

# Release of Tension-Free Vaginal Tape for the Treatment of Refractory Postoperative Voiding Dysfunction

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**OBJECTIVE:** To report our experience with surgical release of tension-free vaginal tape (TVT) for the treatment of persistent post-TVT voiding dysfunction.

**METHODS:** A total of 1175 women underwent TVT placement for treatment of genuine stress urinary incontinence and/or intrinsic sphincter deficiency over a 2-year period. Additional procedures and vaginal repairs were performed as indicated. Among these patients, 23 women (1.9%) had persistent voiding dysfunction (urinary retention, incomplete bladder emptying, or severe urgency or urge incontinence) refractory to conservative management. This cohort underwent a simple vaginal TVT release procedure, performed on an outpatient basis. Preoperative characteristics, intraoperative, and postoperative details were assessed by review of operative notes, medical records, and office notes. Continence status was assessed using subjective and objective information.

**RESULTS:** Mean age was 67 years (range 46–86 years), and the mean interval between TVT placement and release was 17.3 weeks (range 2–69 weeks; median 8.6 weeks). For the release procedure, there were no intraoperative complications, and all patients were discharged on the day of surgery. All cases of impaired emptying were completely resolved, and all cases of irritative symptoms were resolved (30%) or improved (70%) by 6 weeks. Fourteen (61%) patients remained continent 6 weeks after the release procedure, six (26%) were improved over baseline, and three patients (13%) had recurrence of stress incontinence.

**CONCLUSION:** Refractory voiding dysfunction after TVT is a relatively uncommon situation and can be successfully managed with a simple midline release procedure. In most cases, the release procedure does not compromise overall improvement in symptoms of stress incontinence. (*Obstet Gynecol* 2002;100:898–902. © 2002 by The American College of Obstetricians and Gynecologists.)

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Since 1907, when Von Giordano described a technique of suturing gracilis muscle flaps beneath the urethra,<sup>1</sup> suburethral slings have been one of the mainstays of treatment for genuine stress urinary incontinence. A wide variety of procedures have been described, and many have enjoyed favorable success rates, but complications and untoward side effects have been relatively common. Tension-free vaginal tape (TVT), a minimally invasive variation on the suburethral sling, has shown great promise in increasing success rates while reducing operative times and complication rates. However, as with all slings, surgical correction of stress urinary incontinence can be associated with persistent voiding dysfunction, including prolonged urinary retention, incomplete bladder emptying, or the development of de novo detrusor instability or overactive bladder.

As use of TVT grows, more of these complications are likely to be encountered. As with all surgical procedures, the development and refinement of methods of managing complications is an important process. To that end, we report our experiences with the surgical management of persistent and refractory post-TVT voiding dysfunction and urethral obstruction.

## MATERIALS AND METHODS

Women included in this analysis underwent TVT placement for treatment of genuine stress urinary incontinence over a 28-month period (May 1998 through September 2000), by six fellowship-trained urogynecologists, at four US centers. Patients were assessed preoperatively using detailed histories, physical examination with pelvic organ prolapse quantification assessment, and multichannel urodynamic testing. Patient counseling and informed consent procedures were carried out in the usual manner. Additional surgical procedures and vaginal repairs were performed at the time of TVT placement as indicated. Perioperative and postoperative

management were performed according to each individual surgeon's routine.

In cases in which impaired bladder emptying (complete urinary retention or incomplete bladder emptying) or severe irritative symptoms (urge incontinence, urgency/frequency, or nocturia) occurred postoperatively, conservative management was employed according to the surgeon's clinical judgment. These measures included continued bladder drainage, urethral dilatation, use of timed voiding protocols, pelvic muscle exercises, and initiation of anticholinergic or  $\alpha$ -antagonist medications where appropriate. Subjective information, physical examination, bladder scan and/or postvoid residual determinations were carried out in these patients; repeat pelvic organ prolapse quantification assessment or urodynamic evaluations were not performed as a matter of routine. In cases where conservative measures proved insufficient, the patient was offered TVT release. Patients who responded satisfactorily to these conservative measures, or who had TVT removed for any other reason (eg, pain or erosion) were not included in this analysis.

