

# Tension-Free Vaginal Tape: Outcomes Among Women With Primary Versus Recurrent Stress Urinary Incontinence

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**OBJECTIVE:** To evaluate the outcomes of tension-free vaginal tape in the treatment of primary versus recurrent genuine stress urinary incontinence.

**METHODS:** A retrospective, multicenter study of 245 consecutive women who were treated with tension-free vaginal tape for genuine stress urinary incontinence (157 for primary and 88 for recurrent genuine stress urinary incontinence) over a 27-month period was performed. Concurrent surgical repairs were performed as required. Subjective and objective outcome data were assessed from routine postoperative visits. Office and hospital records were reviewed to determine patient characteristics, intraoperative findings, and surgical outcomes.

**RESULTS:** Women with recurrent genuine stress urinary incontinence were older (mean age 64.6 versus 59.4 years,  $P = .004$ ) than those with primary incontinence; they were less likely to have an intact uterus (22.7% versus 66.9%,  $P < .001$ ), and were more likely to have intrinsic sphincter deficiency (70.5% versus 47.1%,  $P < .001$ ). The mean duration of follow-up was 38 ( $\pm 16$ ) weeks. Cure rates among patients with recurrent versus primary genuine stress urinary incontinence were similar (85% and 87%, respectively,  $P = .23$ ). Complication rates were similarly low in both groups (4.5% versus 7.6% for recurrent and primary genuine stress urinary incontinence, respectively,  $P = .35$ ). Postoperative voiding dysfunction occurred at low rates in both groups.

**CONCLUSION:** Tension-free vaginal tape is a highly effective treatment among patients with recurrent stress incontinence, with outcomes comparable with those among patients with primary incontinence. (*Obstet Gynecol* 2002; 100:893-7. © 2002 by The American College of Obstetricians and Gynecologists.)

Recurrence of genuine stress urinary incontinence after anti-incontinence surgery remains a challenging situation for patient and surgeon alike. Conventional wisdom

suggests that success rates decline with repeat surgery, and that surgical revision may be associated with increased rates of complication, attributable to a previously altered surgical field.

Tension-free vaginal tape (TVT) has been demonstrated to be a safe and effective treatment for primary genuine stress urinary incontinence, offering the benefits of a minimally invasive technique, with good long-term results.<sup>1</sup> Relatively lacking, however, is support for its use in the population with recurrent genuine stress urinary incontinence. We sought to estimate the safety and efficacy of TVT in the treatment of that population, compared with patients with primary incontinence.

## MATERIALS AND METHODS

A retrospective analysis of 245 consecutive patients undergoing TVT for genuine stress urinary incontinence, between February 1999 and May 2001, by three fellowship-trained urogynecologic surgeons at two US centers, was performed. A positive history of anti-incontinence surgery was noted in any patient who had undergone retropubic urethropexy, anterior colporrhaphy, paravaginal repair, needle suspension, suburethral sling, or periurethral bulking procedures. Patients with bladder or urethral reconstruction, or those with artificial sphincter implants, were excluded. Patients were assessed preoperatively using detailed histories, physical examination with pelvic organ prolapse quantification assessment, and multichannel urodynamic testing; genuine stress urinary incontinence was confirmed in all patients. Intrinsic sphincter deficiency was diagnosed by maximum urethral closure pressure less than 20 cm H<sub>2</sub>O, or by a Valsalva leak point pressure less than 60 mL. In addition, patients with borderline values in both parameters (20–30 cm H<sub>2</sub>O and 60–70 cm H<sub>2</sub>O for maximum urethral closure pressure and Valsalva leak point pressure, respectively), as well as a positive empty

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**Table 1. Patient Demographics and Characteristics**

	Primary incontinence (n = 157)	Recurrent incontinence (n = 88)	P
Mean age (range)	59.4 (27–94)	64.6 (34–87)	
Mean height, in. (range)	63.4 (54–70)	63.2 (53–71)	
Mean weight, lb (range)	161.5 (110–298)	161.0 (110–250)	.91
Mean parity (range)	2.4 (0–9)	2.7 (0–8)	.18
Intact uterus, n (%)	105 (66.9)	20 (22.7)	<.001
ISD, with or without UHM, n (%)	74 (47.1)	62 (70.5)	<.001
Mean number of previous anti-incontinence procedures (range)	N/A	1.3 (1–6)	

ISD = intrinsic sphincter deficiency; UHM = urethral hypermobility; N/A = not applicable.

supine stress test were also considered to have intrinsic sphincter deficiency.

