



Impact of Preoperative Patient Characteristics and Flow Rate on Failure, Early Complications, and Voiding Dysfunction After a Transobturator Tape Procedure: A Multicentre Study

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Purpose: To evaluate the impact of preoperative patient characteristics and flow rate on failure, early postoperative complications, and voiding in patients who underwent transvaginal tension-free vaginal tape-obturator (TVT-O) treatment for uncomplicated stress urinary incontinence (SUI).

Methods: We retrospectively reviewed patients who underwent TVT-O for SUI at 3 Italian centres. The exclusion criteria were predominant voiding and storage symptoms suggestive of detrusor overactivity, the presence of grade > 1 urogenital prolapse, previous pelvic radiotherapy or other clinical contraindications for surgical procedures, neurogenic bladder dysfunction, and collagen diseases. Multivariate logistic regression models were constructed to identify predictors of early voiding dysfunction after TVT-O.

Results: A total of 219 patients underwent TVT-O between January 2010 and December 2015. All patients received follow-up at 3, 6, and 12 months, and underwent a stress test, uroflowmetry, and bladder ultrasound to evaluate the postvoid residual volume. They also responded to the Urogenital Distress Inventory (UDI-6) questionnaire. The rates of persistent incontinence after TVT-O, postoperative complications, and satisfaction were 16.4% (36 of 219), 24.2% (53 of 219), and 86.3% (189 of 219), respectively. Nineteen patients (9.5%) experienced early voiding dysfunction. Based on an analysis of baseline characteristics, we determined that a cutoff value of 9.0 on the UDI-6 predicted postoperative SUI with 62% specificity, 72% sensitivity, and 66% accuracy. In the multivariate logistic regression analysis, a preoperative UDI-6 ≥ 9.0 was an independent predictor of postoperative SUI. The predictors of complications were menopause ($P = 0.04$) and the preoperative UDI-6 score ($P = 0.01$).

Conclusions: Menopause and UDI-6 scores could be prognostic factors for persistent SUI after TVT-O. Well-designed prospective studies with a suitable number of patients are needed to corroborate our findings.

Keywords: Urinary Incontinence; Urethral Sling; Urinary Incontinence, Stress; Tension-Free Vaginal Tape; Urodynamics

- **Research Ethics:** This study was approved by Institutional Review Board of the participating Institutions (90/2015). A written informed consent was obtained from all subjects.
- **Conflict of Interest:** No potential conflict of interest relevant to this article was reported.

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INTRODUCTION

Stress urinary incontinence (SUI) is a debilitating condition with a negative impact on well-being due to sexual dysfunction, physical morbidity, and loss of independence, work, and social life. The diagnostic evaluation is based on a careful clinical history, voiding diaries, pad testing, and urodynamic studies [1].

Midurethral slings (MUS) represent the gold standard for the treatment of uncomplicated female SUI [2-4]. The transobturator and retropubic approaches were found to be equally effective for the treatment of SUI [5]. Although the transient voiding dysfunction risk seems to be equivalent between those 2 approaches, the long-term voiding dysfunction risk is lower in patients who undergo transobturator tape (TOT) treatment [6,7].

Voiding dysfunction following MUS has been reported in between 1.6% and 39% of cases [8,9], and its management includes long-term intermittent self-catheterization, indwelling bladder catheter placement, and tape mobilization and division; these treatment strategies have important impacts on patients' satisfaction.

Age, severe preoperative urge urinary incontinence, and surgical complications are risk factors for long-term sling failure [10].

Preoperative urodynamic studies have a significant impact on the clinical diagnosis and the likelihood of additional postoperative treatment [8], and it is mandatory to distinguish between complicated and uncomplicated cases of incontinence [11].

Controversy exists regarding the preoperative risk factors for postoperative voiding dysfunction, and the impact of urodynamic factors is still debated [9,10,12-15]. As the peak urinary flow rate is an independent predictive factor for urinary retention after tension-free vaginal tape procedures [13], patients with a low preoperative flow rate can safely receive tension-free vaginal tape-obturator (TVT-O) treatment [16].

Furthermore, conflicting results were reported regarding predictors of sling failure [17-21], and sparse data exist on preoperative risk factors of persistent SUI after TOT [8].

The aim of this study was to evaluate the impact of preoperative patient characteristics and flow rate on the failure rate, early postoperative complications, and voiding in patients who underwent TVT-O for uncomplicated SUI.

MATERIALS AND METHODS

Patient Selection

We retrospectively reviewed consecutive patients who underwent a TVT-O procedure for uncomplicated SUI at 3 Italian centres (Florence, Verona, and Catania) between January 2010 and December 2015.

