Long-term Results of Tension-free Vaginal Tape Insertion for Urodynamic Stress Incontinence in Chinese Women at Eight-year Follow-up: a Prospective Study

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Objectives: To assess the long-term effectiveness and patient satisfaction at 8-year follow-up after tension-free vaginal tape insertion for urodynamic stress incontinence in Chinese women.
Methods: A prospective study was conducted from January 1999 to July 2004 at Queen Elizabeth Hospital, Hong Kong, among consecutive patients with urodynamic stress incontinence who underwent tension-free vaginal tape insertion. All patients were assessed at years 1, 3, and 8 according to the designated protocol.
Results: A total of 73 patients were enrolled and 30 (41.1%) patients underwent concomitant vaginal procedures. At the 3-year follow-up, the objective cure rate was 85% and the subjective cure rate was 96%. At the 8-year follow-up, the objective cure rate was 90% and the subjective cure rate was 99%. De-novo detrusor overactivity was seen in 32% and 47% of patients at 3- and 8-year follow-up, respectively. Similar objective and subjective cure rates were seen in the tension-free vaginal tape insertion–only group and the tension-free vaginal tape with concomitant surgery group.
Conclusion: Tension-free vaginal tape insertion is an effective and safe operation for management of urodynamic stress incontinence in a Chinese population. The procedure maintains long-term efficacy, up to 8 years, with good patient satisfaction and objective cure rate. Concomitant vaginal surgery at the time of tension-free vaginal tape insertion does not affect the success rate.
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Introduction

Urinary incontinence is defined as involuntary loss of urine, which has a negative impact on the social, physical, and psychological wellbeing of the female population. The reported prevalence of urinary incontinence in Hong Kong ranges from 21% to 40%, of which 40% of women have stress incontinence[1,2]. The best means of cure of stress urinary incontinence is surgery, which will only be considered after failure of conservative treatment[3]. Although there are many options available, the National Institute for Health and Clinical Excellence has assessed tension-free vaginal tape (TVT) insertion as having similar objective and subjective cure rates to colposuspension, but with a shorter hospital stay[3].

TVT insertion is the best-studied and -documented procedure, and has excellent short-term[4] and long-term outcomes[5]. Groutz et al[6] reported an improvement rate of 77% over 10 years in a Canadian study. As the life expectancy of women increases, quality of life would be improved by continence surgery for patients with stress urinary incontinence. Therefore, long-term data are needed. The aim of this study was to assess the subjective and objective success rates at 8 years after TVT insertion by pre-designed questionnaire, pad test, and standard urodynamic investigations in a local Chinese female population.

Methods

Consecutive patients undergoing TVT insertion at the Queen Elizabeth Hospital, Hong Kong, January 1999 to July 2004 were included in this prospective study. All patients were assessed pre- and post-operatively according to the standardised protocol for at least 8 years after operation. The principal outcome measures were subjective and objective cure rates and operation-related complications.

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All patients were evaluated preoperatively by means of a detailed patient history with documentation on severity of stress incontinence symptoms; urodynamic testing, including uroflowmetry; filling/voiding cystometry; 1-hour pad test; and quality-of-life questionnaire. Diagnosis of urodynamic stress incontinence was based on the findings of urodynamic investigations and diagnosis of detrusor overactivity was based on the cystometry findings. Stratification of the severity of stress incontinence was based on the classification of pad weight gain suggested by the 5th Report of the International Continence Society, Bristol, 1987[7].

Patients who had undergone previous continence surgery or had voiding difficulty were excluded from the study. All patients signed an informed consent form. Three surgeons in the urogynaecology team performed the operations. The methods of anaesthesia were usually regional or general anaesthesia, depending on whether concomitant vaginal surgery was performed.

After the procedure, an indwelling Foley catheter was inserted for drainage of urine for 1 day and antibiotic prophylaxis with metronidazole 500 mg and cefuroxime 750 mg intravenously for three doses (preoperatively and postoperatively every 8 hours for two more doses) was given.

Patients were encouraged to void after Foley catheter removal the next day when they were mobile. Patients were discharged once they had voided satisfactorily (two consecutive residual urine <150 ml). The time for bladder training and duration of hospitalisation were recorded.

Postoperative complications such as bladder injury, voiding difficulty, tape erosion, urinary tract infection (with positive culture), wound infection, and fever were also recorded. Objective outcome was assessed by urodynamic testing and 1-hour pad test, while subjective outcome was defined by a patient's perception as satisfied (great improvement without urine leakage) or not satisfied (no change or worse). All patients were invited for regular follow-up at 1, 3, and 8 years after the procedure, and assessment was done by 1-hour pad test, urodynamic tests, and completion of a standardised pre-set questionnaire.

