

Are the Treatment Outcomes of Tension-free Vaginal Tape Insertion the Same for Patients with Stress Urinary Incontinence with or without Intrinsic Sphincter Deficiency? A Retrospective Study in Hong Kong Chinese Women

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Objective: To assess whether there is a difference in treatment outcomes for patients with or without intrinsic sphincter deficiency after tension-free vaginal tape insertion for stress urinary incontinence in a Chinese population.

Methods: This retrospective study of Chinese women undergoing tension-free vaginal tape insertion for confirmed urodynamic stress urinary incontinence was carried out in a local regional hospital from 2000 to 2008. Valsalva leak point pressure and / or maximum urethral closure pressure were checked and intrinsic sphincter deficiency was defined as Valsalva leak point pressure of <60 cm H₂O or maximum urethral closure pressure of <20 cm H₂O. Patient satisfaction and subjective and objective cure rates were compared between the groups with and without intrinsic sphincter deficiency. A p value of <0.05 was regarded as statistically significant.

Results: Of 132 patients enrolled in the study, 17 had intrinsic sphincter deficiency. At 1-year follow-up, patient satisfaction rates were high in both groups. There was a significant difference between the groups for subjective cure rates (76.5% in the intrinsic sphincter deficiency group vs. 87.8% in the group without intrinsic sphincter deficiency) but not for objective cure rates. There were no significant differences between the groups for patient satisfaction and subjective and objective cure rates at the 3-year follow-up.

Conclusion: Tension-free vaginal tape insertion is an effective and highly satisfactory procedure for treatment of stress urinary incontinence in Chinese women, whether or not they have intrinsic sphincter deficiency.

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Introduction

Stress urinary incontinence (SUI) is defined as involuntary loss of urine on effort or physical exertion, or on sneezing or coughing. SUI is a common condition¹. According to a territory-wide telephone survey conducted in Hong Kong in 2006, 40.8% of women interviewed reported SUI, while 20.4% had urge incontinence and 15.9% had mixed incontinence. Among these women, 16% reported quality-of-life impairment².

There are several different theories as to the causes of SUI. Enhorning³ suggested that proximal urethral hypermobility prevents transmission of intra-abdominal pressure to the urethra, causing a negative pressure gradient and SUI. The 'integral theory' by Petros and Ulmsten⁴ and the 'hammock theory' by DeLancey⁵ both explained that good urethral support is important for maintaining urethral pressure above vesical pressure during increased

intra-abdominal pressure. However, in a group of patients with SUI, the urethra was well-supported. Therefore, the concept of urethral intrinsic sphincter deficiency (ISD) was described⁶.

ISD is usually diagnosed by objective urodynamic measurements. Sand et al⁷ found that the surgical failure rate following retropubic colposuspension was higher in patients with maximum urethral closure pressure (MUCP) of <20 cm H₂O. McGuire et al⁸ found a strong correlation with an open bladder neck on fluoroscopy and low urethral pressure when Valsalva leak point pressure (VLPP) was <60 cm H₂O. Therefore, ISD is commonly defined as MUCP of <20 cm H₂O or VLPP of <60 cm H₂O.

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Treatments for SUI include non-surgical and surgical methods. Surgical treatment should be considered if conservative treatment has failed⁹. Tension-free vaginal tape (TVT) insertion was first introduced by Ulmsten et al in 1996¹⁰. TVT insertion provides a similar cure rate when compared with open retropubic colposuspension¹¹. A recent meta-analysis showed that the re-operation rate was significantly higher for retropubic colposuspension than for TVT insertion ($p=0.02$)¹². Therefore, mid-urethral sling procedures have become the first-line surgical treatment for SUI in most units.

The effectiveness of TVT insertion for treating SUI patients with ISD has been studied, and high success rates of 73 to 82% have been reported¹³⁻¹⁸. However, all these studies were performed in non-Chinese populations. Previous studies have shown that Caucasian women are at increased risk for SUI^{19,20}. It is postulated that the difference in prevalence rates may be attributed to inherent anatomical and physiological differences among racial groups²⁰. Therefore, the aim of this study was to compare the treatment outcomes in local Chinese women with SUI with or without ISD.

Methods

This was a retrospective study carried out in the Department of Obstetrics and Gynaecology, Queen Elizabeth Hospital, Hong Kong, from 2000 to 2008. Urodynamic studies, including uroflowmetry and filling and voiding cystometry, were performed in patients presenting with SUI. The urodynamic procedures and diagnoses were done according to the guidance of the International Continence Society¹. Urodynamic SUI was defined as the presence of involuntary urine leakage during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction. Patients who had genital prolapse requiring concomitant prolapse surgery were excluded.

A total of 132 Chinese patients were included in the study. All patients with confirmed urodynamic SUI had VLPP and / or MUCP checked. VLPP was checked during the filling phase of cystometry at a bladder volume of around 300 ml. Patients were instructed to perform the Valsalva manoeuvre and VLPP was defined as the lowest value of the intentionally increased intravesical pressure that provoked urinary leakage in the absence of a detrusor contraction. Urethral pressure profile was assessed with the patient lying supine using a 7F dual sensor microtip catheter. The catheter was withdrawn through the urethra at 1 mm/second. MUCP was defined as the maximum

difference between the urethral pressure and the intravesical pressure. ISD was defined as VLPP of <60 cm H₂O or MUCP of <20 cm H₂O.

