SK Yip 葉承楷
MW Pang 彭敏華

Tension-free vaginal tape sling procedure for the treatment of stress urinary incontinence in Hong Kong women with and without pelvic organ prolapse: 1-year outcome study

以無張力陰道懸吊帶手術治療或有盆腔器官膨出的香港女性壓力尿失禁患者：一年期治療效果研究

Objective. To assess the outcome of patients who underwent a tension-free vaginal tape sling procedure alone versus patients who underwent concomitant pelvic floor surgery.

Design. Retrospective cohort study.

Setting. Urogynaecology unit of a university teaching hospital, Hong Kong.

Patients. Patients diagnosed with moderate-to-severe urodynamic stress incontinence and underwent a tension-free vaginal tape sling procedure from September 1999 to August 2004.

Main outcome measures. Objective cure rate of stress urinary incontinence 1 year following tension-free vaginal tape sling procedure was assessed. Patients were considered objectively cured if no stress urinary incontinence was evident on urodynamic studies at 1-year follow-up. Subjective cure rates at 4 months and 1 year after tension-free vaginal tape sling procedure were also assessed. Other outcome measures included intra-operative and perioperative complication rates, and the rate of de-novo detrusor overactivity at 1 year.

Results. Of 302 patients recruited, 250 (82.8%) completed 1-year follow-up. There were 157 (62.8%) patients who had a tension-free vaginal tape sling alone, and 93 (37.2%) had tension-free vaginal tape sling and concomitant pelvic floor surgery for pelvic organ prolapse. All patients had urodynamic studies before and 1 year following surgery. The objective cure rate was 87.3% for patients with tension-free vaginal tape sling alone, and 80.6% for tension-free vaginal tape sling with concomitant procedures (Chi squared test, P>0.05). The subjective cure rates for tension-free vaginal tape sling alone and tension-free vaginal tape sling plus concomitant procedures were 89.2% and 86.0% at 4 months, and 93.0% and 94.6% at 1 year, respectively (Chi squared test, P>0.05). The most common complication was postoperative urinary retention (15.2%), followed by de-novo detrusor overactivity at 1 year (10%), and bladder perforation (8%).

Conclusion. The tension-free vaginal tape sling procedure alone or in combination with pelvic floor surgery are equally effective for the treatment of female stress urinary incontinence.

目的：對病人只接受無張力陰道懸吊帶手術，和同時接受骨盤底手術，兩者結果作出評估。

設計：隊列式回顧性研究。

安排：香港某大學教學醫院的泌尿婦科。

患者：1999 年 9 月至 2004 年 8 月期間，所有患有中等至嚴重程度壓力尿失禁而接受無張力陰道懸吊帶手術的病人。

主要結果測量：本研究評估了接受無張力陰道懸吊帶手術一年後壓力尿失禁的客觀痊癒率。病人若在一年跟進期的尿流動力學研究時沒有壓力尿失禁的情況，便算是客觀痊癒。研究亦評估了接受上述手術後四個月和一年的主觀痊癒率。其他的結果測量包括手術中及前後的併發症，和一年內膀胱逼肌過度活動的比率。

Key words:
Surgical procedures, operative;
Urinary incontinence, stress;
Urodynamics;
Uterine prolapse;
Vagina

關鍵詞：
外科程序，手術；
尿失禁，壓力；
尿流動力學；
子宮脫垂；
陰道

Hong Kong Med J 2006;12:15-20

Department of Obstetrics and Gynaecology, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin, Hong Kong
SK Yip, MD, FHKAM (Obstetrics and Gynaecology)
MW Pang, MB, ChB, FHKAM (Obstetrics and Gynaecology)

Correspondence to: Prof SK Yip (e-mail: yipsk@cuhk.edu.hk)

結果：共有 302 名病人接受無張力陰道懸吊帶手術，當中有 250 人（82.8%）完成一年跟進過程。有 157 名病人（62.8%）只接受無張力陰道懸吊帶手術，另 93 名病人（37.2%）因盤骨內器官膨出，故同時接受了盤骨底手術。所有病人在手術前和手術後一年都進行過尿流動力學研究。只接受無張力陰道懸吊帶手術的病人，其客觀痊癒率是87.3%；同時接受盤骨底手術的病人，其客觀痊癒率是 80.6%（Chi squared test ， P>0.05）。主觀痊癒方面，只接受無張力陰道懸吊帶手術的病人和同時接受盤骨底手術的病人，其四個月的主觀痊癒率分別為 89.2% 和 86.0%；而一年期的主觀痊癒率則分別為 93.0% 和 94.6%（Chi squared test ， P>0.05）。最普遍的併發症為手術後尿瀦留（15.2%），其次為一年內膀胱逼肌過度活動（10%）以及膀胱穿刺（8%）。