Statistical analysis was performed for variables following normal distribution by using the Student's *t* test for independent samples and for variables not following normal distribution by using the Mann-Whitney test for independent samples.

As this was a single-centre study, type 1 error–alpha 0.10 would be sufficient to provide a meaningful result. It was estimated that, for a type 1 error–alpha 0.10 and a type II error–beta 0.10 (power of the study, 90%) and an 82% success rate for TVT insertion at the 8-year follow-up, a null hypothesis value to detect a success rate of 65% required a sample size of at least 54 patients. A p value of <0.05 was considered statistically significant.

Results

A total of 73 consecutive patients underwent TVT insertion from 1999 to 2004. The mean age of the patients at time of surgery was 62.5 years. The median number of previous vaginal deliveries was 3 (range, 0-14). The mean duration of stress incontinence was 5.3 years (Table 1). Mild-to-moderate urine loss was observed in 26% of patients, severe loss in 26%, and very severe loss in 16% (Table 2).

Among the 73 patients, 11 (15%) had undergone previous abdominal gynaecological surgery, 44 (60%) were found to have genital prolapse according to the International Continence Society Classification on clinical examination, and 8 (11%) had preoperative detrusor overactivity (Table 1). In total, 30 (41%) patients underwent concomitant surgical procedures (mesh repair, vaginal hysterectomy, and/or pelvic floor repair) with TVT insertion. The remaining

Table 1. Patients' characteristics (n=73)

Characteristic	Data*
Age (years)	62.5 ± 10.1
Previous vaginal deliveries	3 (0-14)
Parity	3 (0-14)
Duration of stress incontinence (years)	5.3 ± 6.2
Preoperative 1-hour pad test (g)	28.7 ± 49.9
Preoperative detrusor overactivity	8 (11%)
Previous abdominal gynaecological surgery	11 (15%)
Genital prolapse	44 (60%)
Concomitant vaginal surgery	30 (41%)

* Data are shown as No. (%), mean ± standard deviation, or median (range)

Table 2. Degree of urinary incontinence according to the 1-hour pad test (n=73)

Severity	No. (%) of patients
Dry (<2 g)	23 (32)
Mild-to-moderate (2-9.99 g)	19 (26)
Severe (10-50 g)	19 (26)
Very severe (>50 g)	12 (16)

43 (58.9%) patients underwent TVT insertion only.

Complete postoperative assessment was performed for all 73 patients, and all patients completed a patient satisfaction questionnaire.

There were three (4%) patients with bladder injury, which was identified intra-operatively during a check cystoscopy (Table 3). The tapes were removed immediately and new tapes were re-inserted. Repeat cystoscopy after the second insertion showed no perforation. The patients were treated successfully with conservative management, including bladder drainage and antibiotics. All three patients with bladder injury were from TVT insertion–only group.

Two (2.7%) patients had voiding dysfunction requiring tape incision (Table 3). One patient developed voiding difficulty requiring intermittent clean self-catheterization on the second postoperative day and one patient had voiding difficulty 3 years after TVT insertion. Urodynamic investigation showed voiding dysfunction in both patients, and tape incision was performed. Subsequent urodynamic tests according to the protocol showed negative stress test results with residual urine of less than 50 ml. Both patients were from TVT with concomitant surgery group. No patients had recurrent urodynamic stress incontinence requiring repeat surgery.

No patients had urinary tract infection, chest infection, or deep vein thrombosis. Two patients (3%; one from each group) had postoperative fever (after 24 hours) and were treated successfully with antibiotics and antipyretics (Table 3).

Table 3. Immediate postoperative complications (n=73)

Complication	No. (%) of patients
Bladder injury	3 (4)
Urinary tract infection	0
Postoperative fever	2 (3)
Wound infection	0
Deep vein thrombosis	0
Chest infection	0
Voiding dysfunction	2 (3)

Objective Cure Rate

The objective success rate according to a negative stress test result was 85% at both 1 and 3 years, and 90% at 8 years (Table 4). There was no significant difference in objective cure rate between year 1 and year 3 (p=0.054), but a significant difference was found between year 1 and year 8 (p<0.01).

There was a statistically significant difference in 1-hour pad test when comparing the preoperative results with the 1-, 3-, and 8-year postoperative results (28.7 g vs. 4.5 g, p<0.001; 28.7 g vs. 9.2 g, p=0.013; 28.7 g vs. 9.8 g, p=0.009, respectively) [Table 5].

