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The clinical and urodynamic effects of the tension free bladder neck sling procedure

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Abstract This study evaluated the clinical and urodynamic findings before and after tension-free bladder neck sling (TBS) procedure with Prolene tape. We enrolled 32 women who underwent TBS for genuine stress incontinence without intrinsic sphincter deficiency or severe uterovaginal prolapse. All subjects received 1-h pad test, Q-tip test, multichannel urodynamic testing, introital ultrasonography, and the Bristol Female Lower Urinary Tract Symptoms Questionnaires before and 1 year after surgery. Of the 32 subjects 27 were cured of stress incontinence, two improved, and three failed. The incidence of irritative symptoms and incomplete bladder emptying were significantly lower after surgery. The mean urethral straining angle showed a significant decrease from 73.8° preoperatively to 30.1° postoperatively. At rest the postsurgical position of the bladder neck (BN) was localized more cranially. During straining both ventral and caudal mobility of the BN decreased significantly following TBS, causing a more cranial and dorsal position of the BN. Urodynamic parameters including functional urethral length, maximal urethral closure pressure, and pressure transmission ratio showed significant increases after surgery. TBS could decrease the hypermobility of the BN and restore the BN support to prevent urinary leakage during straining, instead of urethral obstruction. The subjective and objective cure rate of stress incontinence is 84%, similar to those results reported after retropubic urethropexy and tension-free vaginal tape procedure. It is also worth emphasizing that no postoperative urinary retention occurred, although the limited number of cases makes it hard to confirm the significance of findings over the retention rate of tension-free vaginal tape.

Keywords Bladder neck · Sling · Ultrasound · Stress incontinence

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Introduction

Although more than 100 different surgical procedures for the treatment of female stress urinary incontinence have been described in the current literature, it was accepted that the retropubic urethropexy and pubovaginal sling are the most popular operations due to their excellent cure rates [1, 2]. Apart from sphincteric insufficiency the defects of anatomical support also play the important role in the pathophysiology of stress urinary incontinence. Therefore retropubic repairs aim to elevate and fixate the bladder neck (BN) to the intrapelvic structures. The propensity to create obstructive urodynamic changes reflects its mechanism in curing stress incontinence [3].

In 1995 Ulmsten and Petros [4] introduced a new, minimally invasive surgery for female stress incontinence, namely the tension-free vaginal tape (TVT) procedure. Based on their integral theory, continence can be achieved by placing a vaginal tape under the midurethra without tension to replace the elongated pubourethral ligaments [4, 5]. TVT seems not to be associated with a change in BN hypermobility [6, 7], implying no effect of pelvic reconstruction in this procedure. In fact, the TVT tape may slide towards the proximal urethra in patients undergoing wide dissection, but it does not compromise the efficacy of the TVT [8]. We here described a simple operation, tension-free bladder neck sling (TBS) procedure with a Prolene tape for patients with genuine stress incontinence without intrinsic sphincter deficiency. The aim of our prospective study was to investigate the clinical and urodynamic findings before and after TBS. In addition, the surgical complications were also evaluated.

Materials and methods

Between June 2001 and June 2002 a total of 51 patients underwent TBS procedure at our hospital. Nineteen patients receiving concomitant vaginal hysterectomy and/or anterior colporrhaphy ($n=13$), and laparoscopic hysterectomy ($n=6$) were excluded due to the possible effects on vesicourethral function [9, 10]. Data pertaining to 32 women therefore were assessed for this study. Their ages ranged from 36 to 54 years, with an average of 47; parity ranged from 2 to 6, with a median of 3. The previous history of pelvic surgery in these 32 patients was: three laparoscopically assisted vaginal hysterectomies, two total abdominal hysterectomies, two vaginal hysterectomy and anterior/posterior colporrhaphies, two subtotal abdominal hysterectomies, one ovarian cystectomy, and one myomectomy; none had undergone an anti-incontinence surgery before TBS. Eleven women were postmenopausal and had received hormone replacement therapy. All patients had urodynamically confirmed genuine stress incontinence without detrusor overactivity or urge incontinence. Before the operation all subjects signed an informed consent approved by the Institutional Review Board of the Kaohsiung Medical University.