結論：無論單以無張力陰道懸吊帶手術，或加上盤骨底手術，對治療女性壓力尿失禁同等有效。

Introduction

Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are distressing and common problems among Hong Kong women.[1-3] Corrective surgery is often required.[2] Tension-free vaginal tape (TVT) [Gynecare, Somerville, US] is used in a minimally invasive surgical procedure for the treatment of female SUI. The surgical procedure was first described by Petros et al,[4] and became commercially available as a disposable surgical kit in the mid-1990s.[5] Mesh tape is inserted at the mid-urethral region to create a sling on which the urethra can rest when there is a sudden increase in abdominal pressure.[5] The surgical kit consists of a polypropylene (Prolene; Ethicon, Somerville, US) mesh tape connected to two curved metal needle trocars that allow introduction of the tape through a vaginal incision. Short-term and long-term results of TVT in the treatment of female SUI are encouraging and compare well with those of the Burch colposuspension procedure.[6-8]

Vaginal hysterectomy with or without colporrhaphy, performed via a vaginal approach, forms the principal surgical treatment for POP.[9,10] Since SUI and POP frequently co-exist,[2] gynaecologists commonly perform TVT sling and pelvic floor surgical procedures concurrently. Nonetheless studies that have evaluated such combined surgery have been small or uncontrolled.[11-13] This study aimed to compare the outcome for patients undergoing concomitant pelvic floor surgery and TVT sling procedure, with those undergoing TVT sling procedure alone.

Methods

A surgical database of a cohort of patients with POP, who had undergone TVT sling procedure alone or combined with pelvic floor surgery (vaginal hysterectomy and/or colporrhaphy) between 24 September 1999 and 20 August 2004 at a university teaching hospital, was retrospectively analysed. The primary outcome measure was the objective cure rate of SUI 1 year following TVT. Patients were considered objectively cured if no SUI was evident on urodynamic study at 1-year follow-up. Secondary outcome measures included the following: subjective cure rate of SUI at 4 months and 1 year following TVT, intra-operative and perioperative complication rates, and the rate of de-novo detrusor overactivity (DO) at 1 year. Patients were asked at 4-month follow-up to rate their SUI as better, same, or worse than before surgery. Patients were considered subjectively cured if they replied 'better'.

The TVT surgical database is part of the urogynaecological research database maintained by the urogynaecology unit of the university teaching hospital. The urogynaecology unit is a tertiary referral centre that manages women with urinary incontinence and POP. All urogynaecological patients' clinical data were entered into the database: patient demographics, preoperative urogynaecological symptomatology and physical findings, preoperative urodynamic diagnoses, perioperative clinical data (operating time, blood loss, and febrile morbidity), postoperative urodynamic diagnoses, and follow-up symptomatology and physical findings.

Standardised routine clinical management protocols were used throughout this study. All patients had a diagnosis of SUI confirmed by preoperative urodynamic studies that were repeated 1 year following TVT. All patients were also assessed routinely 4 months after TVT for the presence of SUI.

The tension-free vaginal tape procedure

All patients received one dose of intravenous Augmentin 1.2 g (amoxycillin 1 g + clavulanic acid 200 mg) [GlaxoSmithKline, Middlesex, UK] preoperatively. A standardised, conventional TVT sling procedure was performed[5] alone (TVT alone group) or combined with pelvic floor surgery (TVT with concomitant procedure group). Concomitant pelvic floor surgery consisted of vaginal hysterectomy and/or colporrhaphy. All TVTs were performed by the authors. A 1.5-cm long incision was made in the midline of the suburethral vaginal wall, starting approximately 0.5 cm from the outer urethral meatus. Laterally from this incision, a dissection of 0.5 to 1.0 cm long was made with scissors to each side of the urethra to allow the tip of a TVT needle trocar to be introduced in the correct starting position. Two 0.5-cm transverse abdominal skin incisions were made close to the superior rim of the pubic bone to facilitate trocar exit. Using the handle with the trocar attached, the TVT tape was placed around the mid-urethra: the tip of the trocar was inserted into the paraurethral incision on the right side of the urethra (Fig a). The urogenital diaphragm was perforated and the tip of the trocar brought up to the abdominal incision (Fig b). When the trocar tip reached the abdominal skin incision, the proximal end of the trocar was disconnected from the

