

# The Three Years Results of Tension Free Vaginal Tape (TVT) for the Treatment of Stress Urinary Incontinence in Thai Women

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**Objective:** To evaluate the three years result of TVT procedure in Thai women with genuine stress urinary incontinence (SUI).

**Material and Method:** Sixty three women, aged 35-71 years attending the gynecology clinic at King Chulalongkorn Hospital from February 2000 to May 2001 were recruited in the present study. Pre-operative evaluation included history taking and physical examination. All had stress urinary incontinence urodynamically confirmed genuine stress urinary incontinence and were treated with TVT. Follow up at 3, 6, 12, 18, 24, 30 and 36 months were scheduled after surgery.

**Results:** The mean  $\pm$  SD of operative time for TVT was  $32.3 \pm 10.0$  min the mean  $\pm$  SD of hospitalization was  $1.8 \pm 2.0$  days. Two patients had bladder perforations by the trocar without severe bleeding and needed no reparation. No healing defect or rejection of the prolene mesh was found. The cure rate and improved rate were 95.2% and 4.8% respectively (60 from 63 cases) at 3 years follow up.

**Conclusion:** The three years results revealed that TVT was effective and safe in the treatment of SUI in Thai women.

**Keywords:** Tension free vaginal tape, Stress urinary incontinence

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Female stress urinary incontinence (SUI) is a common disorder in women. The prevalence is high but varied, depending on the definition used, the design of the study, and the target population. The reported prevalence varied from 3% to 67%<sup>(1-5)</sup>.

Age and parity were reported to be the risk factors<sup>(4-7)</sup>. There was an increase in the number of these patients, because of the growing number of the aging population in Asia<sup>(8,9)</sup>. The SUI that interfered with quality of life can be cured and the symptoms can be alleviated. Tension free Vaginal Tape (TVT) procedure was introduced as a minimal invasive procedure<sup>(10-12)</sup>. This new technique can be performed on an outpatient

basis<sup>(10-12)</sup>. The recovery time after surgery is short<sup>(10-12)</sup>. This procedure is associated with a high cure rate and low morbidity<sup>(13,14)</sup>. Up to now there has been no report of the long term follow up in women with SUI in Thailand. The aim of this study was to evaluate the 3 years results of TVT in the treatment of SUI in Thai women.

## Material and Method

From February 2000 to May 2001, 63 Thai women diagnosed as having SUI were recruited in the study. All patients had the typical history of SUI without previous surgery.

Before surgery, all the patients underwent preoperative assessments, including detailed medical history, pelvic examination, the cough provocation test, urinalysis and urine culture. All cases had a full urodynamic study including filling and voiding

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cystometry, uroflowmetry and valsava leak point pressure measurement. The surgical procedure was carried out as previously described by Ulmsten et al<sup>(15)</sup>.

#### **TVT procedure<sup>(15)</sup>**

The patients were operated on under spinal anesthesia. TVT operations were done by the first author (One year - Clinical Fellowship training from Urogynecology Unit, Clermont Ferrand University hospital, France). Two minimal incisions 5 cm apart were made in the abdominal skin just above the superior of the pubic bone. A 1.5 cm long sagittal incision was made in the vaginal wall starting 1 cm from the external urethral meatus. After minimal bilateral paraurethral dissections of the vaginal wall, a specific prolene tape covered by a plastic sheath was introduced using a two-component needle instrument. The tip of this first perforated the urogenital diaphragm and within the space of Retzius. The needle tip (in close contact with the back of the pubic bone) was brought up to the abdominal incision. The procedure was then repeated on the contralateral side, placing the tape in a U shape around the mid urethra. After cystoscopy to ensure the intact bladder, the tape was adjusted without tension under the urethra. During this adjustment, the patient was asked to cough to check that she had become continent by the procedure. Then, the plastic sheath covering the tape was removed. The vaginal incision site was closed by simple suturing with chromic catgut number 2/0.

