



# Transobturator Tape for Female Stress Urinary Incontinence: Preoperative Valsalva Leak Point Pressure Is Not Related to Cure Rate or Quality of Life Improvement

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**Purpose:** We investigated whether the Valsalva leak point pressure (VLPP) is valuable for predicting postoperative outcome measurement after transobturator suburethral tape (TVT-O) implantation for treating stress urinary incontinence (SUI) in women. **Materials and Methods:** A total of 204 female patients who underwent TVT-O placement for treatment of SUI from March 2008 to February 2012 were enrolled in this retrospective study. All patients completed the incontinence quality of Life questionnaire (I-QoL), a self-reported quality of life measure specific to urinary incontinence, and the cure rate of incontinence was measured before and 6 months after surgery. Cure was defined as no leakage of urine postoperatively both subjectively and objectively. We compared pre- and postoperative I-QoL scores according to preoperative VLPP and Stamey grade.

**Results:** The numbers of patients with Stamey grades I, II, and III were 99 (48.5%), 84 (41.2%), and 21 (10.3%), respectively. A total of 30 (14.7%), 87 (42.6%), and 87 patients (42.6%) showed VLPP ≤ 60, 60 < VLPP ≤ 90, and VLPP > 90 cm H<sub>2</sub>O, respectively. Preoperative VLPP was not significantly different according to preoperative I-QoL or change in I-QoL after surgery. However, I-QoL after surgery improved in patients with a high preoperative Stamey grade (p=0.001).

**Conclusions:** VLPP was not a factor related to surgical outcome from the midurethral sling procedure. Stamey grade rather than VLPP was important for predicting subjective quality of life and improved incontinence-related quality of life after surgery.

**Keywords:** Suburethral sling; Treatment outcome; Urinary incontinence; Urodynamics

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## INTRODUCTION

Stress urinary incontinence (SUI), which is a complaint of involuntary urine leakage on effort, exertion, sneezing, or coughing [1], is a common functional disease in women. Understanding of the physiopathological concepts of female SUI has steadily developed and the application of this improved understanding has led to improved surgical procedures aimed at correcting this disorder. Since the tension-free vaginal tape (TVT) procedure was first reported by Ulmsten et al. [2] in 1996, midurethral sling procedures

have been considered safe and effective for treating female SUI. In 2002, Delorme et al. [3,4] described the transobturator technique for a midurethral sling in which they passed the tape through the obturator foramen from outside to inside. De Leval [5] demonstrated a transobturator midurethral sling procedure in which the sling passes the obturator foramen from inside to outside. In long-term follow-up studies, the transobturator technique has similar efficacy and safety compared with that of TVT [6,7]. Despite the popularity of these procedures, prognostic factors for the surgical outcome of correcting SUI are still

debated.

Valsalva leak point pressure (VLPP) is defined by the International Continence Society (ICS) as the intravesical pressure generated by the Valsalva maneuver at which urine leakage occurs owing to increased abdominal pressure in the absence of detrusor contraction [1]. VLPP has been used as an indicator representing the objective severity of SUI [8]. Clinical application of VLPP remains controversial, however, and the effect of VLPP on treatment outcome of distal polypropylene sling procedures or pubovaginal sling procedures is undetermined [9,10]. Only a few studies have examined outcomes of transobturator midurethral slings stratified by the preoperative severity of urinary incontinence [11-13]. Additionally, few studies have assessed the relationship between incontinence severity and validated disease-specific quality of life [13]. Thus, we designed this study to assess the influence of preoperative VLPP and Stamey grade on quality of life and surgical outcome from transobturator midurethral tape implantation for treating SUI in women.