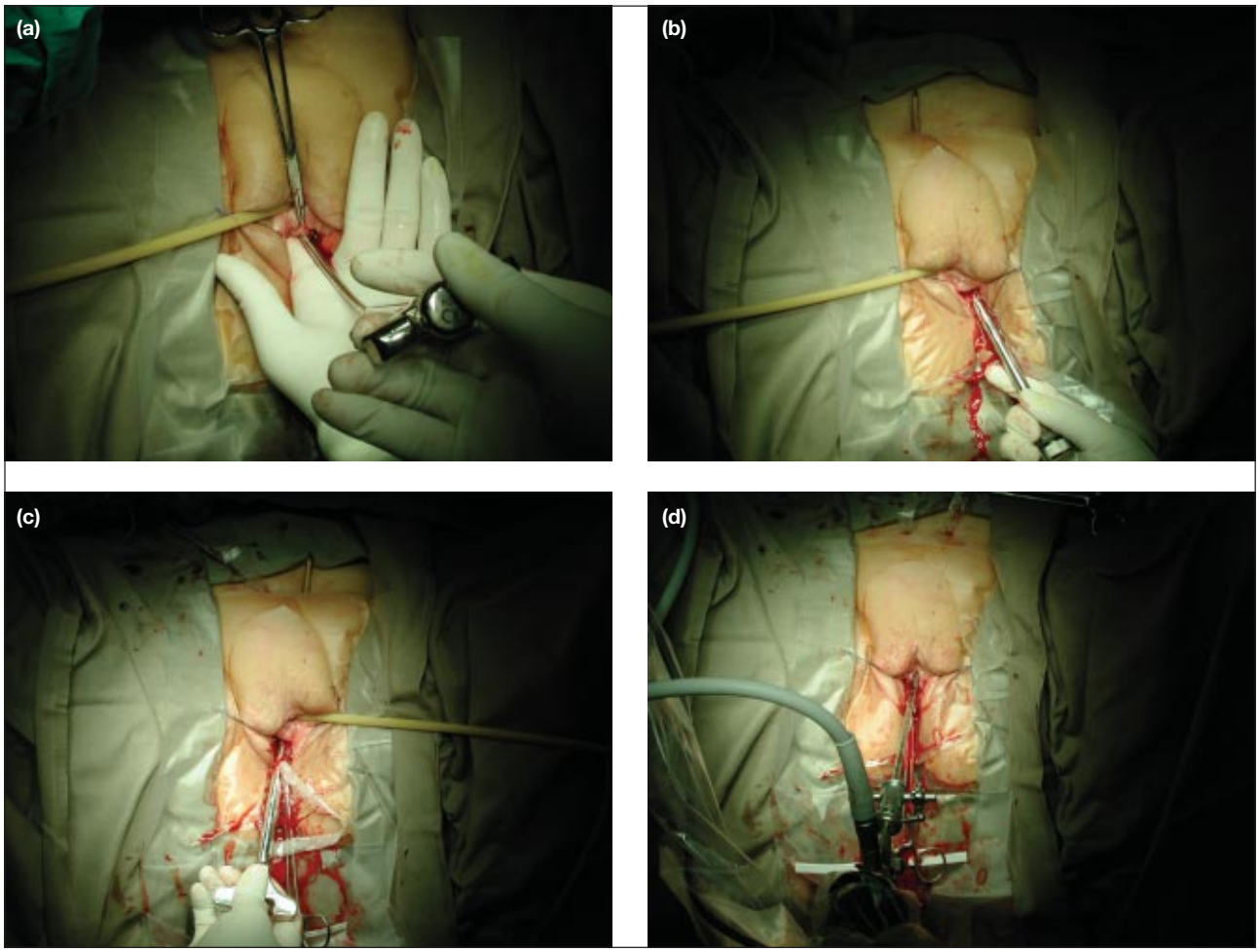

Fig. The surgical procedures of tension-free vaginal tape for the treatment of urodynamic stress incontinence
(a) The tip of the trocar was inserted into the paraurethral incision on the right side of the urethra. **(b)** The urogenital diaphragm on the right side was perforated and the tip of the trocar was brought up to the abdominal incision. **(c)** The procedure was then repeated on the left side. **(d)** Cystoscopy was performed after application on each side to check for bladder perforation

handle and the tape, covered by the plastic sheath, and was brought into position on this side of the urethra by pulling the needle upwards with the tape attached. The procedure was then repeated on the left side (Fig c). Cystoscopy was performed after application on each side to check for bladder perforation (Fig d). When the tape had been placed in a U shape around the mid-urethra, the plastic sheath was withdrawn.

In patients who needed concomitant vaginal hysterectomy and/or colporrhaphy, the TVT sling was inserted afterwards with the anterior vaginal wall incision extended to reach the level of the mid-urethra. The tape was then inserted as described above.

