

Tension-Free Vaginal Tape For Treating Stress Urinary Incontinence (Types I And II) : Experience With 32 Cases.

*M. H. El-Shazly, and **Nagwa A. Ghaffar.

**Urology Department; El-Sahel Teaching Hospital;
**Ob/Gyn Department, Al Azhar University (Girls), Cairo, Egypt.*

Abstract:

Objectives: To evaluate the clinical outcome of using tension-free vaginal tape (TVT) for treating types I and II genuine stress urinary incontinence. **Patients and Methods:** The study comprised a total of 32 women with genuine stress urinary incontinence types I and II treated with TVT between 1999 and 2002. The mean follow-up period was 19.4 months. **Results:** The success rate was 87.5 % (28/32 patients). The cure rate was durable in the majority of successful cases 26/28 (92.9%) during the one year follow-up period except for 2/28 (7.1%) women in whom stress urinary incontinence recurred in a milder form. Postoperative retention of urine occurred in 2/32 (6.3%) patients, which was transient and responded well to urethral dilatation under local anaesthesia. Details of the clinical outcome variables and complications are represented. **Conclusion:** The TVT procedure is an effective and minimally invasive alternative to surgical options for managing types I and II stress urinary incontinence. The complication rates are low and hospital stay is short and the procedure is feasible under local anaesthesia.

Keywords: stress incontinence, TVT, tension-free vaginal tape.

Introduction:

Tension-free vaginal tape (TVT) is a relatively new minimally invasive procedure for managing stress urinary incontinence which gained a wide acceptance by both urologists and gynecologists during the last decade with high success rates, low morbidity and complication rates [6]. Moreover, the hospital stay is short and the procedure can be done as a day-case under local anaesthesia. The standard procedure implicates the use of a synthetic polypropylene mesh sling placed in the mid-urethral position [4]. However, further randomized controlled comparative studies between the TVT procedure and the gold standard colposuspension options are to be awaited as well as its long term results.

Aim of the work:

To assess the effectiveness and clinical outcome of the TVT procedure in treating types I and II stress urinary incontinence according to the Urodynamics Society classification in 1997 [20]

Patients and methods:

Between 1999 and 2002, a total of 32 women (mean age 53.6 years, range 37-64 years) with urodynamically-proved types I and II genuine stress urinary incontinence were treated with the TVT procedure, and followed-up for one year at minimum, in two centers: Urology Department, El-Sahel Teaching Hospital, Cairo, Egypt and Urology and

Obs/Gyn Departments, Mouwasat Hospital, Dammam, Saudi Arabia.

The study included only types I and II SUI who failed to respond to other medical conservative options. All cases with type III SUI (intrinsic sphincteric deficiency) or mixed SUI (detrusor overactivity + SUI) were excluded. In all cases, the TVT procedure was the primary treatment option with no case of previous surgical management for stress urinary incontinence. Cases with previous major pelvic surgeries like abdominal or vaginal hysterectomy were excluded.

The preoperative work-up included a detailed medical history, physical examination, gynecologic examination, abdominopelvic ultrasound with estimation of post-voiding residual volume. The urodynamic assessment protocol included uroflowmetry, filling cystometry, and urethral pressure profile at rest and during stress recording the leak point pressure (Duet[®] Multi-P, Medtronic, Denmark). The diagnosis of stress urinary incontinence was made whenever urine leakage occurred during coughing or straining with no associated detrusor activity. The filling rate was 50 ml/min with the patient in a semi-sitting position. The same urodynamic evaluation was repeated for all cases 6 and 12 months after the TVT procedure. Subjectively, patient's satisfaction and quality of life (QoL) was post-operatively monitored as cured, markedly improved, improved, no change, or worse in patient's terms besides an enquiry about the voiding pattern regarding hesitancy, sense of incomplete emptying, straining to void, or urgency. Our urodynamic follow-up criteria define outflow obstruction if Q_{max} is ≤ 12 ml/s and significant post-voiding residual volume if $\geq 25\%$ of the bladder capacity.