The TVT procedure was performed according to published guidelines, and additional surgical procedures and vaginal repairs were performed as indicated. Patients underwent retrograde bladder filling with voiding assessment before discharge, and were discharged with bladder drainage in cases of impaired bladder emptying.

Patients were routinely followed at 2 and 6 weeks, 6 months, and 1 year postoperatively. Patients reporting any urine leakage at all after the procedure, or those unable to provide reliable histories, underwent clinical assessment, including sitting and standing cough stress tests performed at 300 mL (or at bladder capacity, if less than that amount).

Success was defined as an absence of urine leakage by patient report, where reliable histories could be obtained; improvement was defined as stress-related leakage that was subjectively improved over baseline. In addition, any case in which genuine stress urinary incontinence was corrected, but some degree of urge incontinence (whether persistent or de novo) was present, was considered improved as long as the patient reported overall improvement from baseline. Failure was defined as full recurrence of genuine stress urinary incontinence (as determined subjectively), or in any case where additional anti-incontinence procedures were considered.

Statistical tests on continuous variables were conducted using the Student *t* test assuming unequal variances for the two samples. The  $\chi^2$  test for independence was used for discrete variables. All terminology con-

**Table 2. Preoperative Comorbidities**

Comorbidities	Primary incontinence (n = 157) n (%)	Recurrent incontinence (n = 88) n (%)	P
Heart disease	10 (6.4)	13 (14.8)	
Diabetes	5 (3.2)	6 (6.8)	
Chronically increased intraabdominal pressure	18 (11.5)	10 (11.4)	
Baseline detrusor instability or overactive bladder syndrome	30 (19.1)	3 (3.4)	<.001
Neurologic disease	5 (3.2)	0	.09

formed to the recommendations of the International Continence Society except where otherwise specified.

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## RESULTS

Two hundred forty-five patients underwent TVT placement at two US centers. Of these patients, 88 (36%) had undergone previous anti-incontinence procedures. Most of these had undergone a single previous repair, although 20 had undergone multiple previous procedures; one patient had undergone six previous procedures.

Preoperative patient demographics, comorbidities, and clinical findings (including cotton-swab angle and urodynamic parameters) are displayed in Tables 1, 2, and 3, respectively. Patients with recurrent incontinence were significantly older, more likely to have undergone previous hysterectomy, and more likely to have a diagnosis of intrinsic sphincter deficiency (with or without concurrent urethral hypermobility). Nineteen (12%) and ten (11%) of the patients in the primary and recurrent incontinence groups, respectively, were diagnosed with

**Table 3. Preoperative Clinical and Urodynamic Findings**

	Primary incontinence	Recurrent incontinence	P
Q-tip angle with Valsalva (degrees from horizontal)	51.6 (± 19)	45.4 (± 21)	
Bladder capacity (mL)	432 (± 221)	365 (± 103)	.01
VLPP (cm H <sub>2</sub> O)	86.5 (± 32)	65.3 (± 26)	<.001
MUCP (cm H <sub>2</sub> O)	31.1 (± 14)	28.7 (± 23)	.31
Postvoid residual (mL)	34.5 (± 46)	29.7 (± 46)	.51

VLPP = Valsalva leak point pressure; MUCP = maximum urethral closure pressure.

**Table 4. Intraoperative and Perioperative Parameters**

	Primary incontinence (n = 157)	Recurrent incontinence (n = 88)	P
Anesthesia, n (%)			
Local	91 (58)	66 (75)	.26
Regional	32 (20)	12 (14)	
General	34 (22)	10 (11)	
Concurrent surgery, n (%)			
None	71 (45)	35 (40)	
Anterior repair	41 (26)	16 (18)	
Posterior repair/perineorrhaphy	44 (28)	28 (32)	
Vault suspension	18 (12)	5 (6)	
Hysterectomy	24 (15)	3 (3)	
Colpocleisis or colpectomy	12 (8)	5 (6)	
Estimated blood loss (mL)	74.3 (± 110.2)	45.8 (± 58.2)	.03
Length of stay (d)	1.1 (± 0.7)	1.0 (± 0.4)	.60
Discharged with catheter, n (%)	60 (38)	28 (32)	.27
Median days to normal voiding	1	1	
Median days to normal voiding (patients discharged with catheter drainage)	4	4	