Urodynamic study

All women underwent uroflowmetry and filling and voiding cystometry using a Dantec Menuet (Dantec Medical A/S, Skovlunde, Denmark) multichannel urodynamic machine. The urodynamic procedures and diagnoses were based on the standards prescribed by the International Continence Society (ICS).[14,15]

Statistical analysis

Descriptive statistics were used to summarise patient demographics and cure rates. The Mann-Whitney *U* test was used to compare continuous variables between the two groups, and the Chi squared test was used to compare categorical variables. A P value of less than 0.05 was considered statistically significant. Statistical analyses were performed using Statistical Package for the Social Sciences (Windows version 12.0; SPSS Inc, Chicago [IL], US).

Results

Between 24 September 1999 and 20 August 2004, 302 patients underwent a TVT sling procedure at the authors' unit, and 250 (82.8%) completed 1-year follow-up (median, 378 days; interquartile range, 360-387 days). All patients had preoperative urodynamic study and were diagnosed with moderate-to-severe urodynamic stress incontinence (USI). None had DO. Of the 250 patients, 157 (62.8%) had only USI and underwent TVT alone, and 93 (37.2%) had SUI and POP (ICS stage II or above) and underwent TVT with pelvic floor surgery.

Table 1. Comparison of patient demographics between tension-free vaginal tape alone (TVT alone group) and TVT with pelvic floor surgery (TVT with concomitant procedure group)

Demographic data	TVT alone group, n=157	TVT with concomitant procedure group, n=93	P value
Mean age (IQR) [years]	51 (45-59)	68 (58-74)	<0.0001*
No. of patients reaching menopause	97 (61.8%)	83 (89.2%)	<0.0001†
Median parity (IQR)	3 (2-4)	4 (3-6)	<0.0001*
Median No. of vaginal births (IQR)	3 (2-4)	4 (3-6)	<0.0001*
Largest median birth weight (IQR) [kg]	3.3 (3.2-3.7)	3.2 (3.1-3.6)	0.488*
Patient's median weight‡ (IQR) [kg]	60.1 (54.1-65.7)	58.9 (51.8-64.2)	0.140*
Patient's median height‡ (IQR) [m]	1.5 (1.50-1.58)	1.5 (1.47-1.56)	0.007*
Patient's median body mass index‡ (IQR)	25.4 (23.1-27.7)	25.1 (22.7-26.9)	0.420*

* Mann-Whitney *U* test
† Chi squared test
‡ Data at the time of operation

Table 2. Comparison of perioperative details between tension-free vaginal tape alone (TVT alone group) and TVT with pelvic floor surgery (TVT with concomitant procedure group)

Perioperative details	TVT alone group, n=157	TVT with concomitant procedure group, n=93	P value
Median duration of operation (IQR) [minutes]	30 (20-30)	70 (60-90)	<0.0001*
Median intra-operative blood loss (IQR) [mL]	50 (40-100)	200 (150-300)	<0.0001*
Median level of haemoglobin drop (IQR) [g/L]	0.6 (0-1.1)	1.6 (0.7-2.5)	<0.0001*
Median hospital stay (IQR) [days]	3 (3-5)	5 (4-6)	<0.0001*
Median postoperative Foley catheterization (IQR) [days]	0 (0-2)	0 (0-1)	0.453*
No. of postoperative urinary retention‡	22 (14.0%)	16 (17.2%)	0.310†
No. of bladder perforation	15 (9.6%)	5 (5.4%)	0.349†
No. of postoperative febrile morbidity§	0	1 (1.1%)	-
No. of pelvic haematoma	1 (0.6%)‖	1 (1.1%)¶	0.469†

* Mann-Whitney *U* test
† Chi squared test
‡ Unable to void immediately after operation and required Foley catheterization for ≥24 hours
§ Two consecutive episodes of temperature ≥38°C with 4 hours apart
‖ Required laparotomy to evacuate the haematoma
¶ Diagnosed after operation and no evacuation was required

Patient demographics are shown in Table 1. Patients who received TVT alone were younger, taller, and had fewer obstetric deliveries.

The operation-related data are shown in Table 2. The TVT alone group had a shorter surgery time, less blood loss, and was discharged sooner. There was no difference in perioperative complications. No patients sustained any neurological damage, or complained of persistent vaginal bleeding after surgery. No cases of tape erosion were observed during follow-up.

All intra-operative bladder injuries were through-and-through perforations by the TVT needle trocar during insertion, and were diagnosed intra-operatively by routine cystoscopy. The trocar was withdrawn and repositioned immediately, and a Foley urethral catheter left in place for 5 days. None of the patients had abnormal urinary symptoms or urodynamic findings at 1-year follow-up.

