

# FACTORS PREDICTIVE OF URINARY RETENTION AFTER A TENSION-FREE VAGINAL TAPE PROCEDURE FOR FEMALE STRESS URINARY INCONTINENCE

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## ABSTRACT

**Purpose:** We performed this study to evaluate factors related to urinary retention after a tension-free vaginal tape (TVT) procedure for female stress urinary incontinence.

**Materials and Methods:** We retrospectively analyzed the records of 375 women with a followup of at least 6 months from among patients who underwent the TVT procedure between March 1999 and May 2002 at our institution. We analyzed multiple parameters, including patient characteristics, symptoms and urodynamic studies, using univariate and multivariate regression analyses with respect to postoperative urinary retention, as defined by the need for intermittent catheterization for at least 3 days after the procedure. All patients in the nonretention (343) and retention (32) groups answered a global satisfaction question.

**Results:** In answer to a global satisfaction question 338 of the 375 patients (90.1%) favored the procedure. Univariate analysis demonstrated that patient mean age, parity, peak urinary flow and a history of hysterectomy predicted urinary retention. However, on multivariate analyses the peak urinary flow rate was the only significant independent predictive factor ( $p = 0.007$ ). While 28 patients (87.5%) in the retention group regained normal voiding without a specific procedure, 4 required tape release or cutting within 3 month of surgery. The global satisfaction question showed a significant difference between the nonretention and retention groups (91.5% vs 75% satisfaction,  $p = 0.03$ ).

**Conclusions:** An accurate measurement of the peak urinary flow rate could predict women at risk for postoperative urinary retention that compromises global satisfaction after the highly curative TVT procedure.

**KEY WORDS:** vaginal, urinary incontinence, urinary retention, implants and prostheses, urethra

According to the hammock hypothesis of DeLancey, which describes the pathophysiology of female stress incontinence, an unstable hammock-like supporting layer of the bladder neck in the incontinent woman is ineffective in providing a resistant backstop against which the urethra can be compressed.<sup>1</sup> Based on this hypothesis, the sling procedure has become popular as the most effective surgical treatment for female stress incontinence. The procedure involves repositioning the bladder and providing a stronger suburethral support mechanism. However, the relatively high incidence of voiding difficulties after sling surgery has prevented more widespread use of the technique. The incidence of urinary retention is 2.2% to 16% with 1.5% to 7.8% of patients requiring long-term self-catheterization.<sup>2</sup>

Of the latest technical advances in the treatment of female stress incontinence the tension-free vaginal tape (TVT) procedure is known to provide reconstruction of the supporting tissue on the urethra using polypropylene mesh and without repositioning the bladder or securing the periurethral tissues to pelvic structures.<sup>3</sup> The TVT procedure creates a dynamic urethral kinking at the mid urethra without compressing the urethra at rest, thus, decreasing the obstructive nature of the sling procedure.<sup>4</sup> However, in accordance with the general concept that any surgical procedure to correct stress urinary incontinence is inherently obstructive, even after this minimally invasive technique 2.8% to 14% of patients are in urinary retention or have obstructive voiding symptoms.<sup>5</sup> In contrast to the recent promising cure rates obtained by the procedure, little data exist on this concern. Therefore, we

identified factors related to urinary retention after a TVT procedure.

## MATERIALS AND METHODS

Between March 1999 and May 2002, 437 women with stress urinary incontinence underwent the TVT procedure at the urology department at our institution. Of these women 375 with a minimum followup of 6 months underwent complete preoperative evaluation related to expected factors for postoperative urinary retention. The study population included 13 patients who had previously undergone anti-incontinence surgery, such as the Raz procedure, a fascia lata sling, Burch colposuspension or an anterior vaginal wall sling. Six patients had a history of vaginal hysterectomy and 59 had previously undergone transabdominal hysterectomy. The reasons for hysterectomy were uterine prolapse in 3 cases, cervical cancer in 4 and abnormal uterine bleeding or pain in 58. Concurrent hysterectomy, cystocele correction and vaginal repair were performed in 11, 12 and 28 patients, respectively. Preoperative symptom grade was I (loss of urine only with coughing, sneezing or lifting heavy objects) in 169 patients, II (loss of urine with minimal activity such as walking or arising from the sitting position) in 202 and III (totally incontinent while upright)<sup>6</sup> in 4 (table 1).