After release, patients were seen at 2 and 6 weeks. Outcomes assessed included subjective and objective improvement in impaired bladder emptying, overactive bladder symptoms, and continence status. Postoperative examinations, including assessment of bladder emptying (bladder scan or catheterization), were performed according to the surgeon's judgment. After TVT release, continence status was assessed. Patients were considered "continent" if they denied stress urinary incontinence and had negative cough stress tests. "Improved" patients were patients whose incontinence persisted, but were subjectively improved from baseline. Patients were considered "incontinent" if they reported no improvement above baseline, if objective incontinence was noted, or if additional procedures were deemed necessary. Changes in irritative symptoms were assessed subjectively. Office and hospital records were reviewed retrospectively to retrieve demographic, operative, and outpatient information.

Tension-free vaginal tape release procedures were performed under general or local anesthesia, according to the surgeon's discretion. Patients were placed in dorsolithotomy position, and a Foley catheter was inserted into the urethra. A small midline incision was made, and the suburethral portion of the TVT material was identified by palpation against the catheter. The tape was then minimally undermined (Figure 1) and either transected in the midline, or segmentally excised. More extensive urethrolysis was carried out only at the surgeon's discretion, and cystourethroscopy was carried out when extensive scar tissue or difficult dissection was encountered. Standardized intraoperative measurements of urethral mobility were not performed; the only uniform goal of



**Figure 1.** Tension-free vaginal tape material, revealed and undermined, before transection. Note fibrous ingrowth into mesh interstices. Digital image, captured from video.

*Rardin. TVT Release for Voiding Dysfunction. Obstet Gynecol 2002.*

the procedure was complete division of the tape material. Postoperative assessments of bladder emptying (voiding trials) were carried out in routine fashion. The procedure was performed on an outpatient basis.

## RESULTS

During the 2-year study period, 1175 women underwent TVT procedures by the six urogynecologic surgeons. Among these patients, 23 (1.9%) women were assessed as having persistent voiding dysfunction (urinary retention, incomplete bladder emptying, or severe urgency or urge incontinence) attributed to the TVT, and refractory to conservative management. Of these 23 patients, 13 (57%) had a pre-TVT diagnosis of genuine stress incontinence with urethral hypermobility, five (22%) had intrinsic sphincter deficiency without urethral hypermobility, and five (22%) had intrinsic sphincter deficiency with urethral hypermobility. Intrinsic sphincter deficiency was defined by urodynamic parameters, including maximal urethral closure pressure of less than 20 cm H<sub>2</sub>O, or Valsalva leak point pressure of less than 60 cm H<sub>2</sub>O. Eight (35%) had undergone previous anti-incontinence or prolapse surgery in the past (Table 1), and 15 (65%) patients had undergone other pelvic reconstructive surgery at the time of TVT placement (Table 2). Three of the 23 patients had experienced perioperative complications: bladder perforation was noted during the TVT placement in two patients, and one patient had a postoperative wound hematoma.

Twenty patients experienced impaired bladder emptying after the TVT procedure, three had severe irritative symptoms, and seven had both (Table 3). The mean

Table 1. Patient Characteristics

Patients undergoing TVT release	(n = 23)
Characteristics	
Mean age (range)	67 (46–86)
Mean vaginal parity (range)	3 (0–7)
Pre-TVT data, n (%)	
Previous anti-incontinence surgery	6 (26)
Previous prolapse surgery	3 (13)
Diagnosis of GSUI	
Urethral hypermobility	13 (57)
ISD	5 (22)
Both	5 (22)

TVT = tension-free vaginal tape; GSUI = genuine stress urinary incontinence; ISD = intrinsic sphincter deficiency.

interval between TVT placement and release was 17.3 weeks (range 2–69 weeks; median 8.6 weeks). Two patients had been hospitalized with pyelonephritis after TVT; both had experienced multiple urinary tract infections associated with urinary retention. Attempts at conservative treatment varied; seven patients (30%) underwent urethral dilatation after TVT placement, with one patient demonstrating partial improvement. Twelve patients were started on medications (anticholinergics or  $\alpha$ -antagonists) in the treatment of these symptoms; four had partial relief (Table 3). All cases of urinary retention or incomplete emptying were noted immediately after the TVT procedure, whereas symptoms of urgency or urge incontinence were often delayed (four of nine such cases were delayed by at least 6 weeks).