Our follow-up protocol included regular outpatient clinic visits at 4 weeks, and months 3, 6, 9, and 12. After 12 months the patients were instructed to attend the outpatient clinic in case of any urological complaint or yearly for longer-term follow-up. In each visit subjective assessment of patient's satisfaction, clinical examination, urinalysis, and pelvic ultrasound examination with full bladder and post-voiding were done.

Spinal anaesthesia was used in 12/32 (37.5%) patients, epidural anaesthesia in 9/32 (28.1%) patients, and local infiltration anaesthesia using an average dose of 40 ml of lidocaine 2% in 11/32 (34.4%) patients. The surgical technique followed the original one described by Ulmsten *et al* in 1996 [20]. The tape used is a synthetic polypropylene mesh tape (Ethicon Gynecare[™], UK).

Under local, spinal, or epidural anaesthesia a midline anterior vaginal wall incision is made over the urethra with 18 Fr Foley's catheter in situ to facilitate urethra-bladder neck orientation. Creation of two para-urethral tunnels is then performed and the two TVT needles are then passed para-urethrally at a mid-urethral position and directed posterior to the symphysis pubis to come out through two separate small suprapubic incisions. Each needle-path is checked endoscopically to avoid and detect any bladder or urethral perforations. Then, both needles and the tape plastic covers are removed without exerting any tension on the tape. An on-table stress test is done through asking the patient to cough or strain with a bladder containing 250-300 ml of normal saline. Post-operatively, we did not fix urethral catheter routinely unless a bladder or urethral perforation has occurred or excessive dissections were performed.

This occurred in 2/32 (6.3%) patients where a urethral catheter was kept for 5 days and both of them voided freely after catheter removal.

Results:

Table (1) summarizes the patients, procedural, and clinical outcome data. In this study, the follow-up protocol was 12 months at minimum, with a mean follow-up period of 19.4 (range 12-50) months. Out of the 32 women, 29 patients (90.6%) completed the 12 month follow-up protocol except for two women who did not show at 9th and 12th month visits because they feel cured as explained by phone contact. Another women did not come after the month-3 visit (where she declared cure) and could not be contacted later. The mean hospital stay was 1.2 days (range 12-72 hours) with most of the cases done as day cases (25/32 "78.1%"). The mean operative time was 25.6 minutes (range 20-54 minutes).

The procedure is considered successful if the patient declared being cured, markedly improved, or improved. Our success rate was 87.5% (28/32). Out of the 28 women 21/32 (65.6%) declared complete cure, 5/32 (15.6%) markedly improved, and 2/32 (6.3%) improved. The procedure was not successful in 4/32 (12.5%) women in whom no change was declared with no case getting worse. The successful outcome was durable throughout the

one year follow-up period in 26/28 women (92.9%) with 2/28 women (7.1%) of recurring stress urinary incontinence starting gradually after an average of 6.4 months postoperatively. In both patients the recurring stress urinary incontinence was lesser in severity and did not progress further during the 12 months post-operative follow-up period.

Post-operative retention of urine occurred in 2/32 (6.3%) patients, and was managed by urethral dilatation under local lidocaine 2% gel up to 26 Fr. with the intention of stretching the tape and forcing the straight metal dilator dorsally to decrease the tape tightness. Both women improved after urethral dilatation and no significant post-voiding residual urine was detected in the follow-up period. Newly developed urge sensation with urodynamically-proved detrusor hyperactivity was documented in 3/32 (9.4%) patients which was transient (for a mean of 10.5 months) in all the three cases and responded well to oxybutinin chloride 5 mg tablets 2-3 times daily. In 4/32 (12.5%) patients, urinary tract infection was documented and all responded well to appropriate antibiotic therapy. One case (3.1%) had mild vaginal wound infection with no wound dehiscence. In no case bladder perforation, urinary retention, or urethral erosion had occurred.

Table [1] Patients , Procedural, and Clinical Outcome Data.