Subjective Cure Rate

Among the 73 patients, 95% were satisfied at 1 year, 96% were satisfied at 3 years and 99% were satisfied at 8 years (Table 4). There were no significant differences in subjective cure rate between the 1-, 3-, and 8-year

Table 4. Success rates and complication rates at 1, 3, and 8 years (n=73)

	No. (%) of patients		p Value	No. (%) of patients	p Value
	1 year	3 years		8 years	
Subjective success (satisfaction)	69 (95)	70 (96)	1.0	72 (99)	1.0
Objective success* (cystometrogram)	62 (85)	62 (85)	0.054	66 (90)	<0.01
Detrusor overactivity	15 (21)	23 (32)	-	34 (47)	-

* No urodynamic stress incontinence

Table 5. Preoperative versus postoperative 1-hour pad test (n=73)

1-hour pad test	Preoperative	Postoperative		
		1 year	3 years	8 years
Weight of pad* (g)	28.7 ± 49.8	4.5 ± 4.5	9.2 ± 9.2	9.8 ± 9.8
p Value	-	<0.001	0.013	0.009

* Data are shown as mean ± standard deviation

assessments (95% vs. 96%, p=1.0; 95% vs 99%, p=1.0, respectively).

De-novo Detrusor Overactivity

There were 65 patients without pre-existing detrusor overactivity before TVT insertion. De-novo detrusor overactivity was seen in 17% (11/65) at year 1, 28% (18/65) at year 3, and 45% (29/65) at year 8.

Concomitant Surgery

There were no statistically significant differences in objective and subjective cure rates between patients undergoing TVT insertion alone or TVT insertion with concomitant surgery (Table 6). There were also no statistically significant differences in duration of bladder training between the two groups either (Table 6).

Discussion

Traditionally, Burch colposuspension has been offered as the gold standard procedure for stress urinary incontinence. However, the efficacy of Burch colposuspension declines over time, with a surgical success rate of 62% at more than 10 years[8]. The subjective cure rate may be reduced to 44% after 14 years[9]. Therefore, other options for the management of urinary stress incontinence are explored.

The introduction of TVT insertion for urodynamic stress incontinence is based on the theory that the female urethra is closed at the level of the mid-urethra. Lack of support of the midurethra from pubourethral ligament and the suburethral vaginal wall predisposes to urodynamic stress incontinence[10,11]. Therefore, TVT insertion exerts its effect by supporting the midurethra by using a polypropylene mesh tape[10,11].

Early results from TVT insertion appear promising and the procedure has been shown to be effective[4]. A prospective study by Chen et al[12] of 150 patients undergoing the procedure showed an objective success rate of 95% at 1 year. In this study, a similar objective cure rate of 85% at 1 year was found, with no patients having recurrent urodynamic stress incontinence requiring repeat surgery; this is compatible with the low rate of repeat continence surgery (1.4%) in the study by Schierlitz et al[13].

In the present study, the long-term efficacy of TVT insertion over 8 years showed similar results to Chen et al[12] of 90.4%. The improved objective cure rate of year 8 compared with year 1 might have resulted from the scarring effect and fibrosis supporting the vaginal tape. Aigmueller et al[14] evaluated 210 patients undergoing TVT insertion and found a 10-year objective cure rate of 84%. Olsson et al[15] recruited 147 patients undergoing TVT insertion and showed a similar objective cure rate of 84% and subjective cure rate of 77% up to 11 years.

The high incidence of de-novo detrusor overactivity in this study could be attributed to the small sample size, relatively older mean age of the patients, and concomitant age-related bladder conditions[16]. In large epidemiological studies, the prevalence of overactive bladder symptoms in postmenopausal women according to the International Continence Society definition was 20 to 40%, which increased with age[14]. In Hong Kong, the reported prevalence of urge incontinence in 2006 was 20.1% and of mixed incontinence was 15.2% in a target group aged between 17 and 77 years[2]. Therefore, to identify the impact of old age on the incidence of detrusor overactivity, further study of the target population will be required.