Ten (43%) of the TVT release procedures were performed under general anesthesia; the remaining 13 were performed with local anesthetic injection and intravenous sedation as needed. One release procedure was performed under local anesthesia in the office. In addition to the tape transection as described above, two of these patients also underwent some degree of urethrolysis (sharp dissection of the paraurethral tissue), and four

Table 2. Tension-Free Vaginal Tape Placement Procedure

Mean estimated blood loss (mL)	93 ( $\pm$ 102)
Anesthesia, n (%)	
Local	10 (43)
Regional	3 (13)
General	10 (43)
Concurrent surgery, n (%)	
Anterior repair	7 (30)
Vaginal vault suspension (abdominal)	3 (13)
Vaginal vault suspension (vaginal)	5 (22)
Posterior repair/perineorrhaphy	7 (30)
Colpocleisis/colpectomy	2 (9)
Complications, n (%)	
Bladder perforation	2 (9)
Wound infection	1 (4)

Patients may have undergone multiple concurrent surgeries at the time of tension-free vaginal tape placement.

Table 3. Tension-Free Vaginal Tape Placement-to-Release Interval

Mean duration of interval (wk)	17.3 ( $\pm$ 20) (range 2–69; median 8.6)
Presenting symptoms, n (%)	
Retention (complete)	18 (78)
Incomplete bladder emptying	2 (9)
Urgency/frequency	10 (43)
Medications initiated, n (%)	
With improvement	3
Dilatation attempted, n (%)	7 (30)
With improvement	1

Patients may have presented with multiple symptoms and may have had more than one therapy attempted.

patients underwent some degree of tape excision, with segments ranging from 2 to 11 mm. Average estimated blood loss for the release procedure was less than 25 mL, and mean operative time was 23 ( $\pm$  17) minutes. One patient underwent concurrent umbilical hernia repair, and three patients underwent cystoscopy concurrently. There were no intraoperative complications, and all patients were discharged to home on the same day. All patients were sent home without urinary catheters, with the exception of one patient who requested a suprapubic tube because of her dislike of urethral catheters. That patient resumed normal voiding immediately, and the tube was removed within 4 days.

Outcomes of the release procedure are presented in Table 4. Impaired bladder emptying was resolved in all cases immediately after the release procedure. Irritative symptoms (urge incontinence or urgency/frequency) were improved in all cases, and were completely resolved in

Table 4. Results of Release Procedure

	2 wk	6 wk
Relief of impaired bladder emptying (n = 20), n (%)		
Complete	20 (100)	20 (100)
Partial	0	0
No improvement	0	0
Relief of urge incontinence or urgency/frequency (n = 10), n (%)		
Complete	4 (40)	3 (30)
Partial	6 (60)	7 (70)
No improvement	0	0
Continence status compared with pre-TVT baseline (n = 23), n (%)		
Cure	14 (61)	14 (61)
Improvement*	7 (30)	6 (26)
Failure†	2 (9)	3 (13)

TVT = tension-free vaginal tape.

\* Persistent stress incontinence that was subjectively improved over baseline status, or urge-related incontinence in the absence of stress incontinence.

† No improvement in continence status compared with baseline and confirmed objectively, or in any case where additional anti-incontinence procedures were requested or offered.

three of ten cases (30%) at 6 weeks. Of note, among the seven patients who experienced some degree of persistent urgency and frequency after the release procedure, three (43%) had demonstrated clinical and urodynamic evidence of detrusor instability before TVT placement.

After the release procedure, 14 patients (61%) remained continent. Six patients (26%) reported partial recurrence of stress incontinence or some degree of urge incontinence in the absence of stress incontinence, and were considered improved after the release procedure. In four of these six patients, incontinence was attributed to detrusor instability, and three of these four were noted to have some degree of detrusor instability before the primary TVT procedure.

After release, three patients (13%) reported complete recurrence of stress incontinence equal to or worse than their initial baseline. Two of these patients had had the TVT placement performed under general anesthesia, and had concurrent pelvic reconstructive surgery. Two of these patients underwent a simple tape transection, and the other had a 2-mm segment of tape excised. None of these three patients underwent true urethrolisis. Of these three patients, two chose to proceed with additional surgical procedures (one with repeat TVT, one with periurethral bulking injection), with good results in both cases.