Preoperative evaluation included a medical history, physical examination, urinalysis, urine culture, voiding diary, the 1-hour pad test proposed by the International Continence Society,<sup>7</sup> post-void residual urine volume measurement, uroflowmetry for nonintubated flow rates, a urodynamic study

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TABLE 1. *Demographic characteristics*

Mean age (range)	51.6 (33–74)
Mean parity (range)	2.9 (0–9)
Mean body mass index (kg/m <sup>2</sup> )	24.8
Mean yrs symptoms (range)	7 (1–14)
No. prior hysterectomy (%):	
Vaginal	6 (1.6)
Abdominal	59 (15.7)
No. prior anti-incontinence surgery (%)	13 (3.5)
No. cystocele (%)	26 (6.9)
No. associated urge incontinence (%)	141 (37.6)
No. concomitant surgery (%):	
Hysterectomy	11 (2.9)
Cystocele repair	12 (3.2)
Vaginal repair	28 (7.5)
Caruncula excision	1
No. symptom grade:	
I	169
II	202
III	4

including measurement of Valsava leak point pressure (VLPP) and maximal urethral closing pressure (MUCP), and a pressure flow study. The 1-hour pad test measured the amount of urine leakage. Briefly, after measuring initial pad weight using a scale, each patient wore the pad, drank 500 ml water, sat and rested for 30 minutes, and then walked and climbed stairs for 15 minutes. During the last 15 minutes each patient was requested to perform several specific actions that increase abdominal pressure, including coughing 10 times, sitting and standing 10 times, picking up an object from the floor 5 times, jumping for 1 minute and washing hands. The amount of urine leakage was measured by subtracting initial pad weight from the weight after the test. Nonintubated flow rates were determined by a Dantec 1000 (Dantec Medical, Santa Clara, California) uroflowmeter calibrated by trained study assistants. Electronically measured peak urinary flow rates, average flow rates and voided volume were determined. Measurements were repeated if voided volume was less than 150 ml. In cases of duplicate measurements we used the highest rate in analyses. Filling cystometry was performed at a rate of 100 ml per minute using sterile saline with the subject seated in a chair. A 7Fr double tip microtransducer catheter was placed into the urethra and bladder. VLPP was determined at a bladder volume of 200 ml by asking the patients to perform a Valsalva maneuver until leakage occurred. When the patient felt the maximal desire to void, the patient was asked to void. During the voiding phase intravesical pressure, detrusor pressure, abdominal pressure, flow rate and detrusor pressure at maximal flow (Pdet Qmax) were recorded. MUCP was measured by withdrawing the intravesical catheter at a rate of 1 mm per second to create a urethral pressure profile. It was calculated by subtracting baseline bladder pressure from maximal urethral pressure. All definitions corresponded to those of the International Continence Society.<sup>7</sup>

The procedure was performed as previously described<sup>3</sup> using local anesthesia with sedation (1.5 mg midazolam and 1.5 mg/kg propofol) in 322 patients who were not scheduled for combined surgery. All surgery was performed by 1 urologist with even tension adjustment using long Mayo scissors as a spacer. A vaginal pack was removed 2 to 3 hours after surgery. The bladder was emptied with a catheter but no Foley drain was placed at the end of the procedure in most cases performed using local anesthesia except cases of bladder penetration by a needle instrument. If an adequate voiding function was noted, determined as 2 consecutive voidings with a post-void residual urine volume of less than 100 ml, patients were discharged home later on the day or next day according to patient desire. If a patient failed to void or the bladder was injured during the procedure, a urethral catheter was placed, which was removed the next day. Only 2 patients elected general anesthesia for the TVT procedure

alone. Concomitant gynecologic surgery required spinal anesthesia in 6 patients and general anesthesia in 45. In all patients under spinal or general anesthesia a urethral catheter was placed and removed the next day. For patients who failed to void or were found to have a post-void residual urine volume of greater than 100 ml twice consecutively clean intermittent self-catheterization was recommended.

We defined postoperative urinary retention by the need for intermittent catheterization for at least 3 days after the procedure. Three patients who failed to void immediately after the procedure but readily regained normal voiding with a urethral catheter, which was removed the next morning, were sorted into a nonretention group. A total of 32 patients (8.6%) were included in urinary retention group. Between the 343 nonretention and 32 retention group patients we retrospectively compared multiple factors related to patient characteristics (age, parity, body mass index, history of hysterectomy or anti-incontinence surgery), symptoms and physical examination (symptom grade, 1-hour pad test, concomitant urge incontinence proved by urodynamic study and cystocele), preoperative urodynamic study (peak urinary flow, MUCP, VLPP, maximal detrusor pressure and Pdet Qmax), combined surgeries (simultaneous hysterectomy, anterior and posterior vaginal repair or cystocele correction) and bladder perforation by a needle instrument. As self-reported, if patients had no urine loss after the procedure or social continence, a term coined in a previous report meaning that any perceived wetting by the patient was controlled with by tissues or a small minipad,<sup>8</sup> we considered them to be subjectively cured. We determined the objective cure rate by a 1-hour pad test and a stress test. Patients with pads weighing less than 2 gm and a negative stress test were considered cured. All patients were requested to answer a global satisfaction question in 4 ways, such as very satisfied, satisfied, so-so and dissatisfied, 6 months after their surgery. The chi-square test was used to compare percent frequencies. Univariate and multivariate analyses were performed using the log rank test and multiple logistic regression method with  $p < 0.05$  considered statistically significant.