## MATERIALS AND METHODS

### 1. Subjects and study design

A total of 204 female patients who underwent transobturator midurethral sling placement for the treatment of urodynamic SUI from March 2008 to February 2012 were included in this retrospective study. Inclusion criteria were stress or mixed urinary incontinence defined according to ICS guidelines. The preoperative evaluation consisted of a detailed history, urologic physical examination, and a urodynamic study (UDS). The physical examination included a pelvic organ prolapse quantification system classification [14], Q-tip test, and a stress test in the lithotomy position at physiological maximum bladder capacity. All patients underwent a preoperative UDS, including uroflowmetry, provocative cystometry, and urethral profilometry. The Stamey incontinence score (grade 0, continent; grade 1, loss of urine with sudden increase in abdominal pressure such as from coughing, sneezing, or laughing; grade 2, leaks with lesser degrees of physical stress such as walking, standing erect from a sitting position, or sitting up in bed; grade 3, total incontinence, urine is lost without any relation to physical activity or position) was checked to represent SUI severity in all enrolled patients [15]. In cases of grade 3, we executed cystoscopy or a radiological evaluation to rule out the possibility of a fistula. Patients were then stratified by Stamey incontinence score into three groups (grades 1, 2, 3). All surgery was performed under spinal or general anesthesia according to the decision of the anesthesiologist. Suburethral tape was inserted via an inside-out transobturator midurethral sling (TVT-O; Gynecare, Chaska, MN, USA) by the same experienced surgeon in all patients (S.O.K.). The follow-up examination at 6 months included a physical examination with a stress test, an interview for signs and symptoms, and assessment of patient satisfaction with the procedure. The

procedure for this study complied with the guidelines provided by the Declaration of Helsinki.

### 2. Exclusion criteria

Patients were excluded from this study according to the following criteria: patients who had undergone previous spine or brain surgery, patients with concomitant high-grade pelvic organ prolapse (> grade III), patients with a history of urinary retention with residual urine > 200 mL, and patients with active urinary tract infection (confirmed by Nélaton catheterization and urinalysis) and other urologic disease. Patients using drugs that could have an impact on bladder and urethral function, such as alpha-adrenergic receptor agonists or antagonists, were also excluded. Potential patients who had any possible cause of neurogenic bladder were excluded.

### 3. Outcome measure

The incontinence quality of life questionnaire (I-QoL), a self-reported quality of life measure specific to urinary incontinence, was completed, and the objective cure rate of incontinence was measured by a stress test before and 6 months after surgery. Cure was defined as no leakage of urine postoperatively both subjectively and objectively, and improvement was defined as no urine leakage on a subjective exam with subjective urine leakage sometimes but with overall satisfaction, whereas failure was defined as objective loss of urine during the stress test. We compared the pre- and postoperative I-QoL scores and cure rates according to preoperative VLPP and Stamey grade.

### 4. Measurement of VLPP

Multichannel UDS investigations were done according to the ICS protocol [ISD8]. Conventional filling cystometry was performed with patients in the supine position. The bladder was filled at a constant rate of 50 mL/min by using normal saline solution at room temperature for standard UDS. VLPP was obtained with the subject seated when the total infused volume of sterile water reached 200 mL by asking the patient to perform a Valsalva maneuver until urine loss was directly observed. The VLPP, a measurement of the lowest abdominal pressure required to produce urine leakage, was recorded and was repeated to verify the initial finding. If a urine leak was not noted with the Valsalva maneuver, the patient was asked to cough. Patients were categorized into three groups on the basis of preoperative VLPP: group 1 (VLPP ≤ 60 cm H<sub>2</sub>O), group 2 (60 < VLPP ≤ 90 cm H<sub>2</sub>O), and group 3 (VLPP > 90 cm H<sub>2</sub>O).

### 5. Statistical analyses

SPSS ver. 17 (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. Data were analyzed by one-way analysis of variance and Bonferroni's post hoc test. Data are expressed as mean ± standard deviation. p-values < 0.05 were considered significant.

**RESULTS**

Table 1 shows the patient characteristics. The mean age of the patients was 52.8±9.6 years, and the duration of disease was 61.4±58.0 months. Three patients had a hormonal therapy history, and no patient had undergone radiation therapy. Incontinence was the pure SUI type in 171 patients (83.8%), whereas 33 patients (16.2%) showed a mixed type of stress and urgency urinary incontinence. The numbers of patients with Stamey grades I, II, and III were 99 (48.5%), 84 (41.2%), and 21 (10.3%), respectively, and 30 (14.7%), 87 (42.6%), and 87 patients (42.6%) showed VLPP ≤ 60 cm H<sub>2</sub>O, 60 < VLPP ≤ 90 cm H<sub>2</sub>O, and VLPP > 90 cm H<sub>2</sub>O, respectively.

