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ORIGINAL ARTICLE

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Needle tip control and its effect in reducing intraoperative complications during tension-free vaginal tape placement

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Abstract Tactile needle tip control was used to aid perforation during standard tension-free vaginal tape (TVT) placement to treat urinary incontinence. The success and complications of this novel method were compared retrospectively with the reported results of the standard technique. One hundred nine patients had TVT placement between 1998 and 2001, with follow-up continuing into 2002. Preoperatively, the severity of urinary incontinence was assessed objectively. Postoperatively, TVT effectiveness was assessed subjectively by standardized questionnaire, completed by 78 of the 109 patients (72%). Objective 2-year rates for continence or improvement and most complication rates were similar to previously reported results. Needle tip control was helpful in lowering the occurrence of bladder perforation. Longer postoperative recovery times associated with postoperative dysuria or obstruction did not decrease patient satisfaction if the patient experienced a marked improvement in leakage.

Keywords Bladder perforation · Tension-free vaginal tape · Urinary incontinence

Abbreviations *ISD* Intrinsic sphincter deficiency · *TVT* Tension-free vaginal tape

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Introduction

Since 1994, tension-free vaginal tape (TVT) (Gynecare, Johnson & Johnson, Somerville, New Jersey) has provided a less invasive and more effective surgical option to treat urinary incontinence [1]. Primarily used to treat urinary stress incontinence, secondary indications include failure of prior anti-incontinence surgery, mixed incontinence, intrinsic sphincter deficiency (ISD), urethral hypermobility and instability, and obesity-related incontinence [2]. The surgical advantages of TVT placement show a comparable 3-year success rate to those associated with traditional sling procedures, a shorter learning curve, a shorter operative time and recovery period, and use with concurrent vaginal repairs [1].

As with any procedure, TVT placement has potential complications: postoperative dysuria, infection, erosion, vascular injury, hemorrhage and bladder perforation. Although the risk of these complications is similar to that experienced after conventional anti-incontinence procedures, these complications interfere with a successful surgical outcome, i.e. achieving continence. Adherence to the standard technique [2, 3, 4] is paramount to the relative safety of TVT use. Anecdotally, many surgeons have attested to additional innovations during TVT placement that have helped them improve their results.

In this paper we discuss an addition to the standard technique that has limited our incidence of several complications, particularly inadvertent bladder perforation. We present a series of 109 consecutive patients who had TVT placement with suprapubic needle tip control and were then followed up for 2 years. The objective of the study was to assess retrospectively a series of patients operated on by one surgeon with experience in both transvaginal and retropubic procedures. By focusing specifically on morbidities, whether intraoperative, postoperative or long-term, we aimed to discover whether this additional maneuver yielded better outcomes.

Materials and methods

A retrospective medical record review was used to identify patients who had at least one of the following: incontinence type I, II or III; failure of a previous anti-incontinence operation; mixed incontinence; ISD; urethral hypermobility or instability; pelvic prolapse; or obesity-related incontinence. ISD was defined as loss of urethral coaptation at rest with a maximal urethral closure pressure of less than 20 mmH_2O or Valsalva leak-point pressure of less than 60 mmH_2O [5]. Pelvic prolapse was defined as descent of the anterior vaginal wall, posterior vaginal wall, vaginal apex (cervix, uterus or vaginal cuff), or all three structures [5]. A surgical intervention was offered to patients who had had 3 months of unsuccessful conservative therapy (e.g. Kegel bladder training, estrogen cream, anticholinergic medication). Excluded were patients with psychiatric or neurologic disease, neurogenic or hypocontractile bladders, or pure urge incontinence. All included patients had a standardized preoperative evaluation composed of questions regarding the history and severity of their incontinence, a physical examination, dual-chamber subtracted urodynamic testing, and cystoscopy. Degree of urine loss was determined preoperatively through objective stress testing on cystometry at 300 ml. Overall, this evaluation was consistent with International Continence Society recommendations [6].

