** At long-term follow up, tension-free vaginal tape–obturator is highly effective and safe for the treatment of stress urinary incontinence.

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<http://dx.doi.org/10.1016/j.eururo.2016.08.054>

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Please cite this article in press as: Serati M, et al. Tension-free Vaginal Tape–Obturator for Treatment of Pure Urodynamic Stress Urinary Incontinence: Efficacy and Adverse Effects at 10-year Follow-up. Eur Urol (2016), <http://dx.doi.org/10.1016/j.eururo.2016.08.054>

## 1. Introduction

Stress urinary incontinence (SUI) is the predominant form of urinary incontinence. Depending on age, the prevalence ranges from 29–75%, with a mean of 48% [1]. Several surgical options for treating SUI, after failure of conservative measures, are available. According to the 2013 update of the International Consultation on Incontinence guidelines, the surgical treatments of SUI may include the use of bulking agents, midurethral slings (MUSs), and colposuspension [2]. It has been widely demonstrated that MUSs are the most effective and safe surgical procedures for the management of SUI compared with other techniques [3]. Several randomized controlled trials showed that transobturator insertion of a synthetic MUS gave equivalent patient-reported and clinician-reported cure rates at short- to medium-term follow-up compared with retropubic insertion [4]. Although the long-lasting benefits of the retropubic route have been adequately evaluated [5,6], long-term outcomes for the transobturator route need to be addressed.

Only six studies have assessed medium-term outcomes of the tension-free vaginal tape–obturator (TVT-O) procedure, with a maximum follow-up period of 5 yr [7–12]. In some of these studies, women with overactive bladder (OAB) symptoms or with urodynamically proven detrusor overactivity (DO) were included [8,9,12]. To date, the available evidence concerning long-term outcomes of TVT-O is limited at two studies. In one of these, Athanasiou et al [13] reported subjective and objective cure rates of 124 TVT-O procedures at 7-yr follow-up of 83.5% and 81.5%, respectively; however, this retrospective analysis included 93 procedures associated with concomitant prolapse surgery. In the other prospective, multicenter clinical trial [14], 47 TVT-O procedures were evaluated with median follow-up of 100 mo, and a subjective cure rate of 59.6% and an objective cure rate of 70.2% were found; the authors also considered women with mixed urinary incontinence. We have published a prospective, multicenter study to evaluate transobturator tape for the treatment of SUI at 5-yr follow-up [7]. The aim of the present multicenter study is to report, for the first time in the available literature to our knowledge, the long-term objective and subjective outcomes of women with TVT-O implantation for pure SUI with follow-up of  $\geq 10$  yr to assess the efficacy and safety of this procedure in the case of pure SUI.

## 2. Materials and methods

This was a multicenter, prospective study at five tertiary referral centers in three countries. From January 2004, we have enrolled all consecutive women with pure SUI symptoms with urodynamically proven urodynamic stress incontinence (USI). All patients recommended for surgery were scheduled for a TVT-O procedure (Gynecare TVT Obturator System; Ethicon Inc., Somerville, NJ, USA). Exclusion criteria were as follows: women with a history of radical pelvic surgery, psychiatric or neurologic disorders, concomitant vaginal prolapse greater than stage 1 according to the pelvic organ prolapse

(POP) quantification (POP-Q) system [15], OAB symptoms, urodynamically proven DO, and postvoid residual urine volume  $>100$  ml [16].

Preoperative evaluation included medical history, physical examination, a voiding diary, urinalysis, and complete urodynamic testing. Physical examination was performed with the patient in the lithotomy position, and POP was described during a maximal Valsalva maneuver according to the POP-Q system [15]. All women were evaluated by a trained urogynecologist with urodynamic studies as previously described [17] (including uroflowmetry, filling cystometry, Valsalva leak-point pressure [VLPP] measurement, and pressure/flow study), using a standardized protocol in accordance with the good urodynamic practice guidelines of the International Continence Society [18]. Urethral hypermobility was defined by a Q-tip test result  $>30^\circ$ . Patients were included regardless of Q-tip test results and VLPP values. All methods, definitions, and units were updated in agreement with the last version of the International Continence Society standardization of terminology [19]. All patients also completed the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF) questionnaire [20].

All the TVT-O procedures were performed according to the technique originally described by De Leval [21], using the inside-out approach. The procedure uses a polypropylene sling with two arms that are passed inside to outside through the obturator foramina, pulled to compress the bulbar urethra upward, and tied to each other across the midline. General or spinal anesthesia was used in accordance with the anesthesiologic requirements and/or the patient's preference, as previously reported [22]. Postoperative evaluations were mandatory at 12 mo, 60 mo, and 120 mo in all centers, and intermediate visits were scheduled at the physician's discretion. Every follow-up visit included medical history, physical examination, voiding diary, stress test, and evaluation of subjective satisfaction. A stress test was performed in the lithotomy and upright positions with a full bladder (ultrasonographic measurement  $\geq 400$  ml). Objective cure was defined as the absence of urine leakage during the stress test. To define the subjective outcomes at 1, 5, and 10 yr, all patients completed the ICIQ-SF, the Patient Global Impression of Improvement (PGI-I) scale (a 7-point scale, with a range of responses from 1, "very much improved," through 7, "very much worse") [23], and a patient satisfaction scale (a single, self-answered, Likert-type scale of 0–10 that grades the patient's degree of satisfaction regarding continence: 0 indicates "not satisfied," and 10, "satisfied") [24]. Subjective success was indicated both by "very much improved" or "much improved" (PGI-I score  $\leq 2$ ) and by a patient satisfaction score  $\geq 8$ , as previously described in 2011 by Abdel-Fattah et al [25].

The Declaration of Helsinki was followed, and preoperative written informed consent for TVT-O implantation was obtained from all patients in this observational prospective evaluation.

### 2.1. Statistical analysis

Statistical analysis was performed with IBM-SPSS v.17 for Windows (IBM Corp, Armonk, NY, USA). Continuous variables were reported as median and interquartile range. We used the  $\chi^2$  test and  $\chi^2$  test for trend to analyze and compare the surgical outcomes during the follow-up. The  $\chi^2$  test for trend can better assess if the success of the surgical procedure tends to decrease over time, comparing the cure rates at the different follow-up visits (1, 5, and 10 yr). The null hypothesis is that there is not an association between the cure rate of TVT-O and the time. One-way analysis of variance was used to compare continuous series of variables in the comparison of the scores used to measure the subjective outcomes. The Cox proportional hazards model was used for univariate analysis to evaluate factors potentially affecting the risk of recurrence (subjective or objective) during the study period. Statistical significance was considered achieved when  $p < 0.05$ .

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