Age	<i>Mean, 53.6 years.</i>	<i>Range, 36-64 years.</i>
Follow-up Period.	<i>Mean, 19.4 months.</i>	<i>Range, 12-50 months.</i>
Anaesthesia:		
- Local	<i>11/32 (34.4%) patients.</i>	
- Spinal	<i>12/32 (37.5%) patients.</i>	
- Epidural	<i>9/32 (28.1%) patients.</i>	
Operative Time	<i>Mean 25.6 minutes.</i>	<i>Range 20-54 min.</i>
Hospital Stay:	<i>Mean, 1.2 days.</i>	<i>Range 12-72 hours.</i>
	<i>25/32 (78.1%) as Day Cases.</i>	
Success Rates:		
- Complete Symptom Cure		<i>21/32 (65.6%) patients.</i>
- Marked Improvement.		<i>5/32 (15.6%) patients.</i>
- Improved.		<i>2/32 (6.3%) patients.</i>
	<i>Overall</i>	<i>28/32 (87.5%) patients.</i>
Failure Rates:		
- No Improvement.		<i>4/32 (12.5%) patients.</i>
- Getting Worse.		<i>0/32 (00.0%) patients.</i>
Success Durability at One Year:		<i>26/28 (92.9%) patients.</i>
- Recurrent SUI (milder)		<i>2/28 (7.1%) patients.</i>
Complications:		
- Transient Retention.		<i>2/32 (6.3%) patients.</i>
- Transient de novo Urge		<i>3/32 (9.4%) patients.</i>
- Bladder Perforation		<i>2/32 (6.3%) patients.</i>
- Urinary Tract Infection		<i>4/32 (12.5%) patients.</i>
- Mild Wound Infection		<i>1/32 (3.1%) patients.</i>

Discussion:

Challenging the pressure-transmission theory, the more recent integral theory of female continence stated that stress urinary incontinence in females results from failure of the active closure mechanism due to laxity of the pubourethral ligament [8,16]. Urodynamically, genuine SUI is defined as involuntary urinary leakage with increased intra-abdominal pressure without associated detrusor contractions. According to the classification of Blaivas, in types I and II the urinary leakage is due to urethral hypermobility without intrinsic urethral sphincteric deficiency [4]. In both, the

bladder neck is closed at rest and urine leaks only during straining associated with urethral descent below the inferior margin of symphysis pubis. However, in type I, the descent is less than 2 centimeters and there is no or minimal associated cystocele. In type II, the cystocele is more evident and the urethral descent is more than 2 cm. In type III, the bladder neck is open at rest with maximum urethral closure pressure less than 20 cm water. The urine leaks with no or minimal stress and even by gravity due to deficient intrinsic sphincteric activity with no urethral

hypermobility. In mixed SUI, the genuine SUI is associated with detrusor overactivity or hyper-reflexia.

Although the TVT procedure elevates bladder neck to a much lesser extent than colposuspensions, it mainly acts through inducing a urethral kink at tape level (mid-urethral) during stress which augments the urethral pressure substituting for the hammock-like effect of a normal pubourethral ligament [1]. Historically, pubovaginal slings for treating stress urinary incontinence started almost a century ago [10]. Colposuspensions and pubovaginal slings passed the time test, proved efficacy with durable effect and high success rates and constituted the gold-standard options for managing the three types of stress urinary incontinence [6,9,10,13]. In comparison to the TVT procedure, colposuspensions have higher morbidity and complication rates. The hospital stay is longer and the bladder outlet obstructive sequelae are higher [6].

The overall reported success rate of TVT in multicenter studies including 1339 cases with a mean follow-up period of 21 months, is 88% objective cure rate with 9% of further subjective improvement [6,21]. Our success rate 28/32 (87.5%) is in consistence with most of the reported studies using the same technique [11,13-15,17-19]. We did not include type III stress urinary incontinence “intrinsic sphincteric deficiency” in this study. However, few other studies reported a mean of 75% success rate in using TVT for type III stress urinary incontinence [3,12,13]. Several studies included both genuine and recurrent stress urinary incontinence for TVT procedure. The treatment outcomes of TVT in women as a primary procedure appear marginally better than in patients in whom previous

surgery for urinary incontinence has failed [6,11].