From August 1998 to July 2001, 109 consecutive women under the care of one practitioner (S.P.) associated with the Medical College of Ohio underwent the TVT procedure. The anesthetist chose the method of anesthesia on the basis of the patient's clinical status or preference, and whether additional gynecologic procedures (i.e. hysterectomy, prolapse repairs) were necessary. Cefazolin, 1 g intravenously, was the prophylactic antibiotic of choice. The TVT procedure was performed on all 109 patients using the standard accepted technique [2, 3, 4].

Needle tip control

As the needle was advanced from the vaginal incisions to the suprapubic incisions, proximity to the inferior pubic ramus and then posterior arcus pubis was maintained by gently prodding the periosteum with the needle tip under control by the operator's vaginal hand and index finger. The vaginal finger also served to palpate the inferior ramus laterally and the urethra with the guide medially. Tip migration was minimized by using the second hand to acutely angle, not drive, the needle's arc upward as it passed behind the posterior arcus. Enough force was then placed on the needle by the vaginal index finger to approximate and barely perforate the retropubic fascia. Without advancing the needle, upward pressure on the needle from the vaginal hand was maintained. Blunt dissection of the suprapubic incisions down to the tented rectus fascia located the needle's tip. Apposition of the operator's two index fingers was then achieved to isolate the most minimal amount of tissue through which to pass the needle. Proximity of the needle tip to the urogenital diaphragm and posterior arcus pubis was reconfirmed by adjusting the operator's second and third fingers to either side of the suprapubic incision and providing downward pressure. After confirming the tip's position, the second hand was returned to stabilize the needle driver. Blind directional force was avoided, and a gentle 'pop-through' of the rectus fascia was achieved with the controlled needle tip by the vaginal hand and index finger.

The addition of direct tactile tip control by the vaginal and suprapubic index fingers served two purposes. The first was to lessen any forceful perforation into the bladder. The second was to limit blind maneuvering toward the rectus fascia, thus limiting medial, lateral or superior needle tip migration.

Tape adjustment

Tape adjustment was performed by placing a no. 9 Hegar dilator between the tape and the midurethra. This dilator provided more laxity and room for readjustment than the smaller no. 7 or 8 dilators mentioned in earlier reports [4]. The bladder was filled to 250 ml. If the patient was awake, she was asked to cough or bear down. If she was sedated or under general anesthesia, coughing was initiated by suction stimulation or urine expression by the Credé method, respectively. Proper TVT positioning was evidenced by slight urinary leakage. The absence of urine leakage indicated that TVT placement was too tight, and the tape was consequently readjusted. During the immediate postoperative period, a Foley catheter was placed until the patient had the urge to void and could do so without difficulty. Drainage continued for more than 48 h for patients who underwent more invasive procedures. Follow-up was conducted at 2 weeks; at the end of months 1, 3, 6 and 12; and then yearly through August 2002.

The primary outcome measures were objective cure of urinary incontinence on physical examination and subjective cure by questionnaire. A cure was defined as absence of urinary leakage on stress maneuvers at full capacity, along with a low postvoid residual. A marked reduction in leakage (droplet) was regarded as improvement. Secondary outcome measures included development of voiding problems or operative and postoperative complications. Incidence of bladder perforation was of particular interest as an outcome measure because it is the most common intraoperative complication experienced.

Preoperative and postoperative subjective assessment was performed by means of a standardized self-reporting questionnaire sent to all 109 patients. Seventy-eight patients (72%) completed a 34-question preoperative survey similar to the Bristol Female Lower Urinary Tract Symptoms questionnaire [7]. Subjective severity of incontinence was based on the Ingelman-Sundberg scale (I–III) [8]. Postoperative questions about outcome and subjective improvement are shown in Fig.1.

Informed consent was obtained from each patient studied before data pertaining to her case were extracted for analysis. Data were analyzed with use of the JMP statistical analysis software package (version 4.0.4, SAS Institute Inc., Cary, North Carolina, USA).

Results

Patient characteristics

From August 1998 to July 2001, 109 patients had the TVT procedure. Complete data were available for the 78 women (72%) who completed the questionnaire and 2 years of follow-up visits. Table 1 shows baseline characteristics of these 78 women.