The abdominal incisions were closed after cutting the abdominal ends of the tape subcutaneously without fixation. After the surgery, the patients left the operative theater with postoperative catheterization. The foley catheter was removed the next morning. The residual urine was checked before leaving the hospital on the first day after operation. After the TVT procedure, in women with concomitant genital prolapse, the anterior colporrhaphy, vaginal hysterectomy or posterior colopo-perinorhaphy were carried out. After the operation, the collection of data regarding the intra-operative blood loss, operative time, hospitalization and complications were recorded. Follow up at 3, 6, 12, 18, 24, 30 and 36 months were scheduled after surgery. Patients were considered objectively cured if there was no incontinence on the stress provocation test, and no urinary retention or residual urine volume greater than 150 ml were found. Patients were considered objectively improved if no incontinence on the stress provocation test was found. All other cases were reported as objective failures.

#### **Results**

Most women had the long history of stress incontinence (Table 1). Sixteen women (25.4%) had genital prolapse as shown in Table 1. The mean operative time for TVT only was  $32.2 \pm 10.0$  minutes. The mean  $\pm$  SD of hospitalization was  $1.5 \pm 2.0$  days. The mean  $\pm$  SD of the catheterization was  $1.9 \pm 1.9$  days. When selecting women with the TVT operation only (47 cases), the mean  $\pm$  SD of catheterization was  $1.4 \pm 1.2$  days. The mean  $\pm$  SD of blood loss during TVT was  $300 \pm 100$  ml. Most patients (92%) underwent surgery with spinal anesthesia and 8% were under the conscious sedation technique. The mean  $\pm$  SD of blood loss during the TVT operation was  $15.2 \pm 6.1$  ml. The concomitant prolapse surgery with TVT was: posterior perineorhaphy 4 cases (6.3%), anterior colporrhaphy with posterior perineorhaphy (A-P repair) 7 cases (11.1%), and vaginal hysterectomy with AP repair 5 cases (7.9%).

The overall complication rate were 9.5% (Table 2). The operative complication rate was 3.2% and was mainly the result of bladder injuries. Two cases of bladder perforation were diagnosed during the systematic cystoscopy and were found at the right side. After reinsertion of the tape and a second cystoscopy, a foley catheter was left in place for 5 days. After catheter removal, they could void without any difficulty. One case of urinary retention was noted (postvoid residuals > 100 ml) at 2 days after operation. She needed clean intermittent catheterization for 5 days. The de novo detrusor overactivity was noted in 3 cases at 3 and 6 months follow up (Table 2). After the anticholinergic drug and bladder training, they revealed no symptom at 12 months follow up and up to the present. During the three years follow up, the authors found an overall cure rate of 95.2% (Table 3). There were 3 cases with minimal leakage when they

**Table 1.** Patients' characteristics (N = 63)

	Mean $\pm$ SD	Range
Age (years)	51.7 $\pm$ 9.5	35-71
Parity	3.8 $\pm$ 2.1	1-4
Duration of incontinence symptoms (years)	9.2 $\pm$ 1.5	3-12
	Number (%)	
Menopausal women	50 (79.4)	
Concomitant genital prolapse		
- Cystocele	12 (19.0)	
- Rectocele	16 (25.4)	
- Uterine prolapse	5 (7.9)	

**Table 2.** The operative and postoperative complications (N = 63)

	Number (%)
- Bladder injury	2 (3.2)
- Urinary retention	1 (1.6)
- De novo detrusor overactivity	3 (4.8)
Total	6 (9.5)

**Table 3.** Follow up outcome (N = 63)

Duration and Outcome	6 months	12 months	24 months	36 months
Cured	61 (96.8)	60 (95.2)	60 (95.2)	60 (95.2)
Improved	2 (3.2)	3 (4.8)	3 (4.8)	3 (4.8)
Failed	0	0	0	0

strained and held the urine for a long period. The symptoms of stress incontinence were much improved than before the surgery, and they were satisfied with the results of the treatment.

