

COMPLICATIONS OF THE TENSION-FREE VAGINAL TAPE OPERATION IN WOMEN WITH STRESS URINARY INCONTINENCE

İsmail Mete ITIL, Teksin CIRPAN, Fuat AKERCAN, Pinar Solmaz YILDIZ, Niyazi ASKAR,

Department of Obstetrics and Gynecology, Ege University Faculty of Medicine, Izmir, Turkey

SUMMARY

Objective: To report our experience with tension-free vaginal tape (TVT) operation in patients with stress urinary incontinence and to assess the rate of success and complications associated with this procedure.

Methods: We performed a retrospective review of 153 patients undergoing the TVT procedure in a 4 years period to report intraoperative and postoperative complications and success rate.

Results: Intraoperative complications only included 11 (7,20%) bladder perforations. Postoperative complications included 16 (10,46%) short term voiding dysfunction, 14 (9,15%) overactive bladder. The rate of bladder perforation was significantly higher in patients with previous antiincontinence surgery than in those without previous antiincontinence surgery, (13,46% (7/52) compared with 4,0% (4/101), $p<0,05$). Women with previous antiincontinence surgery had significantly higher short term voiding dysfunction rate than those who did not have any previous antiincontinence surgery, (21,15% (11/52) compared with 5,0% (5/101), $p<0,05$). The rate of overactive bladder was similar in women with or without previous antiincontinence surgery, (9,61% (5/52) compared with 8,91% (9/101), $p>0,05$). The overall subjective cure rate was 90,85% for patients with stress urinary incontinence.

Conclusions: The TVT is an efficacious procedure for the treatment of stress urinary incontinence and a safe procedure with an acceptable complication rate.

Key words: female stress urinary incontinence, TVT procedure

ÖZET

Tension-free Tape operasyonunun Stres Üriner İnkontinanslı Vakalarda Etkinliği ve Komplikasyon Oranları

Amaç: Bu çalışmada kliniğimizde uyguladığımız Tension-free Tape operasyonunun stres üriner inkontinanslı vakalardaki etkinliğini ve komplikasyon oranlarını belirtmeyi amaçladık.

Metod: Retrospektif olarak 4 yıllık süre içerisinde kliniğimizde 153 hastaya uyguladığımız TVT operasyonunun intraoperatif ve postoperatif komplikasyonlarını ve başarı oranını inceledik.

Sonuçlar: İntraoperatif dönemde sadece 11 mesane perforasyonu gözlenmiştir (%7,20). Postoperatif dönemde 16 hastada kısa süreli işeme sorunları (%10,46) ve 14 hastada overaktif mesane (%9,15) izlenmiştir. Mesane perforasyon oranı daha önceden başka bir inkontinans cerrahisi geçirenlerde (%13,4; 7/52) geçirmeyenlere göre anlamlı olarak yüksek bulunmuştur (%4,0; 4/101) ($p<0,05$). Kısa süreli işeme sorunu daha önceden başka inkontinans cerrahisi geçirenlerde (%21,15; 11/52) geçirmeyenlere göre anlamlı olarak yüksek bulunmuştur (%5,0; 5/101) ($p<0,05$) Overaktif mesane oranları daha önceden başka bir inkontinans cerrahisi geçirenlerle (%9,61; 5/52) geçirmeyenlerde aynı bulunmuştur (%8,91; 9/101). ($p>0,05$). Tüm hastalarda sübjektif kür oranı %90,85 bulunmuştur.

Yorum: TVT stres üriner inkontinanslı hastalarda etkili ve kabul edilebilir komplikasyon oranlarıyla beraber güvenli bir operasyondur.

Anahtar kelimeler: kadın stres üriner inkontinansı, TVT

Address for Correspondence: Dr. Teksin Cirpan, Department of Obstetrics and Gynecology, Ege University Faculty of Medicine, Bornova, Izmir, 35100 Turkey
Fax: 0090 (232) 343-07 11
e-mail: cirpanteksin@yahoo.com
Geliş tarihi: 28.11.05, kabul tarihi: 12.12.05

Synopsis: TVT is an efficacious and a safe procedure procedure for the treatment of stress urinary incontinence.