Sample size calculations were based on the hypothesis that a decrease of 20% in the Q-tip straining angle one year following TBS would be statistically significant. Using a two-tailed *t* test at the 5% significance level and a standard deviation equal to twice the hypothesized difference, a sample of 25 subjects would have over 80% power to detect this 20% difference as significant.

Before and 1 year after the TBS operation, patients received urinalyses, one-h pad test, pelvic examination, Q-tip test, multichannel urodynamic testing, introital ultrasonography and a personal interview using the Bristol Female Lower Urinary Tract Symptoms Questionnaire [11]. The anatomical position and dynamic mobility of the BN were evaluated with the patients in the semisupine position by introital ultrasonography and Q-tip test. Hypermobility of the BN was defined as urethrovesical junction descent greater than 10 mm or Q-tip angle larger than 35° during straining with maximal effort [12, 13]. Before introital ultrasonography, the bladder volume was set at about 200–300 ml, and the voiding volume was checked after the procedure was completed. A 3.5-MHz curved linear-array transducer (Toshiba SSA-340A; Tokyo, Japan) was placed just adjacent to the vaginal introitus, underneath the external urethral orifice between the labia major. A sagittal scan was carried out to visualize the symphysis pubis, urethrovesical junction, and urethra.

The BN position (X, Y) was measured in the rectangular coordinate system with the inferior edge of the pubic bone as the reference point [14]. In Fig. 1 the X-axis was constructed by drawing a central line through the symphysis pubis, and the cranial direction was defined as positive value. The Y-axis was the line perpendicular to the X-axis from the inferior edge of symphysis pubis, and the dorsal direction was defined as positive value. The patients were asked to perform Valsalva maneuvers so that the position of maximal BN descent could be recorded. The displacement of BN position between resting and maximal straining (δX, δY) was calculated. In this way the BN position and its mobility were compared before and after TBS.

Urodynamic studies, including uroflowmetry, filling and voiding cystometry, and urethral pressure profilometry, were performed according to the recommendations by the International Continence Society [15] using a six-channel urodynamic monitor (MMS, UD2000, Enschede, The Netherlands). Before uroflowmetry the bladder is scanned in two perpendicular planes (sagittal and transverse) and three diameters [height (H), width (W), and depth (D)] are measured by abdominal ultrasound. The bladder volume was set at approximately 200–300 ml using the formula H×W×D×0.7, proposed by Poston et al. [16]. Catheterization was performed to check residual urine amount after voiding completed. Genuine stress incontinence was defined as involuntary urine leakage with stress in the absence of detrusor contraction during cystometry. The diagnosis of detrusor overactivity was made by the presence of detrusor contractions on filling cystometry. Intrinsic sphincter deficiency was diagnosed by a maximum urethral closure pressure of less than 20 cmH_2O at maximum cystometric capacity.

All patients were given antibiotics prophylaxis (intravenous cefazolin 1 g; Cefamezin, Fujisawa, Tokyo, Japan) administered preoperatively. The TBS operations were performed under epidural anesthesia due to the deeper vaginal wound. A Foley catheter was introduced

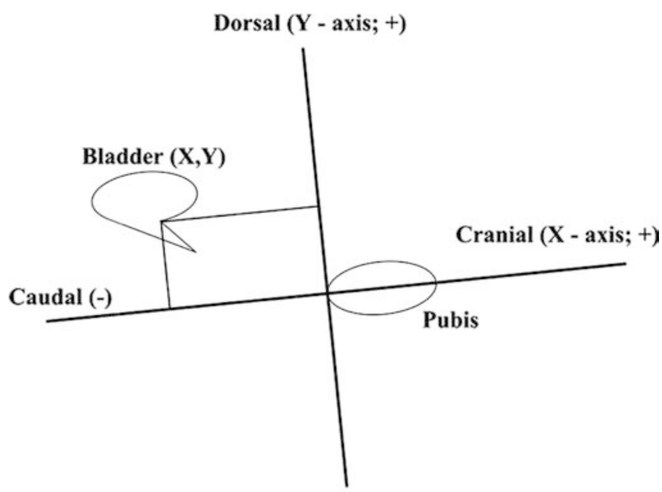

Fig. 1 Evaluation of bladder neck location on introital ultrasonography relative to reference coordinate system. *X-axis* The central line of the symphysis (craniocaudal direction); *Y-axis* the axis perpendicular to the X-axis (ventrodorsal direction); *(X,Y)* the corresponding value of X-Y axis; cranial +, caudal −, dorsal +, ventral −