Testing

Urodynamic testing confirmed leakage during Valsalva stress test maneuvers at 300 ml in all 78 patients. Table 2 shows results of the physical evaluation (urodynamics, cystoscopy and physical findings). No sudden urethral pressure drops diagnostic of urethral instability were detected.

Operative findings

Operative findings and complications are shown in Tables 3 and 4. Operative complications were less common than postoperative complications. Operative secondary outcome measures of high interest showed

Fig. 1 Postoperative outcome questions

Postoperative outcome questions

1. How much improvement in your incontinence have you noticed since your operation?

_____ Little
_____ Moderate
_____ Great

2. How long did it take for you to feel you had recovered completely from your operation?

_____ 0-2 weeks
_____ 2-4 weeks
_____ 4-8 weeks
_____ > 8 weeks

3. How much leakage do you have since you recovered?

_____ None
_____ Drops
_____ Enough for a pad
_____ Unchanged

4. Would you recommend this operation to your friends who have the same problem?

_____ Yes
_____ No
_____ I don't know
_____ Reason: _____

5. Did you have any complications from the surgery?

_____ No
_____ Yes

If yes, what complications did you have?

_____ Trouble urinating
_____ Frequent urination
_____ Sudden urgency
_____ Urinary tract infections
_____ Chronic pain
_____ Other: _____

no bladder perforations or injuries to any other vital structures. One dissection of the needle into the bladder serosa without perforation was seen on intraoperative cystoscopy; this was remedied by repositioning the needle. No hematomas, graft infections or tape erosions were noted at 2 years of follow-up. One vaginal granuloma, evident at the sixth postoperative week, resolved after the application of silver nitrate. Postoperative urinary tract infections developed in 6 patients and resolved with appropriate antibiotic treatment. Four patients experienced postoperative pain for as long as 8 weeks; these patients received narcotic analgesia.

Postoperative success based on indication

In our patients, primary 2-year outcome measures of continence cure and improvement for each major indication are seen in Table 5. These outcomes correlated well with subjective cure and improvement rates reported by the postoperative questionnaire. Subjective patient satisfaction, defined in our postoperative survey as a 'great' improvement over preoperative symptoms, was seen in 55 patients (70%). Another 17 patients (22%) were satisfied with only 'moderate' improvement. Overall, 69 of 78 patients (89%) said they would recommend the procedure to others. We did not test cured

Table 1 Baseline characteristics of 78 patients completing the study

Characteristic	Patients		Mean	Range
	No.	%		
Age, y	–	–	58	29–86
BMI, kg/m^2	78	100	–	–
Obese	8	10	29.9	–
Parity	–	–	2	0–6
Cesarean deliveries	3	–	–	–
Hormone status				
Premenopausal	28	36	–	–
Postmenopausal	50	64	–	–
Incontinence symptoms, mo	78	100	24	3–240
Surgical history[a]				
Abdominal hysterectomy	23	29	–	–
LAVH	1	1	–	–
Vaginal hysterectomy	2	3	–	–
Prolapse repairs	11	14	–	–
Anti-incontinence surgery	11	14	–	–

BMI, body mass index; LAVH, laparoscopy-assisted vaginal hysterectomy
[a]Some patients had more than one procedure

Table 2 Objective physical findings

Characteristic	Patients		Mean	Range
	No.	%		
Physical diagnoses[a]				
Stress incontinence	37	47	–	–
Mixed incontinence	27	35	–	–
Uncontrolled incontinence (ISD)	13	17	–	–
UTI	13	17	–	–
Prolapse with UTI	5	38	–	–
Obstruction with prolapse	3	60	–	–
Urodynamics				
Peak flow, ml/s	78	100	29	10–35
Average flow, ml/s	78	100	19	8–20
Postvoid residual, ml	78	100	40	15–90
VLPP, mmH_2O	78	100	57	18–92
MUCP, mmH_2O	78	100	44	8–86
Cystoscopy[a]				
Urethral hypermobility	13	17	–	–
Open bladder neck at rest	8	10	–	–
Cystocele	7	9	–	–
Poor urethral coaptation	5	6	–	–
Urethral tortuosity	4	5	–	–
Small bladder capacity	4	5	–	–

ISD, intrinsic sphincter deficiency; MUCP, mean urethral closure pressure; UTI, urinary tract infection; VLPP, Valsalva leak-point pressure
[a]Some patients had more than one finding

and improved patients cystometrically after TVT placement.