INTRODUCTION

More than 100 different surgical procedures for the treatment of stress urinary incontinence were reported in the current literature⁽¹⁾. All these diverse procedures have been described reflecting that the exact mechanism of incontinence is not entirely understood, and that there is no reference standart treatment. The procedures suspending the proximal urethra and bladder neck are retropubic urethropexy and transvaginal needle suspension that were based on the understanding that the proximal urethra is the segment of urethra most responsible for the continence mechanism. Suburethral sling procedures are aimed at either supporting the proximal urethra and bladder neck by creating a backboard or, in severe cases of urethral dysfunction, actually creating an obstruction at this level⁽²⁾. Injections of various bulk-enhancing materials are aimed at creating increased urethral resistance by bulking up the proximal urethra and bladder neck^(2,3).

Ulmsten et al. recently described the concept of correcting stress urinary incontinence in women by placing a tape of mesh under the midurethra in 1996⁽¹⁾. This was a minimally invasive procedure under local or regional anesthesia to correct the stress urinary incontinence due to urethral sphincter incompetence. With this technique, continence restored at the level of the pubourethral ligaments, not at the bladder neck as with most anti-incontinence operations^(4,5,6). The original concept has since evolved into what is now known as the tension-free vaginal tape (TVT) operation. The procedure uses a strip of polypropylene mesh which commercially available as a kit from the Ethicon (Norderstedt, Germany) company. The tape is not sutured in place, and placement is supposed to be without tension⁽⁷⁾.

The aim of this study was to report the results of TVT operation in our hospital. We interested in the perioperative and postoperative complications, the success rates of the procedure in patients with or without previous antiincontinence surgery.

MATERIALS AND METHODS

We retrospectively reviewed the hospital records of 153 patients operated on with TVT for stress urinary incontinence from March 2001 to March 2005. We performed this retrospective review to report items regarding patient (age, parity, body-mass index, previous antiincontinence surgery, HRT), the operation (operating time, concomitant procedures, anesthesia and method of postoperative bladder drainage), the postoperative course (days until spontaneous voiding with residual urine volumes less than 100 ml, postoperative hospital stay), intraoperative complications (bladder perforation, blood loss of >500 ml), postoperative complications (de novo urge incontinence, voiding dysfunction, vaginal erosion, poor healing, nerve injury, hematoma formation, urinary tract infection or wound infection) and incidence of reoperation either for voiding dysfunction or recurrent incontinence. The course 12 months after surgery was evaluated using the patients' hospital charts. After the surgery the patients returned monthly for clinical evaluation. They were questioned about presence of spontaneous voiding, involuntary urinary leakage, irritative bladder symptoms, vaginal and suprapubic pain, in addition to questions about their satisfaction with the procedure. In the absence of urinary leakage complaint the patients were accepted as continent. Cure was defined as 90,85% subjective improvement in symptoms of incontinence.

The preoperative examination protocol included a cough stress test, a 24-hour pad test, a micturition diary and urodynamic evaluation. Stres urinary incontinence was objectively documented in all patients by multichannel urodynamic testing, which included substracted cystometry, urethral pressure profile measurements, leak point pressures and urine flow studies.

A Prolene tape was placed under regional anesthesia around the midportion of the urethra via a small sagittal suburethral vaginal wall incision, with intraoperative adjustment of the tension of the tape to minimize leakage while the patient coughed at a bladder volume of 250 ml. If performed in conjunction with other procedures in patients with general anesthesia, intraoperative adjustment of the tension of the tape evaluated with suprapubic pressure. The tape was not fixed. At the end of the operation the bladder was emptied and the patient left the operating room with

an indwelling Foley catheter⁽⁸⁾.

Short-term dysfunction was defined as incomplete bladder emptying (residual volume of >100 ml for <24 hr) that occurred within the first 6 weeks of surgery. Prolonged voiding dysfunction (residual volume of >100 ml for <24 hr) was defined as intermittent self-catheterization or an adjustment or alteration in the sling after 6 weeks postoperatively. Overactive bladder was objectively documented in patients with postoperative incontinence complaint by multichannel urodynamic testing. The diagnoses of infection, hematoma, erosion, poor healing and nerve injury based on clinical findings. Differences in proportions between two groups with or without previous antiincontinence surgery were compared with the X2 test.