The overall prevalence of postoperative urinary retention was 15.2%, with no difference between the two groups (Table 2). These patients complained of urgency and strangury shortly after the operation and were managed conservatively with Foley catheterization and bladder training. No patient required catheterization for more than 1 month.

One patient developed a large pelvic haematoma due to a 2-cm tear in the arcus tendineus levator ani (ATLA) on the right side. She presented with shock and abdominal distention and underwent emergency laparotomy for haemostasis and repair of the tear. The tear was due to swinging of the trocar tip during insertion.[16] Subsequent recovery was uneventful with no long-term sequelae.

The subjective cure rates were assessed at 4-month and 1-year follow-up (Table 3) and were 88% and 93.6%, respectively. There was no difference between TVT alone group and TVT with concomitant procedure group. Nevertheless in both groups, there was progressive improvement in subjective rates from 4 months to 1 year after TVT (McNemar test, P<0.001).

Urodynamic studies at 1-year follow-up revealed complete cure of SUI in 137 (87.3%) of the TVT group and 75 (80.6%) of the TVT with concomitant procedure group (Chi squared test, P=0.22). Eleven (7.0%) patients in the TVT alone group, and 14 (15.1%) in the TVT with concomitant procedure group were found to have

Table 3. Comparison of subjective cure rates at 4-month and 1-year follow-up between tension-free vaginal tape alone (TVT alone group) and TVT with pelvic floor surgery (TVT with concomitant procedure group)

Follow-up findings	TVT alone group, n=157 No. (%)	TVT with concomitant procedure group, n=93 No. (%)	P value*
At 4-month			
Better	140 (89.2)	80 (86.0)	
Same	6 (3.8)	9 (9.7)	0.128
Worse	11 (7.0)	4 (4.3)	
At 1-year			
Better	146 (93.0)	88 (94.6)	
Same	8 (5.1)	5 (5.4)	0.406
Worse	3 (1.9)	0	

* Chi squared test

developed de-novo DO (Chi squared test, P=0.07). Three (1.9%) patients with TVT alone, but none of the patients with TVT with concomitant procedures were diagnosed with voiding difficulties. Three patients presented with slow urine stream and strain-to-void: residual urine volume comprised more than 25% of the voided volume. They were managed conservatively by timed voiding and double voiding.

Discussion

The results of our experience in Hong Kong women show that the cure rate of SUI following TVT is similar to international figures.[6-8] At 1 year postoperatively, the group having TVT with concomitant procedures have a similar cure rate when comparing with the group having TVT alone. The TVT is a simple and effective procedure for the treatment of female SUI. Since SUI and POP commonly co-exist,[2] we recommend TVT with concomitant procedures as the surgery of choice.

Insertion of TVT is an apparently safe procedure, as demonstrated by the low complication rate in our study. Most complications were short-term, and were managed conservatively. One major complication of massive pelvic haematoma occurred due to lacerated ATLA that was managed by laparotomy and surgical repair.[16] Thus the rate of major complications following TVT was only 0.4%. Nonetheless TVT is not a risk-free surgical procedure and significant complications have been reported such as injury to the urethra, intestine, and obturator artery and nerve.[17] It is largely a blind procedure that depends on the use of a needle trocar. Surgical vigilance is necessary during trocar application to avoid inadvertent damage of nearby anatomical structures.

Most other studies of TVT reported only cure rates at a single time point, for example 1 year. A progressive cure rate among a cohort of patients has not been reported. This study is the first to assess subjective cure rates in a cohort of patients 4 months and 1 year following TVT procedure and demonstrated a significant improvement over time. This progressive improvement may be explained by the previous findings of a study on the histological changes induced by an implanted suburethral tape in female dogs.[4] The implanted tape provoked controlled linear deposition of collagen around the tape, continually reforming with time. Our subjective cure rates provide clinical evidence that the collagen-reforming process may continue for up to 1 year after the operation.

Although patients who underwent TVT with concomitant procedures were significantly older, had higher parity, and more vaginal births than patients with TVT alone, there was no significant difference in subjective and objective cure rates at 4 months and 1 year. This supports the notion that TVT is an effective treatment for SUI in patients with POP. Long-term study is required to confirm the effects of parity and age-related risk factors.

Conclusion

Tension-free vaginal tape alone and TVT with concomitant procedures are equally effective treatments for female SUI, with objective cure rates compatible with international figures. Subjective cure rates progressively improve over time.

Acknowledgement

The authors would like to express their gratitude to Ms Loreta Lee for her assistance in the management of the Urogynaecology Database.

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