In 37 patients with stress incontinence, cure occurred in 25 (68%) and improvement in 7 (19%). In 27 patients with mixed incontinence, cure occurred in 16 (59%) and improvement in 7 (26%). The results were consistent with those reported by Ward and Hilton [9]. In the 27 patients with preoperative mixed incontinence, irritative dysuria was reduced postoperatively in 12 (44%). This is consistent with findings of improvement in bladder instability postoperatively in 50%–66% of patients [10, 11].

Table 3 Perioperative findings

Findings	Patients		Mean	Range
	No.	%		
Anesthesia				
Local	40	51	–	–
General	38	49	–	–
Operative time, isolated placement, min	40	51	22	19–46
Concomitant surgery				
LAVH	19	24	–	–
Vaginal hysterectomy	5	6	–	–
Prolapse repair	14	18	–	–

LAVH, laparoscopy-assisted vaginal hysterectomy

Table 4 Complications

Complication	Patients		Rate reported in the literature, %
	No.	%	
Bladder perforation	0	0	2–24
Vascular injury or hemorrhage	0	0	0–3
Bowel perforation	0	0	<1
Postoperative irritative voiding	17	22	3–24
Postoperative retention			
Temporary	21	27	3–19
Obstructive	5	6	2–8

Table 5 Two-year success after TVT placement

Indication[a]	Patients, no.	Patient outcome					
		Cure		Improvement		Failure	
		No.	%	No.	%	No.	%
Stress incontinence	37	25	68	7	19	5	13
Mixed incontinence	27	16	59	7	26	4	15
ISD	13	6	46	5	38	2	15
Obesity	8	5	63	3	37	0	0

ISD, intrinsic sphincter deficiency; TVT, tension-free vaginal tape
[a]Some patients had more than one indication

In the 13 patients with ISD, cure in 6 (46%) and improvement in 5 (38%) were lower than reported rates of 77%–84% [10]. These lower rates may be attributable to a stricter definition of cure involving no leakage. Three of these 13 patients also had urethral hypermobility. One patient with ISD later required α-adrenergic medication for occasional leakage, and another required temporary anticholinergic medication for irritability.

In 8 obese patients (mean body mass index 29.9 kg/m^2) the TVT was successful in maintaining 2-year continence in 5 (63%) and improvement in continence without adverse effects in 3 (37%). Although these numbers are small, results in these patients are relatively similar to those reported elsewhere [12]. Where other procedures traditionally have failed in obese patients, TVT in obesity has become more widely accepted [4].

The success of TVT placement was not affected by concomitant procedures. Five of 26 hysterectomy

patients (19%) had transient postoperative urgency; 2 remained incontinent, and 1 had a high postvoiding residual. Although this outcome was infrequent, less urgency and more retention were noted if vaginal repairs were performed. Neither concomitant hysterectomy nor prolapse repair was associated with obstructive retention requiring tape lysis. This is consistent with other findings that pelvic surgery can be performed safely and successfully in conjunction with the TVT procedure [11].

Overall 11 treatment failures occurred, of which 7 were evident by the eighth postoperative week. This is consistent with reports that most failures occur within 3–6 months after placement [4, 10, 13]. Only 2 of 17 patients (12%) with postoperative dysuria were not satisfied with the procedure, nor would they recommend it. Only 1 patient with preoperative ISD and recurrent incontinence was not satisfied and did not recommend the procedure to others; she also refused further treatment. Four patients with mild preoperative stress symptoms had little postoperative satisfaction, and none recommended the procedure. Therefore, patients with mild incontinence may be better candidates for conservative therapy, given their tendency to be less satisfied with the outcomes of TVT placement. Similarly, 3 of 5 patients (60%) requiring tape lysis would not recommend the TVT procedure. Altogether, 9 of the 78 patients (12%) were not satisfied. Interestingly, longer recovery times were not associated with decreased satisfaction, even if the end result was only 'little' improvement in incontinence in those with severe preoperative symptoms.