RESULTS

A total of 153 patients were included in the study. The hospital records of all women in this study reviewed for 12 months postoperatively. The average age of the women in this study population was 51 (range 30-76), average parity was 3,0 (range 1-7), and average body-mass index was 29,1 (range 19,1-44,4), (Table I). Of 153 patients, 65 (42,48%) underwent the TVT procedure in conjunction with the other gynecologic procedures (simple abdominal hysterectomy, vaginal hysterectomy, anterior repair, posterior repair, salpingo-oophorectomy, sacrospinous vaginal vault suspension, paravaginal repair), (Table II); 88 (57,52%) underwent TVT alone. Fifty-two women (33,98%) had previous anti-incontinence surgery, whereas 101 (66,02%) were undergoing their first incontinence procedures. The operation performed under general anesthesia in 78 of patients (50,98%), under regional anesthesia in 72 of patients (47,06%) and local anesthesia in 3 of the patients (1,96%), (Table III). Postoperative bladder drainage method was urethral foley catheterization. The median operating time for patients undergoing TVT operation only was 30,5 minutes (range 21-49). The median postoperative stay was 3 days (range 1-20) in patients undergoing a TVT only, (Table III). The median number of days until the residual urine volume was less than 100 mL was 1 (range 0-20) after TVT only. None of the patients required reoperation in the postoperative period for reasons related to the TVT

operation. The overall subjective cure rate was 90,85% for patients with urinary stress incontinence.

Table I: Patients' characteristics

Characteristics	Value, mean (range) or n (%)
Age, years	51 (30-76)
Parity	3.0 (1-7)
Body Mass Inde	29,1 (19,1-44,4)
Hormone-replacement therapy	69 (45,09)

Table II: Operative procedures combined with TVT in 65 patients

Procedure	No. of patients (%)
Simple abdominal hysterectomy	32
Vaginal hysterectomy	11
Anterior repair	17
Posterior repair	4
Salphingo-oophorectomy	3
Sacrospinous vaginal vault suspension	1
Paravaginal repair	1

Table III: Surgical data

Operating time of Primary TVTs, min. (median, range)	0,5 (21-49)
Median postoperative stay of Primary TVTs, (days), (median, range)	3 (1-20)
Previous antiincontinence surgery, no. (%)	52 (33,98)
TVT with other procedures, no. (%)	65 (42,8)
General anesthesia, no. (%)	78 (50,98)
Regional anesthesia, no. (%)	72 (47,06)
Local anesthesia, no. (%)	3 (1,96)

There were a total of 11 bladder perforations (7,20%). The perforation rate was higher in patients with previous surgery for urinary incontinence than in those without previous antiincontinence surgery (13,46% (7/52) compared with 4,0% (4/101), $p<0,05$), (Table IV). There were no sequela of bladder perforations in our study. There were a total of 16 short term voiding dysfunction (10,46%). The short term voiding dysfunction rate was higher in patients with previous surgery for urinary incontinence than in those without previous antiincontinence surgery (21,15% (11/52) compared with 5,0% (5/101), $p<0,05$), (Table IV). One woman with short term voiding dysfunction underwent once urethral dilation postoperatively at two weeks.

Two women with short term voiding dysfunction requiring indwelling foley catheterization until 20 days postoperatively. The other 13 women with short term voiding dysfunction had spontaneous resolution of their voiding dysfunction. There were a total of 14 overactive bladder (9,15%) requiring medical treatment. The rate of overactive bladder was similar in women with or without previous antiincontinence surgery (9,61% (5/52) compared with 8,91% (9/101), $p>0,05$), (Table IV).

There were no intraoperative blood loss of >500 ml, urinary tract or vaginal incision infection, prolonged voiding dysfunction, nerve injury/strain (ilioinguinal, femoral or obturator nerve), erosion/poor healing at the site of vaginal incision, postoperative hematoma, reoperation either for voiding dysfunction or for recurrent incontinence in our study group. None of the other variables analyzed as potential risk factors were shown to have a statistically significant increase in rate of bladder perforation, or development of short term voiding dysfunction.

DISCUSSION

The TVT was described by Ulmsten based on an anatomical and pathophysiological study of the urethral closure mechanism⁽⁹⁾. It is designed on the premise that the opening and closure of the inner urethra and bladder neck are mainly controlled by three anatomical structures: (i) the tension within the pubourethral ligaments, (ii) the activity of the pubococcygeus and levator ani muscles and (iii) the condition suburethral vaginal hammock. In this procedure the tension in the pubourethral ligaments ensures that the muscular components of the support and the vaginal hammock interact correctly⁽¹⁰⁾. The TVT procedure has rapidly

become a widely performed operation for stress urinary incontinence⁽¹¹⁾. It offers advantages over more conventional repairs in that it is quick and can be done under local anesthesia. This is a relatively new procedure and done completely different fashion than present conventional procedures. As this is a relatively new procedure that it is done in a completely different fashion than present conventional procedures, it may very well have a unique set of complications and untoward effects⁽¹²⁾.

