

Complications of the tension-free vaginal tape procedure for stress urinary incontinence

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Abstract

Introduction and hypothesis The purpose of the study was to determine the intraoperative and immediate postoperative complications of tension-free vaginal tapes (TVT) and risk factors contributing to these.

Methods The study was a retrospective cohort study of 778 TVT procedures.

Results The intraoperative and postoperative complications from the study are as follows: Intraoperative complications included bladder perforation (6.6%), blood loss requiring transfusion (0.6%), and laparotomy (0.1%). Postoperatively, 3.1% of patients developed UTI, while 56.0% had difficulty voiding, and 16.6% had retention. Upon discharge, 54.8% of patients voided, 34.3% self-catheterized, and 8.0% had indwelling catheters. Surgeons responsible for more than 100 TVT procedures had one third the odds of a bladder perforation. Previous incontinence or prolapse surgery were risk factors for bladder perforation. Women with voiding dysfunction preoperatively had a 1.80-fold odds of difficulty postoperatively.

Conclusion Bladder perforation and postoperative retention are the most common complications of TVTs. Risk factors for perforation include less frequent TVT performance and previous prolapse, or incontinence surgery. Preexisting voiding dysfunction leads to postoperative retention.

Keywords Bladder perforation · Complications · Incontinence surgery · Risk factors · Stress urinary incontinence · Tension-free vaginal tape

Introduction

Urinary incontinence is a pervasive problem, affecting 30–40% of older women, with stress incontinence being the most prevalent type in women [1]. Stress urinary incontinence (SUI) is the complaint of involuntary leakage of urine upon exertion, effort, sneezing, or coughing [2]. With inadequate anchoring of the midurethra, an increase in intra-abdominal pressure leads to leakage of urine in the absence of bladder contraction [3].

It has been estimated that urinary incontinence accounts for up to 2% of health care expenditures [1]. This issue will only become a bigger problem for our health care system as the baby-boomer generation ages.

The tension-free vaginal tape (TVT) procedure is a minimally invasive surgical procedure for the treatment of stress incontinence which can be done under local or regional anesthesia. The procedure employs a retropubic synthetic polypropylene mesh tape to provide support to the middle urethra, and was first proposed by Ulmsten and Petros in 1995 [4].

Several previous studies have looked at the rate of complications associated with TVT procedures. The most common intraoperative complications are bladder perfora-

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tion (3.5–6%) [5–10], significant blood loss (0.5–2.5%) [5–10], and laparotomy (0.1–0.5%) [6, 8, 9]. Postoperative complications include hematoma (1.0–3.4%) [5, 6, 8–10], urinary retention with need for catheterization >24 h (4–49%) [5–7, 9, 10], urinary infection (0.7–11.8%) [6–8], and fever >38°C (0.1–0.8%) [6, 8].

Evidence for a cause–effect relationship between preoperative patient characteristics, type of anesthesia, surgeon experience, and complications is conflicting [6, 7].

In Calgary, urogynecologists have been performing TVT procedures since 1999. In order to be able to effectively counsel patients for whom the TVT is a therapeutic option, we sought to determine the intra- and immediate postoperative complications of these at our centre, as well as to delineate risk factors associated with these complications.

Materials and methods

This study was approved by the Conjoint Health Research Ethics Board of the University of Calgary (E-20089) as a quality assurance initiative for a relatively new procedure at the Calgary Health Region.

We reviewed the charts of women who had TVTs from the time the procedure acquired a unique billing code in 2002 to December 2005 at the Foothills Medical Centre in Calgary. A list of 898 charts was generated by the Health Information Management.

Data were collected from hospital charts with a standardized checklist, following assignment of a study number to each patient in order to keep records confidential. We recorded patient age, BMI, surgeon, clinical diagnosis, presenting symptoms, physical exam, medical and surgical history, urodynamic profile and diagnosis, concomitant surgeries, duration of surgery, intraoperative and postoperative complications, duration of hospital stay, and voiding status upon discharge from hospital. Intraoperative bleeding was assessed by the responsible surgical team on the basis of a subjective account of surgical sponge saturation and suction tallies.

The TVT was performed by or under the supervision of one of nine surgeons—four urogynecologists and five general gynecologists—in a teaching hospital with fellows and residents in training. Self-catheterization was either taught to women preoperatively (in case of postoperative need), or taught during hospital stay as needed based on voiding difficulty in the hospital. We considered only outcomes and complications encountered prior to discharge from hospital following TVT, as recorded by the responsible physicians and nurses.

Simple descriptive statistics are used to describe population characteristics and outcomes of the TVT procedures. Continuous variables are described in terms of their mean

(standard deviation) for normally distributed values. Categorical variables are presented in terms of their proportions among all patients.

Logistic regression was performed considering the following possible explanatory variables for bladder perforation: menopausal status, TVT alone compared to concomitant surgery, BMI, previous prolapse or incontinence surgery, anesthetic and surgeon volume. These variables were chosen based on previous research results and clinical suspicion of increased difficulty of surgery.