## Discussion

The TVT is now gaining popularity around the world due to its minimally invasive surgical technique. This technique is easy to learn with a lower rate of complications and higher rates of success when compared to the previous classic surgical methods<sup>(10-18)</sup>. From the present study, the authors found a small number of complications. Bladder injuries were noted in 2 cases in the authors' experience with the first five cases of the TVT. This rate of bladder injury was lower when compared to previous reports<sup>(10-12,19-20)</sup>. The authors found only one case of urinary retention which spontaneously resolved 5 days after surgery. The patients were asked to cough during the tape adjustment and the surgeon stopped pulling the tape when the last drop of urine stopped leaking. The authors also checked the patient's urethra by Hegar dilator before cutting the tape as previously suggested. The authors believe these careful techniques can help prevent urinary retention<sup>(10,11)</sup>. The main reason for the low incidence of urinary retention in TVT was believed to be due to the minimal dissection and mid urethral position of the tape<sup>(10-12)</sup>. So to avoid the risk of urinary retention, careful mid urethral incision and tape adjustment are important. No other complications such as tape erosion, infection or hematoma were found in the present study. It was found that the concomitant genital prolapse surgery did not interfere with the success rate of TVT as previously reported<sup>(21,22)</sup>.

There was a high cure rate at 3 years follow up similar to previous studies<sup>(10-12)</sup>. Even in cases of improved symptoms, the patients were very satisfied with the outcome. In Thailand, there has only been one report on the short term result of the TVT<sup>(22)</sup>. From the authors' extensive review, the present study was the first long term follow up in Southeast Asia. The present results demonstrate that the TVT procedure is a safe and effective surgical method for the treatment of female urinary incontinence. To avoid complications, pre-service training in a model or practice under supervision is recommended for inexperienced gynecologists before attempting the procedure on their own.

## Conclusion

The authors' three year results revealed that TVT was effective and safe in the treatment of stress urinary incontinence in Thai women.

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## ผลการติดตาม 3 ปีภายหลังการผ่าตัดใส่สายคล้องท่อปัสสาวะชนิดไม่มีแรงดึงทางช่องคลอด (TVT) ในการรักษาโรคโอดจาเมปัสสาวะเล็ดในสตรีไทย

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**วัตถุประสงค์:** เพื่อประเมินผลการรักษา 3 ปีภายหลัง การผ่าตัดใส่สายคล้องท่อปัสสาวะชนิดไม่มีแรงดึงทางช่องคลอด (TVT) ในการรักษาโรคโอดจาเมปัสสาวะเล็ดในสตรีไทย

**วัสดุและวิธีการ:** ทำการศึกษาสตรีไทยจำนวน 63 คน อายุ 35-71 ปี มารับการรักษาที่คลินิกนรีเวช โรงพยาบาลจุฬาลงกรณ์ ระหว่างเดือนกุมภาพันธ์ 2543 ถึง พฤษภาคม 2544 สตรีทุกรายได้รับการวินิจฉัยว่าเป็นโรคโอดจาเมปัสสาวะเล็ดด้วยการตรวจยืนยันโดยการตรวจ Urodynamic และได้รับการผ่าตัด TVT ทำการประเมินประวัติและตรวจร่างกาย ทำการตรวจติดตามที่ 3, 6, 12, 18, 24, 30 และ 36 เดือนหลังผ่าตัด

**ผลการศึกษา:** ค่าเฉลี่ย  $\pm$  ส่วนเบี่ยงเบนมาตรฐานของเวลาในการทำผ่าตัด TVT คือ  $32.2 \pm 10.0$  นาที ค่าเฉลี่ย  $\pm$  ส่วนเบี่ยงเบนมาตรฐานของเวลาในการอยู่โรงพยาบาลคือ  $1.8 \pm 2.0$  วัน มีผู้ป่วย 2 ราย เกิดภาวะแทรกซ้อน บาดเจ็บต่อกระเพาะปัสสาวะ ขณะแทงเข็มโดยไม่มีเลือดออกรุนแรงและไม่จำเป็นต้องทำการเย็บซ่อม ไม่พบภาวะการไม่หายตัวของแผลหรือการต้านเนื้อเยื่อ prolene ของร่างกาย พบอัตราหายขาดจากการรักษา 95.2% และมีอาการดีขึ้น 4.8% (60 รายจาก 63 ราย) ที่เวลา 3 ปี หลังทำผ่าตัด

**สรุป:** จากผลการติดตาม 3 ปี หลังการผ่าตัดรักษาโดยวิธี TVT ประสิทธิภาพดีและปลอดภัยในการรักษาภาวะโอดจาเมปัสสาวะเล็ดในสตรีไทย