## RESULTS

Mean operative time and hospital stay were 28.1 minutes and 1.5 days, respectively. Table 2 shows that patient age, parity, peak urinary flow, spinal anesthesia and a history of

TABLE 2. *Univariate analysis of multiple factors with respect to urinary retention*

Factors	Nonretention	Retention	p Value
No. pts	343	32	
Pt characteristics:			
Mean age $\pm$ SD	51.2 $\pm$ 9.7	56.6 $\pm$ 10.6	0.003
Mean parity $\pm$ SD	2.8 $\pm$ 1.3	3.3 $\pm$ 1.5	0.047
Mean body mass index $\pm$ SD (kg/m <sup>2</sup> )	24.8 $\pm$ 3.1	25.1 $\pm$ 3.1	0.538
% Previous hysterectomy	16.0	34.4	0.009
% Previous anti-incontinence surgery	3.8	0	0.206
Symptom + physical examination:			
Mean symptom grade	1.6	1.6	0.678
Mean 1-hr pad test (gm)	54.6	65.9	0.354
% Combined urge incontinence	37.6	37.5	0.990
% Cystocele	7.0	6.3	0.874
Mean urodynamic parameters:			
Peak urinary flow (ml/sec)	29.7	22.3	0.001
VLPP (cm H <sub>2</sub> O)	64.6	73.8	0.080
MUCP (cm H <sub>2</sub> O)	44.9	44.4	0.854
Maximal detrusor pressure (cm H <sub>2</sub> O)	30.1	28.1	0.444
Pdet Qmax	24.0	23.3	0.410
% Combined surgery:			
TVT + hysterectomy	3.2	0	0.350
TVT, cystocele + A-P repair	10.5	12.5	0.726
% Bladder penetration	14.0	16.5	0.532
% Anesthesia:			
General	12.8	9.4	0.634
Spinal	1.2	6.3	0.028

hysterectomy were significantly associated with an increased risk of postoperative urinary retention on univariate analysis. Mean age and parity of patients in the retention group were significantly higher than in the nonretention group (56.6 vs 51.2 years,  $p = 0.003$  and 3.3 vs 2.2 times,  $p = 0.047$ , respectively). The retention group showed a significantly lower peak urinary flow rate than the nonretention group (22.3 vs 29.7 ml per second,  $p = 0.001$ ). Two of the 6 patients who underwent the procedure under spinal anesthesia for combined surgery were in urinary retention but since the number was too small to be considered significant, we excluded the factor of anesthesia from multivariate analysis. Multivariate analysis using multiple logistic regression method showed that only the peak urinary flow rate remained significant ( $p = 0.007$ , table 3).

Table 4 lists the objective and subjective success rates of the procedure, and patient satisfaction based on the questionnaire. There were no significant differences between the 2 groups in terms of the success rate. However, patients in the retention group showed significantly lower satisfaction, while the success rates were not significantly different from that of the nonretention group. Figure 1 shows the prevalence of urinary retention according to the peak urinary flow rate. Nine of the 33 patients (27.3%) with a flow rate of less than 15 ml per second and 8 of the 67 (11.9%) with a rate of between 16 and 20 ml per second were in urinary retention after the TVT procedure. When we generated an ROC curve, sensitivity and specificity were 46.6% and 84.56% at 18 ml per second, and 65.6% and 53.9% at 25, respectively. Area under the curve was 0.699 (fig. 2).

Of the 32 patients in urinary retention 28 (87.5%) required intermittent self-catheterization for less than a month. Time to normal voiding was 3 to 31 days (mean 12.4, median 8.9). A total of 22 patients recovered normal voiding within 2 weeks of surgery. Four patients underwent sling release or cutting at a mean of 61 days (range 35 to 104) after the TVT procedure. All patients voided to completion 1 to 2 days after the release procedure and there were no further subjective complaints of bladder outlet obstruction and irritative symptoms. Stress incontinence did not recur after the releasing procedure in 1 case. Three patients underwent a second TVT procedure for recurrent stress incontinence and the condition was cured without urinary retention.