Findings at 6 weeks correlated with those at 2 weeks in nearly all cases; one patient noted partial recurrence of urgency, frequency and/or urge incontinence between 2 and 6 weeks, and one patient experienced deterioration in stress incontinence between the two visits.

## DISCUSSION

All anti-incontinence surgery bears the risk of postoperative voiding dysfunction. In most cases, these scenarios may be successfully treated with conservative measures: temporary bladder drainage, timed voiding, biofeedback, and pelvic muscle exercises, or the short-term use of medications. However, a small minority of patients will have persistent symptoms refractory to conservative therapies, and may require surgical revision of the anti-incontinence procedure. Estimates of the incidence of this complication in patients receiving suburethral slings range from 1% to 20% of patients.<sup>2</sup> The American Urological Association's comprehensive review concluded that the incidence of permanent urinary retention is probably higher among patients with suburethral slings as compared with other procedures, but does not exceed 5%.<sup>3</sup>

Urinary retention is only one of the ways in which urethral obstruction can be manifest. Cross et al describe 39 patients who underwent surgical reversal, or urethrolisis, after Burch procedures, pubovaginal slings, or bladder neck suspensions.<sup>4</sup> All patients complained of

urge incontinence, whereas 51% had incomplete bladder emptying, 36% reported irritative symptoms, and only 13% were in complete retention. All patients also had physical examinations consistent with hypersuspension of the bladder neck. This distribution of symptomatology was corroborated by Carr and Webster.<sup>5</sup>

Based on our data, the rate of persistent and refractory voiding dysfunction after TVT is low (less than 2%); however, the burgeoning popularity of the procedure will likely make these scenarios more common. We describe our experience with variations on a simple release procedure which, in all cases, resulted in improvement or complete relief of obstructive symptoms. There were no complications, operative times and blood loss estimates were acceptably low, and all cases were performed on an outpatient basis. In addition, the majority of patients remained continent, or improved above baseline.

Romanzi and Blaivas describe a case of urinary retention requiring urethrolisis after TVT placement.<sup>6</sup> This case was notable for "excessive" blood loss at the time of TVT placement (200 mL), marked tissue edema postoperatively, and a dramatic overcorrection in urethral mobility (post-TVT cotton-swab angle of -30 degrees, both resting and straining). The releasing procedure described involved removal of a total of 6 cm of tape material, followed by bilateral dissection above the pubic rami (urethrolisis). This patient experienced a return to normal voiding and remained continent. Another case was reported by Koelle et al, who described a technique of interposition of synthetic mesh between transected ends, in a process of tape elongation.<sup>7</sup> Klutke relates his experience with post-TVT urinary retention and obstruction, describing a 2.8% incidence of such voiding dysfunction, as well as similar results of outpatient transvaginal release to those we describe here.<sup>8</sup> In the Austrian registry, 39 of 2795 patients (1.4%) required reoperation because of voiding dysfunction.<sup>9</sup>

A much broader body of literature exists with regard to urethrolisis after standard suburethral slings. Brubaker describes both a simple vaginal incisional release of sling material and an abdominal technique of releasing the rectus fascia attachments of the sling arms.<sup>10</sup> Carr and Webster describe vaginal, retropubic, and infrapubic approaches to urethrolisis,<sup>5</sup> whereas Petrou et al describe a suprimeatal approach.<sup>11</sup> McLennan and Bent describe a technique of tissue interposition (vaginal wall or fascia lata) at the time of urethrolisis to address the rate of urethrolisis failure (reported in other sources between 5-16%),<sup>2</sup> and indeed, all four of the patients included in their data did have relief of symptoms, with one recurrence of incontinence.<sup>12</sup> A series of urethrolisis procedures after suburethral sling, reported by Amundsen et al outlines a material-specific technical

approach.<sup>13</sup> In cases where fascia (autologous or allograft) had been used, the sling was incised in the midline, and, when necessary, retropubic and infrapubic dissection was performed to restore adequate urethral mobility. In cases of synthetic slings, the material was removed in its entirety. In that study, 93% of patients experienced restoration of normal bladder emptying, and 67% had resolution of urge incontinence. Nine percent of patients had recurrence of stress incontinence, compared with 84% who reported that incontinence was improved from baseline.