All the TVT procedures were performed by urogynaecologists or urogynaecologist trainees who were competent in performing the procedures. Postoperative evaluation was performed at 1 and 3 years. During follow-up, patients were asked about any urinary symptoms, and urodynamic studies were performed to look for any urodynamic SUI.

Patients were defined as subjectively cured if they did not have SUI symptoms at follow-up. Objective cure was defined as the absence of urodynamic SUI on postoperative urodynamic study.

The Statistical Package for Social Science (SPSS Inc, Chicago, IL, USA) was used for data analysis. Continuous data were tested for statistical significance using Mann-Whitney *U* test. Categorical data were analysed with Chi-square test or Fisher's exact test. A *p* value of <0.05 was considered statistically significant.

Results

Of the 132 patients, 5 patients had MUCP of <20 cm H₂O and 12 had VLPP of <60 cm H₂O. Among the 17 patients with ISD, the mean (\pm standard deviation) MUCP was 6.6 ± 5.9 cm H₂O and for VLPP it was 41.8 ± 14.5 cm H₂O. Among the 115 patients without ISD, the mean MUCP was 49.9 ± 21.8 cm H₂O and for VLPP it was 91.3 ± 24.8 cm H₂O. There were no significant differences between the groups for characteristics of age, parity, duration of SUI, and preoperative pad test results (Table 1). There was no detrusor overactivity in the preoperative urodynamic study for all patients. No patients had previous anti-incontinence surgery.

There were six cases of bladder perforation in the group of patients without ISD and none in the ISD group. This did not reach statistical significance. There were no urinary tract infections in either group. Four cases of tape erosion were identified in the group without ISD (Table 2).

All the patients in the ISD group were either satisfied or very satisfied 1 year after TVT insertion. Among the patients without ISD, 96.5% were satisfied or very satisfied with the results at the 1-year follow-up. There was no significant difference between the two groups in terms of satisfaction ($p=0.477$) [Table 3].

In the ISD group, 76.5% of patients were free of SUI symptoms at 1 year and 87.8% were free of symptoms in the group without ISD (p=0.026). Among the patients who were still symptomatic, only one patient had severe symptoms. There was no difference in objective cure rate among the two groups (p=0.148) [Table 3].

In the ISD group, 17.6% developed de-novo detrusor overactivity as shown on urodynamic study at 1 year compared with 15.7% of women in the group without

ISD. Only one patient from each group had voiding difficulty 1 year after operation. There was no statistical significance in the rate of de-novo detrusor overactivity and voiding difficulty at 1-year follow-up (p=0.734 and p=0.166, respectively) [Table 2].

Fourteen (82.4%) patients with ISD and 99 (86.1%) patients without ISD were also followed up at 3 years after TVT insertion. Patient satisfaction was maintained as high in both groups (100.0% vs. 98.0%), and 78.6% and 87.9%

Table 1. Patient characteristics

Characteristic	Median (range) or mean ± standard deviation		p Value
	With ISD (n=17)	Without ISD (n=115)	
Age (years)	57 (35-81)	54 (39-80)	0.167
Parity	3 (2-8)	3 (0-14)	0.371
SUI duration (years)	5 (1-20)	5 (1-30)	0.539
Preoperative pad test (g)	20.3 (0-57.1)	14.2 (0-275.3)	0.895
MUCP (cm H ₂ O)	6.6 ± 5.9	49.9 ± 21.8	0.001
VLPP (cm H ₂ O)	41.8 ± 14.5	91.3 ± 24.8	<0.001

Abbreviations: ISD = intrinsic sphincter deficiency; SUI = stress urinary incontinence; MUCP = maximum urethral closure pressure; VLPP = Valsalva leak point pressure

Table 2. Operative and postoperative complications in patients undergoing tension-free vaginal tape insertion

Complication	No. (%)		p Value
	With ISD	Without ISD	
Bladder perforation	0	6 (5.2)	1.0
Urinary tract infection	0	0	N/A
Tape erosion	0	4 (3.5)	1.0
De-novo detrusor overactivity*			
1 year	3 (17.6)	18 (15.7)	0.734
3 years	3 (21.4)	19 (19.2)	1.0
Voiding difficulty*			
1 year	1 (5.9)	1 (0.9)	0.166
3 years	0	1 (0.9)	0.858

Abbreviations: ISD = intrinsic sphincter deficiency; N/A = not applicable

* At 1 year, n=17 for patients with ISD and n=115 for those without ISD; at 3 years, n=14 for patients with ISD and n=99 for those without ISD

Table 3. Patient satisfaction and cure rates 1 year after tension-free vaginal tape insertion