Postoperative complications

Postoperative secondary outcome measures of transient postoperative dysuria involving irritative voiding symptoms, urgency and frequency occurred in 17 of 78 patients (22%). This result is comparable to previously reported rates of 3%–24% [14]. We defined irritative voiding symptoms as abnormal symptoms experienced by the patient during voiding, such as slow stream, spraying, intermittency, dribbling, a feeling of incomplete emptying, or pain [6]. Urgency was defined as the sudden, compelling desire to urinate [6]. Frequency was defined as a complaint by the patient that she voids too often during the day [6]. Six patients with urinary stress incontinence and 6 with ISD had transient dysuria. A 2–4-week regimen of anticholinergic medication alleviated the symptoms in all 12. No de novo detrusor instability occurred during the early postoperative period, and late de novo instability (occurring after more than 1 year) was not assessed.

Some form of temporary urinary retention affected 21 of 78 patients (27%). Four of these patients had suprapubic catheters for other indications and required drainage for a mean of 17 days (range 7–28 days). We defined a high postvoid residual as more than 100 ml on two separate occasions; this occurred in 17 patients (22%). We defined obstructive urinary retention as a residual of more than 150 ml on two separate occasions; this occurred in 5 patients (6%). For the 17 patients with retention, double voiding was initiated first; this reduced the residual in only 3 patients. Intermittent self-catheterization was then initiated in the remaining 14 patients, for an average of 15 days (range 3–21 days). In the 5 patients with obstructive urinary retention, midline tape lysis was performed after no improvement in their residuals had occurred by the fourth postoperative week. One of these patients had pre-existing ISD and became incontinent, requiring transurethral collagen injection.

Discussion

Successful TVT placement

As evidenced by the evolution of more than 100 anti-incontinence procedures, there is no ideal surgical correction of urinary incontinence. Although a recent study adequately pointed out more operative morbidity and less postoperative morbidity with TVT placement than with conventional options, most concede that the TVT placement is advantageous as a 'minimally invasive', expeditious procedure, offering the patient quick healing and a high overall success in improving continence [9]. As with any new procedure, TVT placement has a different set of indications and rates of success or complications. Representative studies by Ulmsten et al. [15] and Olsson and Kroon [13] have reported 3-year continence rates, based on the surgeon's perception of a satisfactory outcome, ranging from 87% to 90%.

If proper placement technique is followed without major deviation, there is evidence of improved safety and reduced morbidity compared with more invasive procedures [15, 16, 17]. Two factors are of paramount importance. First, knowledge of anatomy is crucial for safe needle placement [4]. Second, the only tension placed on the tape is during midurethral positioning [4]. On provocation, the tape must allow a drop of urine to appear at the external meatus [10].

Preventing needle tip migration

Blind passage of a 5-mm needle vaginally up through the abdomen necessitates continuous needle tip control. This is especially true if the patient has had a previous anti-incontinence procedure. Fibrosis and scarring from a prior operation often distort the tissues and require the operator to apply more force when passing the needles [4]. We believe the limited operative complications were in part attributable to careful redirection and limited migration of the needle's arc acutely cephalad once the tip had rounded the posterior arcus pubis. In addition, the apposition between the vaginal and abdominal index

Table 6 Intraoperative complications

Author, year	Mean follow-up, mo	Patients, no.	Complication rate, %		
			Bladder perforation	Hemorrhage/vascular injury	Intestinal injury
Niemczyk et al. 2001 [21]	2	100	24	1	–
Jeffry et al. 2001 [22]	25	112	11.6	2.7	–
Tamussino et al. 2001 [23]	–	2,795	2.7	0.74	0.03
Kuuva and Nilsson 2002 [24]	–	1,455	3.8	1.97	–
Karram et al. 2003 [25]	48	350	5.4	2.2	–

fingers lessened the amount of tissue the needle had to transect blindly and may therefore have diverted any important structures to the side (i.e. bladder wall, inferior epigastric vessels). Avoidance of bladder perforation or vascular injury was not guaranteed, and so after each needle was placed, standard cystoscopy was used to verify that the bladder was intact. Careful observation and aggressive management of hemostasis were maintained to rule out vascular compromise. It cannot be overemphasized that controlling the needle tip was not a deviation from the standard technique, but merely a subtle and important addition to aid in TVT placement. We believe this novel enhancement helped to avoid any bladder or vascular injuries.