Table 2 shows the objective cure rate and changes in I-QoL scores according to preoperative VLPP. No significant difference was observed in objective cure rate (p=0.860), preoperative I-QoL (p=0.327), postoperative I-QoL (p=0.560), or changes in I-QoL (P=0.924) between the groups when we compared outcome by preoperative

VLPP. Measuring outcome by preoperative Stamey grade also did not make a significant difference in objective cure rate (p=0.985) or postoperative I-QoL (p=0.944). However, preoperative I-QoL scores were significantly different (p=0.001) between the groups. A significantly lower I-QoL score was found and the score improved remarkably after surgery (p=0.001) when patients had a high preoperative Stamey grade (Table 3).

**DISCUSSION**

We found that VLPP was not related to the cure rate or quality of life after the midurethral sling operation for treating SUI. However, preoperative quality of life was significantly different between the groups, with a significantly lower I-QoL score and pronounced improvement after surgery when patients had a high preoperative Stamey grade. These results suggest that Stamey grade rather than VLPP is important for predicting subjective satisfaction and improved incontinence-related quality of life after midurethral sling surgery in women.

VLPP has been used as an objective determination of SUI severity in women to distinguish between intrinsic sphincter deficiency and urethral hypermobility as a cause of SUI [16]. Women with low VLPP on UDS have been considered to be at increased risk for surgical failure after anti-incontinence surgery [17]. VLPP has been used to predict the surgical outcome of midurethral sling surgery for correcting SUI and to choose an optimal surgical treatment in each woman [17,18]. McGuire et al. [18] demonstrated that VLPP is a reliable method for assessing the urethral sphincter mechanism. These findings were confirmed by O'Connor et al. [12], who reported that 77% of patients with a preoperative VLPP > 60 cm H<sub>2</sub>O were cured compared with 25% of patients with VLPP ≤ 60 cm H<sub>2</sub>O. Similarly, Romancik et al. [19] specifically investigated VLPP as an outcome-predicting factor in 65 patients who underwent TOT and found cure and success rates to be significantly higher in patients with VLPP > 60 cm H<sub>2</sub>O (78% and 100%, respectively) than in patients with VLPP ≤ 60 cm H<sub>2</sub>O (25% and 78%; p < 0.005 and p=0.025, respectively).

In contrast, Rodriguez et al. [9] reported a different result in a recent investigation into preoperative VLPP as a

**TABLE 1.** Patient characteristics

Characteristic	Value
Age (y)	52.8±9.6
Duration (mo)	61.4±58.0
Pregnancy	3.19±1.66
Delivery	3.16±1.63
Hormonal therapy	3 (4.4)
Incontinence type	
SUI	171 (83.8)
MUI	33 (16.2)
Stamey grade	
I	99 (48.5)
II	84 (41.2)
III	21 (10.3)
VLPP (cm H <sub>2</sub> O)	
≤ 60	30 (14.7)
> 60, ≤ 90	87 (42.6)
> 90	87 (42.6)

Values are presented as mean±standard deviation or number (%). SUI, stress urinary incontinence; MUI, mixed urinary incontinence; VLPP, Valsalva leak point pressure.

**TABLE 2.** Changes in I-QoL score according to VLPP

	VLPP (cm H <sub>2</sub> O)			p-value <sup>a</sup>
	≤ 60	> 60, ≤ 90	> 90	
Objective cure rate (%)	98.1	97.5	98.3	0.860
I-QoL score				
Preoperative	49.3±15.0	52.6±20.0	58.7±21.1	0.327
Postoperative	88.1±14.0	89.3±21.3	94.1±18.8	0.560
Changes	38.8±15.3	36.7±26.4	25.3±24.7	0.924

Values are presented as mean±standard deviation.

I-QoL, incontinence quality of life; VLPP, Valsalva leak point pressure.

<sup>a</sup>:One-way analysis of variance.