intrinsic sphincter deficiency by means of borderline values in both parameters (20–30 cm H<sub>2</sub>O and 60–70 cm H<sub>2</sub>O for maximum urethral closure pressure and Valsalva leak point pressure, respectively), as well as a positive empty supine stress test. Mean cotton-swab angle with strain was higher among patients with primary incontinence (51.6 degrees from horizontal, ± 19.9) than were patients with recurrent incontinence (45.4 degrees, ± 21.9; *P* = .03). Patients with recurrent incontinence had a significantly lower mean Valsalva leak point pressure; other mean urodynamic parameters were not significantly different between groups. Patients with primary incontinence were more likely to have been diagnosed with detrusor instability or overactive bladder syndrome before TVT placement (see Table 2).

Distribution of anesthetic type was similar between groups. Rates of concurrent vaginal vault suspension or hysterectomy were higher among patients with primary incontinence; other concurrent surgeries were distributed equally between the groups. Estimated blood loss was higher among patients with primary incontinence; this is likely because of higher rates of more invasive surgery such as hysterectomy. Length of hospitalization after surgery, likelihood of being discharged with a urinary catheter in place, and the median number of days until normal voiding were similar between groups.

Among patients sent home with bladder drainage (Foley catheter, suprapubic tube, or self-catheterization), the median of days until normal voiding was also similar between groups. These data are presented in Table 4.

The overall complication rate was 7.6% and 4.5% among patients with primary and recurrent incontinence, respectively (*P* = .32). Bladder perforation, recognized intraoperatively, was the most common complication, and occurred at similar rates in both groups (3.2% and 3.4% among the primary and recurrent incontinence groups, respectively). All bladder perforations occurred on the patients' right side, which was the first needle passed in all patients. Complications are displayed in Table 5. There was a low incidence of readmission, usually for incision site or pelvic hematoma or abscess. One patient in the primary incontinence group, who underwent concurrent colpocleisis with perineorrhaphy, had a pelvic hematoma attributed to the colpocleisis, received blood transfusions, and had laboratory evidence of a minor myocardial infarction. There was one postoperative death in the primary group of an elderly patient with significant coexisting cardiac comorbidity who underwent TVT and pelvic repairs under local anesthetic after preoperative medical clearance. She was discharged on the first postoperative day in stable condition and died suddenly while asleep the following evening without antecedent symptoms or complications. No postmortem autopsy was done, and the death was presumed due to cardiac factors. One patient, also in the primary incontinence group, had a small vaginal erosion of mesh, which was successfully treated with simple excision of the exposed mesh.

Outcomes of the TVT procedure were generally similar between the groups. The mean duration of follow-up was 38 (± 16) weeks. Among patients with primary and recurrent incontinence, 87% and 85%, respectively, reported complete cure (*P* = .23). An additional 7% and 4.5%, respectively, were improved. Three patients (1.9%) in the primary incontinence group and six pa-

**Table 5. Complications**

	Primary incontinence n (%)	Recurrent incontinence n (%)	P
All patients with complications*	12 (7.6)	4 (4.5)	
Bladder perforation	5 (3.2)	3 (3.4)	
Readmission	4 (2.5)	1 (1.1)	
Hematoma/abscess	3 (1.9)	1 (1.1)	
Perioperative myocardial infarction	1 (0.6)	0	
Transfusion	1 (0.6)	0	
Perioperative death†	1 (0.6)	0	
Tape erosion (vaginal)	1 (0.6)	0	

\* Some patients may have experienced more than one complication.

† Not clearly attributable to perioperative complication.

tients (6.8%) in the recurrent incontinence group experienced failure. All patients with two or more previous procedures were cured. Among the primary and recurrent incontinence groups, six (3.8%) and three (3.4%), respectively, required takedown, or release, for incomplete bladder emptying, irritative bladder symptoms, or pelvic pain. Patients underwent a TVT release procedure, performed for refractory voiding dysfunction, at rates similar between the two groups. This technique, and its outcomes, are described elsewhere.<sup>2</sup>

Patients in the primary incontinence group were more likely to experience impaired bladder emptying or urge incontinence (including de novo urge incontinence); the rates of overactive bladder syndrome were similar between the two groups. These data are displayed in Table 6.