The optimal evaluation of the patient with postoperative voiding dysfunction after anti-incontinence surgery is not entirely clear. In theory, pressure flow studies help to distinguish between patients with outflow obstruction and those with compromised detrusor function. Urodynamic studies may, however, be misleading. Carr and Webster found no consistency in urodynamic parameters among patients who benefited from urethrolisis.<sup>5</sup> As a result, these authors relied on a clear temporal relationship between the original surgery and the onset of voiding dysfunction in selecting patients for urethrolisis. Petrou et al came to similar conclusions regarding the limited utility of urodynamics in selecting patients for urethrolisis.<sup>11</sup> Cystoscopy should be considered to rule out mesh erosion as a cause of irritative symptoms.

The data presented here represent the clinical experience of six urogynecologists at different pelvic reconstructive surgery centers in the United States. Each of the surgeons had, at the time of this study, performed between 150 and 400 TVT procedures. Although limited by its descriptive and retrospective nature, and by a lack of formal standardization of prerelease evaluation and release techniques, this article represents a large-scale assessment of clinical considerations and outcomes with regard to postoperative voiding dysfunction after TVT and the clinical results of a simple releasing procedure. At the time of this writing, complete data on the 1152 patients who did not require surgical revision are not available, and thus no conclusions regarding risk factors for postoperative voiding dysfunction after TVT can be made. Evaluation of the long-term outcomes of these patients is ongoing.

With future study, it may be possible to identify patients who are at particular risk for obstructive symptoms after TVT, or to identify those patients who are most likely to benefit from a releasing procedure. Other surgical interventions, such as "stretching" of the tape, may have their place, particularly in the immediate postoperative period; however, at this point, evidence supporting other interventions is lacking. In the meantime, refractory voiding dysfunction after TVT can be successfully managed with a simple transvaginal releasing

procedure. In most cases, the release procedure does not compromise overall improvement in symptoms of stress incontinence. In light of these benefits, this intervention may be considered in cases of persistent post-TVT voiding dysfunction.

## REFERENCES

1. Hohenfellner R, Petrie E. Sling procedures in surgery. In: Stanton SL, Tanagho E, eds. *Surgery of female incontinence*. 2nd ed. Berlin: Springer-Verlag, 1986:105-13.
2. Goldman HB, Rackley RR, Appell RA. The efficacy of urethrolisis without re-suspension for iatrogenic urethral obstruction. *J Urol* 1999;161:196-9.
3. Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Lubner KM, et al. Female stress urinary incontinence clinical guidelines panel: Summary report on surgical management of female stress urinary incontinence. *J Urol* 1997;158:875-87.
4. Cross CA, Cespedes RD, English SF, McGuire EJ. Transvaginal urethrolisis for urethral obstruction after anti-incontinence surgery. *J Urol* 1998;159:1199-201.
5. Carr LK, Webster GD. Voiding dysfunction following incontinence surgery: Diagnosis and treatment with retropubic or vaginal urethrolisis. *J Urol* 1997;157:821-3.
6. Romanzi LJ, Blaivas JG. Protracted urinary retention necessitating urethrolisis following tension-free vaginal tape surgery. *J Urol* 2000;164:2022-3.
7. Koelle D, Stenzl A, Koebl H, Marth C. Treatment of postoperative urinary retention by elongation of tension-free vaginal tape. *Am J Obstet Gynecol* 2001;185:250-1.
8. Klutke C. Urinary retention after tension-free vaginal tape procedure: Incidence and treatment. *Urology* 2001;58:697-701.
9. Tamussino K, Hanzal E, Kölle D, Ralph G, Riss PA. Tension-free vaginal tape operation: Results of the Austrian registry. *Obstet Gynecol* 2001;98:732-6.
10. Brubaker L. Suburethral sling release. *Obstet Gynecol* 1995;86:686-8.
11. Petrou SP, Brown JA, Blaivas JG. Suprameatal transvaginal urethrolisis. *J Urol* 1999;161:1268-71.
12. McLennan MT, Bent AE. Sling incision with associated vaginal wall interposition for obstructed voiding secondary to suburethral sling procedure. *Int Urogynecol J* 1997;8:168-72.
13. Amundsen CL, Guralnick ML, Webster GD. Variations in strategy for the treatment of urethral obstruction after a pubovaginal sling procedure. *J Urol* 2000;164:434-7.

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