The reported common morbidity and complications of the TVT procedure include bladder perforation, haematomas, urinary tract infections, wound infections, wound dehiscence, urethral erosion, *de novo* urge incontinence, and bladder outlet obstructive sequelae. The overall reported mean complication rate of the TVT procedure is 6% with *de novo* urge incontinence or persistent urge as the most common and most troublesome one (15%) and urethral erosion the most serious [15,18]. In our study the complication rates are compatible with those reported previously [6,15,16]. Transient post-operative urinary retention occurred in 2/32 (6.3%) women. *De novo* urgency due urodynamically-proven detrusor hyperactivity was recorded in 3/32 (9.4%) women. In all the three cases, the urge was transient, not associated with significant post-voiding residual volume increase, and effectively controlled by oxybutinin chloride 5 mg tablets 2-3 times daily. A recent randomized controlled study concluded that obstructive voiding dysfunctions including detrusor hyperactivity are similar after TVT and colposuspensions [13]. However, Atherton and Stanton concluded that TVT may be even more obstructive than colposuspension and that although TVT procedure has been introduced as “a tension-free vaginal tape” the sling can have tension applied by the surgeon [2]. This indicates the vital technical importance of not exerting any tension on tape positioning which is a common tendency noticed to be shared by most surgeons. Positioning the tape at the bladder neck level and not at the mid-urethral level is suggested by some that it might be less obstructive [17].

However, this awaits further randomized controlled studies to reach a solid conclusion in this concern. Documented urinary tract infections occurred in 4/32 (12.5%) women which responded well to appropriate antibiotic therapy in all cases. Overall, the complications reported in our study were mild, transient, and successfully managed conservatively. No general complications were documented in this study. Other rare major complications are reported in the literature like major vascular injuries and bowel perforations with increased risk in patients with previous open pelvic surgeries [6-7].

Conclusion:

The TVT procedure is a minimally invasive alternative for surgical options in managing uncomplicated stress urinary incontinence with low morbidity and complication rates. It can be done as a day-case under local anaesthesia with a short hospital stay. The long term results of the TVT procedure and data of further randomized controlled studies on the use of TVT in managing recurrent and/or mixed stress urinary incontinence are to be awaited.

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**علاج السلس البولى الإجهادى عند السيدات
باستخدام الشريط المهبلى بدون الشد
د. محمد حامد الشاذلى و **د. نجوى عبد الغفار.
*قسم المسالك البولية, مستشفى الساحل التعليمى
** و قسم النساء والولادة, جامعة الأزهر "بنات", القاهرة, مصر**

هدف البحث: تقييم المردود الإكلينيكى لاستخدام الشريط المهبلى بدون الشد لعلاج السلس البولى الإجهادى الأولى (النوعين 1 و 2) عند السيدات.

المرضى و اسلوب البحث: تضمنت الدراسة 32 سيدة يعانين من سلس البول الإجهادى الأولى (النوعين 1 و 2) و تم علاجهن باستخدام الشريط المهبلى بدون الشد فى الفترة ما بين 1999 وحتى 2002 بمتوسط فترة متابعة 19.4 شهراً.

النتائج: كان معدل الشفاء 87.5% (32/28 سيدة) واستمر بدون انتكاس طوال السنة الأولى للمتابعة فى 28/26 (92.9%) سيدة فيما عدا 28/2 (7.1%) سيدة حيث عادت أعراض السلس ولكن بصورة أخف وطأة. وقد حدث إحتباس بولى مؤقت فى 32/2 (6.3%) سيدة وعولج بنجاح بواسطة توسيع مجرى البول تحت مخدر موضعى. ويتضمن البحث تفاصيل النتائج الإكلينيكية والمضاعفات. **الإستنتاج:** الشريط المهبلى بدون الشد وسيلة فعالة قليلة التدخل و تمثل بديلاً للجراحات التقليدية لعلاج السلس البولى الإجهادى الأولى عند السيدات (النوعين 1 و 2). وهو أسلوب علاجى ذو معدل مضاعفات منخفض وفترة مكوث بالمستشفى قصيرة و يمكن إجراؤه باستخدام التخدير الموضعى.