Table 6. Objective and subjective success rates, and duration of bladder training by tension-free vaginal tape (TVT) insertion alone or TVT insertion plus concomitant surgery (n=73)

Success rate	No. (%) of patients*		p Value
	TVT alone (n=43)	TVT plus concomitant surgery (n=30)	
Objective			
Year 1	35 (81)	27 (90)	0.508
Year 3	35 (81)	27 (90)	0.508
Year 8	37 (86)	29 (97)	0.228
Subjective			
Year 1	41 (95)	28 (93)	0.548
Year 3	42 (98)	28 (93)	0.075
Year 8	43 (100)	29 (97)	0.666
Duration of bladder training (days)	3.5	3.6	0.949

* Except otherwise indicated

Three patients (4%) with bladder injury and two patients (3%) with postoperative voiding dysfunction requiring tape incision were noted in this study. Similar results for complications of bladder perforation (5%) and voiding dysfunction (3%) were reported by Brubaker et al[17]. These complications could potentially be minimised by more experienced surgeon.

To ascertain whether early postoperative impaired bladder emptying and reduced peak flow rate are important risk factors for long-term failure[6], further prospective randomised controlled trials might be required. Cheng and Liu[18] found that 17.4% of patients had postoperative voiding difficulties requiring urethral bladder catheterization for various periods.

Concomitant vaginal surgery with TVT insertion did not compromise the success rate and patient satisfaction rate, but did require longer operating time and duration of anaesthesia. Similar finding were also shown among patients undergoing TVT insertion with concomitant surgery in the study by Aigmueller et al[14]; 86% of patients had negative stress test results at 10 years compared with 81% in the TVT insertion–only group.

The strengths of this study were the high response rate (100%) and clinical assessment completion rate (100%). The study limitations included lack of data about readmission and body mass index.

Conclusion

Objective and subjective cure rates for TVT insertion are satisfactory. The procedure is safe and remains effective up to 8 years. There is no difference in subjective and objective cure rates between patients undergoing TVT insertion with or without concomitant vaginal surgery.

References

1. Brieger GM, Yip SK, Hin L, et al. The prevalence of urinary dysfunction in Hong Kong Chinese women. *Obstet Gynecol* 1996; 88:1041-4.
2. Wong T, Lau BY, Mak HL, et al. Changing prevalence and knowledge of urinary incontinence among Hong Kong Chinese women. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17:593-7.
3. Royal College of Obstetricians and Gynaecologists. Surgical treatment of urodynamic stress incontinence. Greentop Guideline No. 35. *RCOG*; 2003.
4. Ulmsten U, Johnson P, Rezapour M. A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* 1999; 106:345-50.
5. Glavind K, Glavind E, Fenger-Grøn M. Long-term subjective results of tension-free vaginal tape operation for female urinary stress incontinence. *Int Urogynecol J* 2012; 23:585-8.
6. Groutz A, Rosen G, Cohen A, et al. Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. *J Minim Invasive Gynecol* 2011; 18:726-9.
7. Liapis A, Bakas P, Creatsas G. Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. *Int Urogynecol J Pevlic Floor Dysfunct* 2008; 19:1509-12.
8. El-Toukhy T, Mahadevan S, Davies AE. Burch colposuspension: a 10 to 20 years follow up. *J Obstet Gynaecol* 2000; 20:178-9.
9. Kjølhede P. Long-term efficacy of Burch colposuspension: a 14-year follow-up. *Acta Obstet Gynecol Scand* 2005; 84:767-72.
10. Petros PE, Ulmsten UI. An integral theory of female urinary incontinence. Experimental and clinical considerations. *Acta Obstet Gynecol Scand Suppl* 1990; 153:7-31.
11. Petros PE, Ulmsten UI. An integral theory and its method for the diagnosis and management of female urinary incontinence. *Scand J Urol Nephrol Suppl* 1993; 153:1-93.
12. Chen X, Tong X, Jiang M, et al. A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for treatment of SUI: a prospective comparative study. *Arch Gynecol Obstet* 2011; 284:1461-6.
13. Schierlitz L, Dwyer PL, Rosamilia A, et al. Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. *Obstet Gynecol* 2012; 119(2 Pt 1):321-7.
14. Aigmueller T, Trutnovsky G, Tamussino K, et al. Ten-year follow-up after the tension-free vaginal tape procedure. *Am J Obstet Gynecol* 2011; 205:496.e1-5.
15. Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. *Int Urogynecol J* 2010; 21:679-83.
16. Li B, Zhu L, Lang JH, et al. Long-term outcomes of the tension-free vaginal tape procedure for female stress urinary incontinence: 7-year follow-up in China. *J Minim Invasive Gynecol* 2012; 19:201-5.
17. Brubaker L, Norton PA, Albo ME, et al. Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study. *Am J Obstet Gynecol* 2011; 205:498.e1-6.
18. Cheng D, Liu C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol* 2012; 161:228-31.