	No. (%)		p Value
	With ISD (n=17)	Without ISD (n=115)	
Satisfied or very satisfied	17 (100)	111 (96.5)	0.477
Subjective cure rate	13 (76.5)	101 (87.8)	0.026
Objective cure rate	12 (70.6)	99 (86.1)	0.148

Abbreviation: ISD = intrinsic sphincter deficiency

Table 4. Patient satisfaction and cure rates 3 years after tension-free vaginal tape insertion

	No. (%)		p Value
	With ISD (n=14)	Without ISD (n=99)	
Satisfied or very satisfied	14 (100.0)	97 (98.0)	0.836
Subjective cure rate	11 (78.6)	87 (87.9)	0.517
Objective cure rate	11 (78.6)	86 (86.9)	0.416

Abbreviation: ISD = intrinsic sphincter deficiency

of women who had no SUI symptoms. The objective cure rates were 78.6% and 86.9% in the group with ISD and the group without ISD, respectively (Table 4). Statistical significance was not reached.

De-novo detrusor overactivity on urodynamic study was noted in three (21.4%) patients with ISD at 3 years and in 19 (19.2%) patients without ISD. Only one patient from the group without ISD had voiding difficulty after 3 years. There was no statistical significance between the two groups in terms of postoperative complications after 3 years (Table 2).

Discussion

High success rates of TVT insertion for treating SUI patients with ISD have been shown in previous studies. A study performed in South Korea found cure rates at 1 year after TVT insertion, defined as absence of urine leakage on cough stress test with a full bladder and no subjective urinary incontinence symptoms, of 74% in patients with ISD and 84% in patients without ISD¹⁷. There was no statistical significance between the two groups, and no objective cure rates were reported. Meschia et al¹⁶ reported that 1-year objective cure rates, defined as no urine leakage while coughing during postoperative cystometry with ≥ 300 ml of saline solution in the bladder, were 77% and 86% in women with MUCP of ≤ 20 cm H₂O and MUCP of >20 cm H₂O, respectively. This difference did not reach statistical significance. However, both studies only reported short-term follow-up results.

Liapis et al¹⁴ prospectively followed up 37 women with SUI and MUCP of <20 cm H₂O preoperatively for a mean of 26 months after TVT insertion. Objective cure was defined as urine loss at 1-hour pad test less than 1 g of urine, and more than 50% reduction of urine loss on 1-hour pad test when compared with the preoperative results. The objective cure rate in this study was 73%. However, there was no control group, and the cure rate by postoperative urodynamic study was not measured¹⁴.

A recently published retrospective study carried out by Choo et al¹⁸ also found a high subjective cure rate of 76.6% in women with ISD at a minimum of 3 years post-TVT insertion, with no significant differences seen when compared with the group without ISD. However, patients with previous anti-incontinence surgery and patients with concomitant cystocele repair were included in the analysis. Although the number of patients with subjective cure did not reach statistical significance between the two groups, it is possible that previous surgery may have affected the results. Similar to some of the other studies described, there was no measurement of urodynamic cure¹⁸.

All of the above-mentioned studies were performed in non-Chinese populations. Studies have shown that Caucasian women are at increased risk for SUI^{19,20}, and there are racial differences in the incidence of pelvic floor prolapse²¹. It is therefore postulated that inherent anatomical and physiological differences among racial groups may be the reason for the difference in prevalence rates²⁰.

In this study, all the patients were Chinese women. The subjective and objective cure rates at 1 and 3 years after TVT insertion were high irrespective of MUCP and VLPP levels. Both the subjective and objective cure rates at 1 and 3 years after TVT insertion were lower in patients with ISD, which is consistent with other studies¹⁵⁻¹⁷. However, the difference in objective cure rates at 1 and 3 years follow-up did not reach statistical significance between the two groups.

Although there was a significant difference in subjective cure rates between the two groups at 1 year, almost all of the patients were either satisfied or very satisfied with the treatment outcomes. This may be explained by the fact that most of the women had mild SUI symptoms only, even if they remained symptomatic after TVT insertion. Importantly, both the subjective and objective cure rates were maintained in both groups 3 years after TVT insertion.

Regarding factors influencing outcomes after TVT insertion in patients with ISD, Paick et al¹⁵ found that urge symptoms and low MUCP were independent factors for treatment failure. Liapis et al¹⁴ reported a low success rate in ISD patients with 'fixed' urethra, while Choo et al¹⁸ observed lower VLPP values among ISD patients with treatment failure.

The results of this study may be limited by the relatively small number of patients with ISD. A multicentre study is probably needed in order to include a larger number of patients with ISD. The strengths of this study were that all patients were Chinese and were undergoing primary anti-incontinence surgery. Patients

undergoing concomitant genital prolapse surgery were excluded. In addition, urodynamic studies were done for all patients 1 year after TVT insertion, and more than 80% of patients at 3 years postoperatively; therefore, reliable objective cure rates were shown, as well as the persistence of the high cure rates in both study groups.

In conclusion, TVT insertion is an effective and highly satisfactory procedure for treatment of SUI in Chinese women, whether or not they have ISD. Larger-scale multicentre studies should be performed in the future to confirm the results and to investigate the risk factors for treatment failure.

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