The exclusion criteria were predominant voiding and storage symptoms suggestive of detrusor overactivity, based on an analysis of a bladder diary; the presence of grade >1 urogenital prolapse (according to the Baden and Walker classification [22]) beyond the hymen or symptomatic prolapse; previous pelvic radiotherapy or other clinical contraindications for surgical procedures; neurogenic bladder dysfunction; and collagen diseases. After receiving instructions and providing written informed consent, all patients underwent a TVT-O procedure.

Patient Evaluation

Before surgery, all patients underwent a comprehensive assessment including a clinical history (especially for pelvic reconstructive procedures or hysterectomy), a physical examination, pad usage analysis, and uroflowmetry (UFM) according to good urodynamic practices [21]. The Urogenital Distress Inventory (UDI-6), the International Consultation on Incontinence Questionnaire Urinary Incontinence form, a bladder diary, a visual analogue scale, demographic information, medical history, and symptoms of lower urinary tract and pelvic floor dysfunction were assessed before and after MUS surgery. Conservative measures, such as bladder retraining and/or pelvic floor physiotherapy, had been previously tried in all patients, but did not succeed.

Uroflowmetry

Noninstrumented UFM was performed before the procedure. All patients voided, with a comfortably full bladder, in sitting position into a gravimetric uroflowmeter (Danflow 1100, SynMed Medicinteknik AB, Silkeborg, Denmark). According to good urodynamic practices [21], peak flow rate (PFR), voided volume, and postvoid residual (PVR) volume were recorded.

Surgical Procedure

Surgery was performed using a TVT-O sling. All patients received broad-spectrum intravenous antibiotic prophylaxis 1 hour before surgery. The operations were performed as previously described [23,24]. All procedures were performed under

local analgesia with light sedation, and a cough stress test was performed intraoperatively to avoid postoperative voiding difficulties.

Cystoscopy was performed in the operating room if visceral lesions were suspected, or during follow-up if the patient presented with postoperative moderate or severely irritative urinary symptoms or recurrent urinary tract infections.

The MUS was adjusted using the cough stress test with an intravesical volume of 300 mL to prevent urinary leakage and to avoid overtension. Patients were discharged after 2 spontaneous micturition episodes with a PVR < 100 mL. Patients were admitted overnight and discharged with 24 hours of oral antibiotics.

Follow-up After Surgical Procedure

All patients received follow-up at 3, 6, and 12 months and underwent a stress test, UFM, and bladder ultrasound to evaluate the PVR volume. They also responded to the UDI-6 questionnaire. The patients were considered cured when there was no subjective or objective evidence of SUI. We defined successful SUI treatment as the loss of < 200 mL of urine or the use of one pad per day, in addition to a negative stress test [20,21]. Early voiding dysfunction was considered to be present when the patient required catheterisation within 48 hours of the procedure [15]. The procedure was considered a failure when the cure criteria were not achieved. The presence of complications, according to the Clavien-Dindo classification [25], and the reoperation rates were evaluated over the course of follow-up as secondary endpoints. Patient satisfaction after treatment was evaluated according to the Patients' Global Impression of Change scale [26].

Statistical Analysis

Continuous variables are presented as median (interquartile range), and differences between groups were tested by the Student independent t-test or the Mann-Whitney U-test depending on whether their distribution was normal, as tested by the Kolmogorov-Smirnov test.

Multivariate logistic regression models were constructed to identify predictive factors of early voiding dysfunction by including all the collected variables. One thousand bootstrap resamples were used for all accuracy estimates and to reduce the overfit bias. Area under the curve values were also calculated to identify the UDI-6 cutoff score most suitable for predicting postoperative SUI.

All tests were conducted using IBM SPSS Statistics ver. 19.0 (IBM Co., Armonk, NY, USA). For all statistical comparisons, P-values < 0.05 were considered to indicate statistical significance.

RESULTS

A total of 219 patients underwent TVT-O between January 2010 and December 2015. Their baseline characteristics are presented in Table 1. All patients completed follow-up as scheduled, at 3, 6, and 12 months. Their mean age was 59 years, with a median body mass index (BMI) of 27 kg/m²; 63.9% of the patients were in menopause. No patients underwent hormone replacement therapy. Table 2 shows the characteristics of the patients according to preoperative PFR.

Diabetes and hypertension were present in 7.7% and 27.3% of the cases, respectively. We observed significant changes in the mean PFR (24.95 mL/sec vs. 30.34 mL/sec, $P < 0.05$), mean PVR (40.85 mL vs. 7.37 mL, $P < 0.01$), and mean UDI-6 score (9.47 vs. 1.36, $P < 0.01$) after surgery.