Major complications after the TVT procedure included nerve injury in 1 case but there was no sling infection or massive bleeding that required transfusion. The patient with nerve injury complained of mild limitation of adduction of the left lower extremity. Electromyogram and a nerve conduction velocity test suggested partial injury to the left obturator nerve. Neurological consultation suggested that the patient may have had an unusual running course of the nerve. The patient completely recovered all neurological symptoms after 3 weeks of conservative treatment. The 2 most common complications were bladder penetration by a needle instrument in 9.3% of cases and transient obstructive urinary symptoms with a post-void residual urine volume of less than 100 ml in 9.3%, which disappeared within 2 to 3 weeks of the surgery, followed by immediate urinary retention in 8.5%. Table 5 lists complications after the TVT procedure in the current study.

TABLE 3. Multivariate analysis using multiple logistic regression method

	SE (95% CI)	p Value
Age	0.0963 (1.000–1.091)	0.051
Parity	0.0125 (0.768–1.354)	0.771
Peak flow rate	0.0012 (0.897–0.981)	0.007
Previous hysterectomy	0.0005 (0.997–1.021)	0.198

TABLE 4. Success rates and patient satisfaction between nonretention and retention groups

	% Nonretention	% Retention	p Value
Subjective success rate	94.46	87.50	0.117
Objective success rate	90.96	87.50	0.521
Pt satisfaction	91.50	71.00	0.003

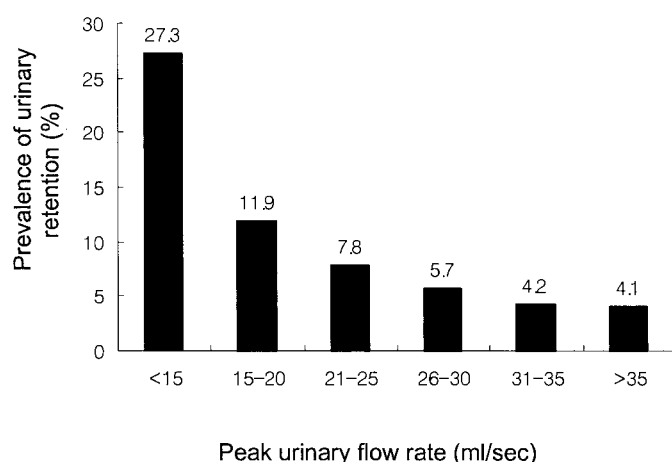


FIG. 1. Prevalence of urinary retention according to peak urinary flow.

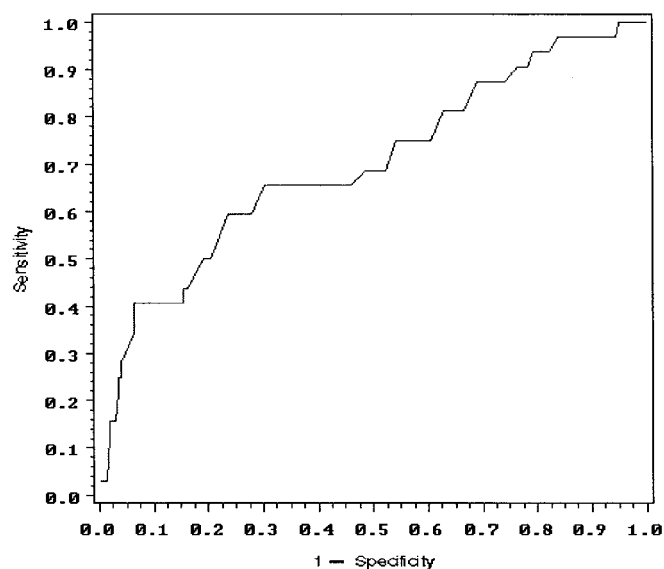


FIG. 2. ROC curve for peak urinary flow. Area under curve was 0.699.