Logistic regression was also used to determine which of the following possible explanatory variables may lead to postoperative urinary retention: age, voiding dysfunction preoperatively (i.e., overactive bladder), BMI, maximum recorded preoperative bladder volume (<500 mL), TVT alone compared to concomitant surgery, and volume of TVTs undertaken by responsible surgeon during the study period (a surrogate for experience with TVT).

Results

Of 898 charts identified, 68 described trans-obturator tape and other procedures, 37 were missing, and 15 were duplicated chart numbers and therefore excluded.

Among the 778 women included in our study, the mean age was 54±12 years (range, 27–86). The average BMI was 28±6 kg/m². There were 246 (31.6%) premenopausal women and 502 (64.7%) postmenopausal women. Overall, 180 (23.1%) had had a previous continence procedure. Patient characteristics are given in Table 1.

The TVT procedure alone was done in 405 (52.1%) women. The median total time for the TVT procedure was 24 min, with an interquartile range of 11 min (19 to 30 min). One or more additional procedures were done in the other 373 women (47.9%). For these women, the median time of surgery was 84 min, with an interquartile range of 57 min (57 to 114 min). Operative details are given in Table 2.

A total of 56 patients (7.2%) had intraoperative complications. These included bladder perforation in 51 women (6.6%), blood loss requiring transfusion in five women (0.6%), with one of these women requiring a laparotomy (0.1%). Postoperatively, 24 patients (3.1%) had UTI, and voiding difficulty occurred in 436 women (56.0%). Complete urinary retention, defined as inability to void initially post-op, was seen in 129 patients (16.6%).

Of the 436 patients with immediate postoperative voiding difficulty, defined as initial residual volumes greater than 100 cc, 161 (36.0%) went home voiding on their own, 241 (55.0%) were self-catheterizing, 26 (6.0%) with an indwelling catheter, and data were missing on eight (1.8%). Of the 129 women with complete urinary retention postoperatively, defined as inability to void initially, 25

Table 1 Preoperative patient characteristics

Characteristic	Value ± standard deviation or (%)
	<i>N</i> =778
Mean age (years)	54±12
Mean BMI (kg/m ²)	28±6
Premenopausal women	246 (31.6)
Postmenopausal women	502 (64.5)
Not recorded	30 (3.9)
Previous continence surgery	180 (23.1)
Urodynamic diagnosis	<i>n</i> (%)
Stress urinary incontinence alone	299 (38.4)
Voiding dysfunction alone	41(5.3)
Hypotonic bladder alone	3 (0.4)
Detrusor overactivity alone	2 (0.3)
2 diagnoses	132 (17.0)
3 diagnoses	16 (2.1)
No diagnosis	83 (10.7)
Not recorded	202 (26.0)
Prolapse	<i>n</i> (%)
Cystocele alone	89 (11.4)
Vaginal vault prolapse alone	7 (0.9)
Uterine prolapse alone	12 (1.5)
Rectocele alone	21 (2.7)
Enterocoele alone	82 (10.5)
2 diagnoses	174 (22.4)
3 diagnoses	133 (17.1)
4 diagnoses	45 (5.8)
5 diagnoses	1 (0.1)
None	109 (14.0)
Not recorded	105 (13.5)
Medical conditions	450 (57.8)

(19.0%) went home voiding on their own, 87 (67.0%) were self-catheterizing, 12 (9.0%) had an indwelling catheter on discharge, and data were missing on five (3.0%).

Upon discharge from the hospital, 427 patients (54.9%) overall were voiding on their own. A total of 267 patients (34.3%) were self-catheterizing, and 62 (8.0%) had an indwelling catheter. The average length of stay was 3 days ±3 days, although 289 (37.1%) were discharged on the day of surgery. Information about the postoperative course is given in Table 3.

Logistic regression revealed that surgeons who oversaw more than 100 TVT procedures in the study period had one-third the odds of having a bladder perforation compared with those who did the procedure less often (OR=0.34, 95% CI 0.15 to 0.75, *P*=0.007). Patients who had previous incontinence or prolapse surgery were more likely to suffer bladder perforation (OR=2.29, 95% CI 1.20 to 4.38, *P*=0.012). The women who had voiding dysfunction

preoperatively had 1.80 times the odds of having voiding difficulty postoperatively (OR=1.80, 95% CI 1.05 to 3.08, *P*=0.033). We did not find a relationship between menopausal status, concomitant surgery, BMI, or anesthesia and intraoperative complications. Nor was there a relationship between age, BMI, bladder capacity, or concomitant surgery and postoperative complications.

Discussion

Our study reports one of the largest single centre retrospective case series of patients who had the TVT procedure. We found that the most common intraoperative complication was bladder perforation, which occurred in 6.6% of patients. Transfusion of packed red blood cells occurred in five surgeries (0.6%), including one where laparotomy was performed to control bleeding. The most common postoperative complication was voiding difficulty in 56% of women, followed by complete urinary retention in 16.5%, temperature > 38.5°C in 15.6%, UTI in 3.1%, and recognized hematoma in 0.8%.