**TABLE 3.** Changes in I-QoL score according to Stamey grade

	Stamey grade			p-value <sup>a</sup>
	I	II	III	
Objective cure rate (%)	97.9	98.1	98.0	0.985
I-QoL score				
Preoperative	67.3±17.6	45.1±14.7	34.0±2.16	0.001 <sup>b</sup>
Postoperative	90.6±21.7	92.1±17.2	90.1±16.6	0.944
Changes	23.3±20.0	46.9±22.0	56.1±15.0	0.001 <sup>c</sup>

Values are presented as mean±standard deviation.

I-QoL, incontinence quality of life.

<sup>a</sup>:One-way analysis of variance. <sup>b</sup>:Bonferroni *post hoc* test, I vs. II (p=0.001), I vs. III (p=0.001), II vs. III (p=0.288). <sup>c</sup>:Bonferroni *post hoc* test, I vs. II (p=0.001), I vs. III (p=0.001), II vs. III (p=0.881).

predictor of outcome after the urethral sling procedure. They evaluated 174 patients who underwent a distal urethral sling procedure in four groups according to VLPP values (group 1, no leakage; group 2, VLPP > 80 cm H<sub>2</sub>O; group 3, VLPP 30–80 cm H<sub>2</sub>O; group 4, VLPP < 30 cm H<sub>2</sub>O). Regardless of the VLPP, the overall objective cure rates were similar in all groups (95%, 92%, 93%, and 92%, respectively) as were patient-reported outcomes and the number of daily pads used, even though patients with low VLPP had used more pads per day before surgery [9]. Consistent data were reported in a study on 75 consecutive patients with urodynamically proven SUI who underwent TVT surgery [20]. When stratified according to preoperative VLPP, 36 patients (48%) had VLPP ≤ 60 cm H<sub>2</sub>O and 39 patients (52%) had VLPP > 60 cm H<sub>2</sub>O. When cure rates were compared with preoperative VLPP, no significant difference emerged at a mean follow-up of 21.6 months (89.7% vs. 88.9%, respectively). Furthermore, a multicenter well-powered study confirmed that VLPP does not predict outcome success after Burch or an autologous fascia lata sling procedure in women with pure or predominant SUI at a 24-month follow-up [10]. Thus, consensus is lacking on whether preoperative VLPP predicts outcome from anti-incontinence surgery, but the current trend on this issue is that surgical outcome is not associated with preoperative VLPP.

Reports suggesting that all types of incontinence can be treated by a similar surgical method and that a distal urethral sling cures incontinence without correcting urethral hypermobility support the results of the present study. However, our results showed that Stamey grade rather than VLPP was important for predicting baseline subjective score of quality of life and improvement in incontinence-related quality of life after midurethral anti-incontinence surgery in women with SUI. Our results suggest that preoperative UDS fails to improve the rate of treatment outcome.

The necessity and usage of preoperative UDS is still questioned, and related studies have been conducted. Nager et al. [21] recently reported in their multicenter randomized study that a preoperative office evaluation alone is not inferior to a UDS for surgical outcome in women

with uncomplicated, demonstrable SUI. The National Institutes for Health and Clinical Excellence advised against routine UDS in women with a clearly defined clinical diagnosis of pure SUI, although some organizations recommend routine UDS before surgery for SUI [22,23].

Moreover, it is not easy to use VLPP to assist in choosing the surgical method or surgical decision because the methodology is not standardized. Many related factors such as catheter size, bladder volume, patient position, and Valsalva method or cough could influence the VLPP measurement, and all clinicians must recognize this fully when they analyze the results [24].

This study had some limitations. We could not analyze the subdomains of I-QoL. We could not address the role of VLPP in women with more challenging issues including urgency-predominant incontinence, incontinence combined with neurologic disease, previous surgery, or SUI concomitant with pelvic organ prolapse. We included some patients with mixed urinary incontinence, and the urgency component of incontinence was not completely excluded when we analyzed the data, which possibly affected the results.

## CONCLUSIONS

Preoperative VLPP was not correlated with surgical outcome after a transobturator midurethral sling procedure. Stamey grade rather than VLPP was related with preoperative baseline quality of life and improvement of quality of life after surgery.

## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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