## DISCUSSION

Because the TVT procedure theoretically creates dynamic kinking of the mid urethra without compressing the urethra at rest, the incidence of urinary retention is expected to be low. However, recent series regarding this issue reported a 2.8% to 14% incidence of postoperative urinary retention or obstructive voiding symptoms after the procedure.<sup>5</sup> The current study showed an 8.5% incidence of immediate urinary retention, similar to described reports. Suburethral slings have been reputed to be more obstructive than other incontinence operations, with an incidence of retention of 2.2% to 16% and 1.5% to 7.8% of patients requiring long-term self-catheterization.<sup>9–11</sup> In the current study 8.5% of patients in urinary retention recovered normal voiding with intermittent self-catheterization for less than a month. Four patients



TABLE 5. *Complications after TVT procedure*

Complication	No. (%)
Needle instrument bladder penetration	35 (9.3)
Immediate urinary retention	32 (8.5)
Transient obstructive symptoms	35 (9.3)
De novo urgency	12 (3.2)
Pelvic discomfort	16 (4.3)
Urinary tract infection	5 (1.3)
Hematoma	4 (1.1)
Wound infection	3 (0.1)
Nerve injury	1 (0.03)

(0.01%) who needed sling release for retention more than a month in duration voided to completion 1 to 2 days after release without further voiding symptoms. In a recent study 17 patients (2.8%) underwent sling release a mean of 64 days (range 6 to 228) after the TVT procedure.<sup>7</sup> All patients voided to completion within 24 hours of release and reported no further subjective complaints of outlet obstruction, while 16 who underwent sling release remained dry.<sup>7</sup> This result suggests that, while the incidence of urinary retention after a TVT procedure is similar to earlier results after various types of sling procedures, the clinical course is favorable in cases of urinary retention after the TVT procedure. In another study of 39 patients who underwent transvaginal urethrolisis for urethral obstruction following an anti-incontinence procedure such as retropubic urethropexy, pubovaginal sling and bladder neck suspension 13% were in urinary retention, 51% had incomplete bladder emptying and 36% voided to completion but had irritative voiding symptoms.<sup>12</sup> However, these less favorable results definitely originated due to much more complicated cases, of which many had failed previous attempts at urethrolisis.

Because postoperative urinary retention is not only embarrassing to patients and practitioners, but also significantly compromises patient satisfaction with this highly curative surgery, as shown in the current study, patients expected to be in urinary retention must be counseled preoperatively about the risk of catheterization and tape release. However, to our knowledge predicting which patients are at risk for postoperative urinary retention has not been fully investigated despite its importance. There have been several reports in which a decreased detrusor contraction of less than 15 cm H<sub>2</sub>O or voiding by increased Valsalva pressure rather than by detrusor contraction was associated with impaired postoperative voiding in women who underwent Burch colposuspension or Pereyra-type bladder neck suspension.<sup>13-15</sup> Regarding the sling procedure, 1 study showed a trend toward longer voiding time in women who voided by the Valsalva maneuver alone compared with those with other voiding patterns after receiving a rectus fascia suburethral sling.<sup>16</sup> However, another group was unable to detect an association between preoperative pressure flow voiding data and voiding time after a fascia lata suburethral sling procedure.<sup>17</sup> In a recent report of determinants of voiding after Burch colposuspension, a sling procedure and suburethral plication voiding time primarily depended on the type of surgery.<sup>18</sup> There appear to be sparse data with respect to predictive factors of urinary retention after the TVT procedure. The current study included comprehensive factors that could influence the development of postoperative urinary retention. Of the multiple variables analyzed only the peak urinary flow rate was independently associated with an increased risk of urinary retention on multivariate analysis. The probability of urinary retention increased as the peak urinary flow rate decreased. The current data seem to contradict several previous studies, in which no definite correlation between a preoperative urodynamic study and postoperative voiding dysfunction was identified. However, there is inherent difficulty in comparing the various results of postoperative voiding dysfunction following different surgical

procedures. Not only are there differences among sling procedures, but also the TVT procedure using polypropylene mesh to reconstruct the urethral support without repositioning the bladder or securing the periurethral tissues to pelvic structures is a procedure distinct from previously tried procedures.

Much controversy surrounds the usefulness of peak urinary flow rate in clinical practice because the measurement of this rate is associated with a considerable degree of variability resulting from within-person variability, low voided volume at measurement and measurement technique.<sup>19,20</sup> However, as in the current study, when peak urinary flow rate is measured by trained personnel and repeated when voided volume is less than 150 ml, uroflowmetry can be a relatively simple methodology that provides useful information on the voiding pattern of patients who intend to undergo certain anti-incontinence surgery. As the TVT procedure becomes popular, there may likely be a trend toward applying this minimally invasive and instrument assisted, simple procedure with a simple preoperative evaluation to exclude comprehensive urodynamic study. In this context we consider that uroflowmetry is prerequisite test to evaluate the patient voiding pattern and the risk of postoperative urinary retention.

#### CONCLUSIONS

The incidence of urinary retention after a TVT procedure is not much lower than after earlier sling procedures. Low peak urinary flow rate is an unfavorable sign in this regard. However, most patients in retention can attain normal voiding within less than a month after the TVT procedure.

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