Assessing postoperative complications

The main postoperative complications encountered were temporary dysuria (22%) and urinary retention (27%). Obstructive urinary retention occurred in 5 patients (6%). We believe that dysuria and retention in the patients we studied were not attributable to any direct tension caused by the use of a larger dilator. The Hegar dilator provided more space between the tape and the midurethra than typical clamps used in some procedures. Hegar dilator use has been advocated by some [4] as a method of loosening a tight placement. We theorize that the space created by the dilator may have allowed for slight proximal tape migration toward the urethrovesical junction. Irritative symptoms and transient retention may have been caused by some sling 'tension' at the urethrovesical junction as its anatomy returned to normal. Because the urethra is relatively short, any migrational change would be difficult to quantify objectively. Concomitant surgery and a more aggressive approach in some patients with milder stress leakage may also have added to the transient retention rate. Although general anesthesia delayed the onset of spontaneous voiding, it did not seem to contribute to marked dysuria or obstruction.

In patients with unimproved obstruction, we preferred to perform midline tape lysis within 4 weeks of the initial TVT placement. Obstruction is traditionally defined as a blockage in urine flow resulting in flow of less than 10–15 ml/s [18]. In addition, the detrusor muscle has a pressure greater than 20 mmHg at maximum flow [6]. A postvoid residual greater than 150 ml also may indicate obstruction. Our diagnosis of obstruction was based on two separate residuals of more than 150 ml and previously normal voiding and emptying. We did not use repeat urodynamic studies as a basis for diagnosing obstruction, in light of the finding by Nitti et al. [19] that differences between urodynamic studies are not observed in 10%–64% of patients with retention, yet these patients improve with lysis.

Dissection and midline transection of the tape were easily accomplished in 5 patients, 4 of whom remained continent. Early lysis was preferred to relieve obstruction while maintaining continence, and we believed that it was not necessary for the patient to undergo a new tape procedure as fibrosis along the tape maintained urethral support [20]. To reduce the risk of obstruction, it has been suggested that a patient selected for the TVT procedure should have normal preoperative cystometric flow without a hypocontractile bladder, 'tensionless' placement, and a drop of urinary leakage during tape adjustment [10].

One limitation of our study is its retrospective nature and the lack of a control group to compare standard technique versus the technique with needle tip control. Additional postoperative urodynamic studies would have provided more objective data to measure TVT outcomes. Finally, validated questionnaires, particularly regarding quality of life, would have been beneficial in quantifying patient satisfaction and the amount of subjective improvement. Nevertheless, we believe that our success and complications are comparable to those reported in the literature (Table 6).

Conclusion

Our results show that additional needle tip control during traditional TVT placement results in similar success rates for the major indications of stress incontinence, mixed incontinence, ISD and obesity. Furthermore, expected untoward effects of postoperative dysuria, obstruction and major complications (i.e. vascular injury, hemorrhage, bowel injury) also occurred within previously reported frequencies. Bladder perforation was limited by the addition of this technique. Further studies must be done prospectively with larger numbers of patients to assess whether the addition of needle tip control truly aids the surgeon in TVT placement.

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Editorial comment

The authors report a single-center single-surgeon experience with the TVT sling procedure. It is a series of 109 women in a 'real-world' setting. As such, inclusion and exclusion criteria as well as endpoints are not well defined and not objective. The study demonstrated good results with the procedure, which are very consistent with many previously published papers. The authors stress important technical aspects of the procedure to avoid migration of the tip of the needle.