## DISCUSSION

It is generally accepted that recurrent incontinence is associated with a higher risk of failure with subsequent anti-incontinence procedures, and that the risk of failure continues to rise with the passage of time.<sup>3-5</sup> The risk of failure also appears to rise with the number of previous surgical attempts, especially for retropubic urethropexy.<sup>4,6</sup> Additionally, the dissection involved with vaginal surgery, often the route of anti-incontinence procedures or other concurrent pelvic repairs, has been shown to impair the function of the pudendal and perineal nerve.<sup>7</sup> Our data support this hypothesis, if indirectly, in that patients in this study with a history of anti-incontinence surgery were more likely to have the diagnosis of intrinsic sphincter deficiency.

Tension-free vaginal tape offers an attractive alternative, in its minimally invasive nature and low morbidity.<sup>8,9</sup> Extrapolation of outcomes data from other sling

techniques in the treatment of recurrent incontinence to TVT, however, must be done with caution, as several features of TVT are distinctive, including its midurethral placement and its minimal dissection. Tension-free vaginal tape has recently been assessed in patients with recurrent incontinence, demonstrating efficacy with an 82% cure rate and 91% cured/improved rate, with a good safety profile.<sup>10</sup> However, patients with intrinsic sphincter deficiency and those with symptoms of prolapse were excluded from that study.

This evaluation of TVT for the treatment of recurrent incontinence, in a population inclusive of intrinsic sphincter deficiency and prolapse, demonstrates that the efficacy and safety of TVT in this group of patients are not significantly different from that observed in the primary incontinence population. Rates of cure and complication compare favorably with those quoted for other techniques of anti-incontinence surgery.<sup>11</sup>

For the purposes of this study, patients who had no complaint of postoperative incontinence were not routinely subjected to objective measures. It has been previously demonstrated that subjective cure rates are often higher than objective cure rates.<sup>4,12</sup> It is important to the scientific evaluation of surgery to confirm subjective data, as it is prone to bias on the part of both surgeon and patient. However, as suggested by Arnold et al, the subjective complaint of the patient is usually the stimulus to seek care, and therefore should be our primary endpoint in evaluation of a patient's progress.<sup>13</sup> We do not know the prevalence of objective evidence of incontinence in the general, healthy population (false-positive rate), and therefore should not use it as a gold standard in the incontinent population.

The finding that patients with recurrent incontinence were more likely to have heart disease may be a function of their older age. The fact that they were less likely to have baseline detrusor instability or overactive bladder syndrome, compared with their counterparts with primary incontinence, may reflect the surgeons' reluctance to perform surgery on older, more complicated patients with mixed incontinence.

The low rates of failure in both groups do not permit formal analysis of time dependence; it may be presumed, however, that such a pattern is likely to arise, as they have with other anti-incontinence procedures. These data do not support the generally accepted hypothesis that risk of failure increases with number of previous procedures, in that all patients with two or more previous procedures were cured; however, the number of such patients is low (five), and no formal conclusions in this regard should be drawn. Similarly, the small numbers of failures did not permit analysis of the risk of failure as a function of the specific previous procedure. The incidence of mesh erosion, al-

Table 6. Outcomes

	Primary incontinence (n = 156)* n (%)	Recurrent incontinence (n = 88) n (%)	P
Continence status			
Cured	136 (87)	75 (85)	.23
Improved	11 (7.0)	4 (4.5)	
Failed	3 (1.9)	6 (6.8)	
Release procedure	6 (3.8)	3 (3.4)	
Voiding dysfunction			
Retention	11 (7.0)	2 (2.2)	.08
Incomplete emptying	14 (8.9)	1 (1.1)	.01
Urge incontinence	10 (6.4)	2 (2.2)	.15
De novo	8 (5.1)	2 (2.2)	
Overactive bladder	52 (33.3)	25 (28.4)	.43
De novo	39 (25)	24 (27)	

\* One patient not evaluable because of postoperative death.

though uncommon in the extant TVT literature,<sup>14</sup> is likely to be time dependent; in these and other respects, longer-term evaluation will be of much use.

The current data provide evidence that TVT is comparably safe and effective among patients with recurrent incontinence, with or without intrinsic sphincter deficiency or pelvic organ prolapse, as it has been shown to be among patients with primary incontinence.

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