The main difference in this procedure is that needles of 5 mm in diameter are passed blindly from the vaginal area up through a suprapubic stab wound⁽²⁾. The surgeon should learn the specific anatomic landmarks of the urogenital area very well for the success of the procedure. Bladder perforation remains one of common complications and varies between 0 and 11,6% (7,20% in our series)⁽¹⁰⁾. We didn't have any postoperative hematoma, nerve injury and vaginal erosion.

Postoperative voiding dysfunction can occur after any operation for stress urinary incontinence⁽²⁾. Because of the different structure of the TVT procedure, management of the voiding dysfunction should be different. We had short term voiding dysfunction in 16 (10,46%) of the patients. But there were no prolonged voiding dysfunction. The 13 (81,25%) of these patients recovered spontaneously without a need of treatment. Because the TVT procedure does not involve fixation or tying of the tape to any structures, this would loosen or stretch the tape and thus improve the voiding dysfunction or incomplete bladder emptying⁽²⁾.

The onset of postprocedure bladder instability is known to occur in patients undergoing colposuspension procedures (3,4-18%) and is thought to occur as a result of the obstruction caused by the procedure. The TVT also carries the risk of patients developing bladder instability, with the rate varying between 0 and 25,9%

Table IV: Intraoperative and postoperative complication in TVT operations

	Overall (n=153) (%)	Primary TVTs (n=101) (%)	Secondary TVTs (n=52) (%)	p
Intraoperative complications				
Bladder perforation	11 (7,20%)	4 (4,0%)	7 (13,46%)	<0,05
Postoperative complications				
Short term voiding dysfunction	16 (10,46%)	5 (5,0%)	11 (21,15%)	<0,05
Overactive bladder	14 (9,15%)	9 (8,91%)	5 (9,61%)	>0,05

(9,15% in our study had new onset of urgency)⁽¹⁰⁾. In conclusion, TVT is a minimal invasive surgical procedure and can be recommended for surgical treatment of female stress urinary incontinence not only in first operative choice, also where previously traditional incontinence operations have failed. It should be remembered that the intraoperative and postoperative complication rate might be increased because of possible adhesions and/or distorted anatomy from previous antiincontinence operations⁽¹²⁾.

REFERENCES

1. Stanton SL (2001) Some Reflections on Tension-Free Vaginal Tape- A New Surgical Procedure for Treatment of Female Urinary Incontinence. *Int Urogynecol J Suppl 2*: 9- 11.
2. Karram MM, Segal JL, Vassallo BJ, Kleeman SD (2003) Complications and Untoward Effects of the Tension-Free Vaginal Tape Procedure. *Obstet Gynecol 101*: 929- 32.
3. Dmochowski RR, Appell RA (2000) Injectable agents in the treatment of stress urinary incontinence in women: Where are we now? *Urology 12*: 32- 40.
4. Ulmsten U, Petros P (1995) Intravaginal slingplasty (IVS): An ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol 29*: 75- 82.
5. Ulmsten U, Henriksen L, Johnson P, Varhos G (1996) An ambulatory surgical procedure for treatment of female urinary incontinence. *Int Urogynecol J 7*: 81- 6.
6. Atherton M, Stanton SL (2000) A comparison of bladder neck movement and elevation after tension-free vaginal tape and colposuspension. *Brit J Obstet Gynaecol 107*: 1366- 70.
7. Tamussino KF, Hanzal E, Kölle D, Ralph G, Riss PA (2001) Tension-Free Vaginal Tape Operation: Results of the Austrian Registry. *Obstet Gynecol 98*: 732- 6.
8. Rezapour M, Falconer C, Ulmsten U (2001) Tension-Free Vaginal Tape (TVT) in Stress Incontinent Women with Intrinsic Sphincter Deficiency (ISD)- A Long-Term Follow-up. *Int Urogynecol J Suppl 2*: 12- 4.
9. Petros P, Ulmsten U (1993) An integral theory and its method for the diagnosis and management of female urinary incontinence. *Scand J Urol Nephrol Suppl 153*: 1- 93.
10. Manikandan R, Kujawa M, Pearson E, O'reilly PH, Brown SCW (2004) Results of the tension-free vaginal tape procedure for stress incontinence: Patient's perspective. *Inter J Urol 11*: 206- 212.
11. Vassallo B, Kleeman S, Segal J, Walsh P, Karam MM (2002) Tension free vaginal tape: A quality of life assessment. *Obstet Gynecol 100*: 518- 24.
12. Rezapour M, Ulmsten U (2001) Tension-Free Vaginal Tape (TVT) in Women with Recurrent Stress Urinary Incontinence- A Long-term Follow up. *Int Urogynecol J Suppl 2*: 9- 11.