Incontinence persisted after surgery in 16.4% (36 of 219) of the participants, while the satisfaction rate was 86.3% (189 of 219). The postoperative complication rate was 24.2% (53 of 219), including 41 cases of Clavien-Dindo classification grade I complications (18.7%) and 12 cases of Clavien-Dindo classification

Table 1. Baseline characteristics of patients (n = 219)

Characteristic	Value
Age (yr)	59 (50–67)
Body mass index (kg/m ²)	27 (24–29)
Number of childbirth	2 (1–2)
Pad/day	3 (2–4)
Peak flow rate (mL/sec)	23.25 (18.15–31.37)
Postvoid residual (mL)	40.85 (37.85–45.22)
UDI-6	10 (6–12)
Menopause	140 (63.9)
Diabetes	17 (7.8)
Hypertension	60 (27.4)
Type of childbirth	
Normal	145 (66.2)
Episiotomy	20 (9.1)
Dystocic	21 (9.6)
Laceration	33 (15.1)

Values are presented as median (interquartile range) or number (%). UDI-6, Urogenital Distress Inventory.

Table 2. Characteristics of patients according to preoperative peak flow rate

Characteristic	Qmax (mL/sec)		P-value
	< 15 (n=21)	≥ 15 (n=180)	
Age (yr)	59.87 (53.83–72.76)	58.0 (50.48–65.93)	0.58
Body mass index (kg/m ²)	27.34 (24.57–30.31)	26.56 (23.88–29.38)	0.43
Number of childbirth	2 (1–2)	2 (1–2)	0.47
Pad/day	3 (2–4)	3 (2–4)	0.42
Preoperative UDI-6	9.47 (7.5–13.0)	9.47 (9.0–11.0)	0.43
Preoperative voided volume	370.0 (318.5–408.52)	-	
Menopause	15 (71.4)	125 (69.4)	0.85
Type of childbirth			0.18
Normal	12 (57.1)	115 (63.9)	
Episiotomy	1 (4.8)	19 (10.6)	
Dystocic	5 (23.8)	16 (8.9)	
Laceration	3 (14.3)	30 (16.7)	
Postoperative PFR	30.34 (25.50–30.34)	30.34 (26.62–30.34)	0.68
Postoperative UDI6	1.36 (0–1.68)	1.36 (0–1.36)	0.89
Postoperative voided volume	329.16 (319.20–335.6)	329.16 (307.50–339.16)	0.35
Postoperative PFR–preoperative PFR	17.5 (15.17–22.09)	4.74 (-4.17 to 9.46)	<0.01
Postoperative voided volume–preoperative voided volume	-79.35 (-101.02 to -13.83)	-79.35 (-128.14 to 59.62)	0.36

Values are presented as median (interquartile range) or number (%).
 Qmax, maximum flow rate; UDI-6, Urogenital Distress Inventory; PFR, peak flow rate.

Table 3. Multivariate logistic regression of predictive factors of failure of TVT-O

Variable	OR (95% CI)	P-value
Age (yr)	1.02 (0.94–1.10)	0.60
Body mass index (kg/m ²)	1.17 (0.97–1.40)	0.09
Number of childbirth	0.62 (0.32–1.18)	0.15
Pad/day	1.12 (0.95–1.32)	0.18
Peak flow rate (mL/sec)	0.97 (0.90–1.04)	0.43
Postvoid residual (mL)	1.00 (0.99–1.01)	0.43
UDI-6	1.24 (1.04–1.50)	0.02
Menopause	6.19 (0.68–56.45)	0.03
Type of childbirth	1.64 (0.11–23.22)	0.72

TVT-O, tension-free vaginal tape-obturator; OR, odds ratio; CI, confidence interval; UDI-6, Urogenital Distress Inventory.

cation grade II complications (5.5%). No major complications (Clavien-Dindo classification grade ≥ III) were observed.

In the multivariate logistic regression analysis, the preoperative UDI-6 score (odds ratio [OR], 1.21; 95% confidence interval [CI], 1.04–1.50; P=0.02) and menopause (OR, 6.19; 95% CI, 0.68–56.45; P=0.03) were independent predictors of failure after a TVT-O procedure (Table 3).

Based on a receiver operating characteristics analysis, we determined that a cutoff value of 9.0 on the UDI-6 scale predicted postoperative SUI with 62% specificity, 72% sensitivity, and 66% accuracy. In the multivariate logistic regression analysis, a preoperative UDI-6 score ≥ 9.0 (OR, 2.81; 95% CI, 0.96–8.22; P=0.04) was an independent predictor of postoperative SUI. The only predictors of complications were menopause (OR, 6.44; 95% CI, 1.26–32.94; P=0.04) and the preoperative UDI-6 score (OR, 1.23; 95% CI, 1.05–1.34; P=0.01). After surgery, 19 patients (9.5%) experienced early voiding dysfunction. In the multivariate logistic regression analysis (adjusted for age, BMI, number of children, and the UDI-6 score), the preoperative PFR (OR, 0.98; P=0.62) and preoperative PVR (OR, 0.99; P=0.25) were not associated with early voiding dysfunction.