When a bladder perforation occurs, it is promptly detected on cystoscopy, and the application needle is reinserted correctly. They appear to heal well without sequelae. A Foley catheter is left in situ for 2 days while the bladder heals from the perforation. The rate of perforation found in our study is comparable to previous reports [5, 6, 8, 9].

Over half of our patients experienced voiding difficulty in the immediate postoperative period. This occurred despite the standard use of an operative scissor contact point to create an intervening space between the posterior urethra and the TVT tape in order to ensure tension-free placement. This number is larger than expected because we defined it as residual urine volumes greater than 100 mL with initial postoperative voids, as measured with a bladder scanner or an in and out catheter. Of these women, only a small fraction went home with an indwelling catheter. Approximately half of the women with initial voiding difficulty were instructed to self-catheterize until resolution of the urinary retention, according to the postoperative protocol of their surgeon. As our study collected data only prior to patient discharge, we do not have information on the rate of voiding dysfunction at 24 and 48 h. Over a third of these women went home voiding on their own, reflecting the resolution of voiding difficulty in the early postoperative period for a large portion of women. Our rate is comparable to two previous Canadian studies, one of which recorded a 19.7% rate of urinary retention (residual volumes >100 mL for >24 h) [5] and another reporting a rate of 49% (residuals >200 mL beyond 2 days) [10]. Complete urinary retention—inability to void in the

Table 2 Operative details

Characteristic	<i>N</i> =778
Intraoperative complication	<i>n</i> (%)
Bladder perforation	51 (6.6)
Urethral injury	0 (0.0)
Transfusion of packed cells	5 (0.6)
Laparotomy	1 (0.1)
Concurrent surgery (%)	373 (47.9)
Length of surgery	Median (IQR: 1st quartile–3rd quartile)
Time of TVT alone (<i>n</i> =405)	24 min (11 min: 19–30 min)
Total time of TVT plus other surgery (<i>n</i> =373)	84 min (57 min: 57–114 min)
Anesthesia type	<i>n</i> (%)
Local only	319 (41.0)
General only	278 (35.7)
Spinal only	98 (12.6)
Spinal and general	12 (1.5)
Local and spinal	51 (6.6)
Local and general	7 (0.9)
Local, spinal and general	1 (0.1)
Not recorded	12 (1.5)

immediate postoperative period—was seen in 16.5% of patients. One-fifth of these patients were able to void on their own upon discharge, and two-thirds were able to self-catheterize.

We determined that surgical experience plays a role in intraoperative complications—specifically, that surgeons who were responsible for less than 100 TVT procedures during the 3-year study period had more frequent bladder perforations. One possible explanation is that our data capture a period where some operators had several years' experience with the TVT, while others were at the start of their learning curve. Alternatively, it may be that this procedure is safer in the hands of those who perform it

regularly. Previous incontinence or pelvic prolapse surgery was also found to be a risk factor for bladder perforation. Urinary retention postoperatively was more common among those women who had voiding dysfunction on preoperative urodynamic testing.

Four urogynecologists and five obstetrician/gynecologists were responsible for the procedures, with postgraduate trainees in the majority of cases. As the charts were reviewed retrospectively, it was impossible to ascertain with certainty whether a procedure was done by a surgical trainee or the staff. This would be an interesting subject to explore with a prospective study. Conversely, by including operations where postgraduate trainees assisted the staff surgeon, we capture a variety of levels of experience with the TVT procedure, and our complication rates reflect what patients are likely to encounter in tertiary centres.

Another limitation of the study is that it is confined to the duration of hospital stay; therefore certain long-term complications such as tape erosion, de novo urgency, unresolved urinary retention, and thromboembolic phenomena are not captured in our data. Since the period of this study, practice has changed somewhat and 84% of patients who have the TVT procedure only are now discharged on the day of surgery with postoperative homecare [11].

In conclusion, the present study confirms previous reports of the safety of the TVT procedure for management of stress urinary incontinence performed at a tertiary Canadian centre with postgraduate trainees and with concomitant surgeries. The study empowers us to give realistic complication rates to our patients and to let them know of a potential increased risk of bladder perforation when a surgeon performs a lower

Table 3 Postoperative course until discharge

Postoperative complication	<i>n</i> (%)
	<i>N</i> =778
Complete urinary retention	128 (16.5)
Voiding difficulty	436 (56.0)
Urinary tract infection	24 (3.1)
Hematoma	6 (0.8)
Wound abscess	0 (0.0)
Venous thrombosis/Pulmonary embolus	0 (0.0)
Fever	121 (15.6)
Voiding at discharge	<i>N</i> (%)
Voiding on own	427 (54.9)
Self-catheterizing	267 (34.3)
Indwelling catheter	62 (8.0)
Not recorded	22 (2.8)

volume of TVTs, or when the patient has had previous incontinence or prolapsed surgery. We were also able to document that preoperative voiding dysfunction is a risk factor for voiding difficulty postoperatively.

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