DISCUSSION

MUS represent the gold standard treatment for SUI, with high rates of recovery of continence. Since transvaginal tape was introduced in 1996, this procedure has become one of the most commonly used SUI treatments [21]. The TOT procedure appears to be associated with a lower incidence of postoperative

voiding dysfunction [27]. However, some patients may present voiding dysfunction after surgery. In fact, no standard definition exists of postoperative voiding dysfunction after anti-incontinence surgery.

The International Urogynecological Association/International Continence Society joint report on the terminology for female pelvic floor dysfunction defines voiding dysfunction as follows: “Voiding dysfunction, a diagnosis by symptoms and urodynamic investigations, is defined as abnormally slow and/or incomplete micturition. Hesitancy is a complaint of a delay in initiating micturition. Slow stream is a complaint of urinary stream perceived as slower compared to previous performance or in comparison with others. Intermittency is a complaint of urine flow that stops and starts on one or more occasions during voiding. Feeling of incomplete (bladder) emptying is a complaint that the bladder does not feel empty after passing urine. PVR (urine volume) quote upper limits of normal of 50 or 100 mL” [28].

The treatment of voiding dysfunction is still controversial and depends from the timing of onset. Several options can be used, including short- (up to 48 hours) or long-term self-catheterisation, tape mobilisation (2.4% of cases), or tape loosening to achieve a more desirable tension without interfering with the urinary flow [29].

In our study, we identified early voiding dysfunction in 19 of 219 patients (9.5%) who underwent TVT-O and required urethral catheterization within 24–48 hours after Foley catheter removal.

Mutone et al. [15] demonstrated that, in 153 patients who underwent TVT, previous incontinence surgery and previous prolapse ($P=0.08$ and $P=0.06$) were associated with voiding dysfunction.

Lucena et al. [13] reviewed 100 patients who underwent a retropubic MUS procedure. The univariate analysis demonstrated that an abnormal PFR for voiding was associated with an increased risk of voiding dysfunction ($P=0.046$) and that women with a larger bladder capacity (490 mL vs. 457 mL, $P=0.04$) were slightly protected.

Preoperative urodynamic assessments aim to confirm the diagnosis (in case of doubt), to demonstrate the mechanism(s), and to identify factors that may affect treatment outcomes. However, whether urodynamic assessments improve long-term outcomes following surgery remains controversial, and there is a lack of high-level evidence to support the assertion that urodynamic assessments can predict the complications of surgery [30].

Some studies have demonstrated that preoperative urody-

dynamic findings, such as high preoperative PVR, low preoperative PFR, and low detrusor pressure during a pressure-flow study, might predict postoperative voiding dysfunction after anti-incontinence surgery [31–33].

Nevertheless, other studies have failed to demonstrate urodynamic predictors of post-MUS voiding dysfunction. Chang et al. [34] postoperatively evaluated 449 patients who underwent TOT. Preoperative urodynamic parameters did not demonstrate reproducible predictors of voiding dysfunction.

In our study, the preoperative flow rate was not shown to be a potential risk factor for the occurrence of early voiding dysfunction after a TVT-O procedure. The postoperative incontinence rate was 16.4%, the complication rate was 24.2%, and the satisfaction rate was 86.3%.

Serati et al. [16], in a prospective, multicentre, observational study of 191 women presenting with urodynamically proven pure SUI treated by TVT-O, documented that failure of a previous incontinence treatment procedure was the only independent predictor of subjective recurrence of SUI (hazard ratio [HR], 4.4; $P=0.009$) or objective recurrence (HR, 3.7; $P=0.02$).

In our study, menopause and the UDI-6 score were the only preoperative risk factors for early TVT-O failure and early complications. An interpretation of these findings could be related to the sensitivity of the lower urinary tract to estrogens due to its shared common embryological origin with the female genital tract [35]. Substantial hormonal changes happen at menopause, with impacts on all oestrogen-sensitive tissues. In particular, oestrogens target the functional layers of the urethra (epithelium, vasculature, connective tissue, and muscle) which are fundamental for maintaining continence.

However, some limitations should be addressed. First, the retrospective nature of the study should be considered. Moreover, we did not collect more details about diabetes, such as glycated haemoglobin levels, which may be risk factors for incontinence.

In conclusion, women suffering from uncomplicated SUI with a low preoperative flow rate can safely undergo TVT-O. The short-term treatment success rate was found to be high. Menopause and the UDI-6 score may be prognostic factors for persistent SUI after TVT-O. Well-designed prospective studies with a suitable number of patients are needed to corroborate our findings.

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