into the urethra and the balloon was inflated with 20 ml saline for easy identification of the BN. Two minimal abdominal incisions (1 cm) 4–5 cm apart were made over the upper border of the pubic bone. A semicircular vaginal incision was made at the level of the BN (Fig. 2). A special Prolene tape covered by a plastic sheath, with a two-component needle instrument (TVT, Ethicon, Somerville, N.J., USA), was introduced via the vaginal incision and brought up to the abdominal wound bilaterally. After cystoscopy to ensure the bladder was intact, suprapubic pressure tests were performed repeatedly at a bladder volume of 300 ml. The tape was adjusted to allow a few drops of saline to escape from the urethral orifice to avoid postoperative voiding dysfunction. Thereafter the plastic sheath was removed and no fixation was carried out. Finally, the abdominal and vaginal wounds were closed after the abdominal ends of the Prolene tape had been cut subcutaneously. Briefly, the TBS procedure was similar to the TVT previously described by Ulmsten et al. [4] except for the location of the tape.

Patients were encouraged to micturate at the first desire to void, and they received intermittent catheterization every 4 h. They were discharged from the hospital once the postvoid residual urine was less than 20% of that from self-voiding twice consecutively. The result of surgery was assessed objectively. Objective cure was defined as the weight of pad less than 2 g/h without urinary leakage on the stress urethral pressure profilometry. Improvement was defined as urine loss of 2–5 g/h on pad test and/or the presence of urinary leakage during the stress urethral pressure profilometry. Leakage of more than 5 g/h was defined as failure [8].

A statistical analysis of the data was performed using Student's *t* test or Wilcoxon signed rank test for parametric or nonparametric continuous variables, and McNemar's test for categorical variables. Differences at the level of $P < 0.05$ were considered statistically significant.

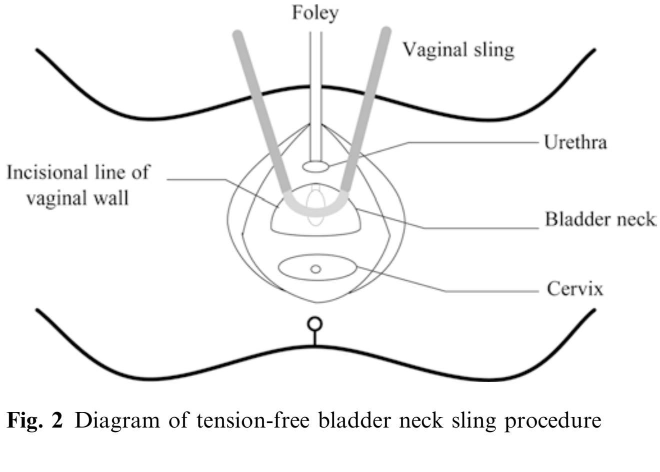

Fig. 2 Diagram of tension-free bladder neck sling procedure

Results

The mean operative time, postoperative stay, and blood loss were 27 min (range15–42), 1.4 days (range 0.8–5), and 65 ml (range 20–150), respectively. Postoperative pad test and urinary questionnaires showed 27 (84.4%) patients were cured of stress incontinence, two improved, and three failed. Urine loss on pad test significantly decreased from a mean of 15 g (range 5–80) preoperatively to a mean of 1 g (range 0–15) postoperatively (Wilcoxon signed rank test, $P < 0.001$). A routine ultrasonography within 12 h following TBS showed small hematoma (5–8 cm) in 5 (15.6%) patients. No surgical intervention was needed and the hematomas were absorbed spontaneously within 2 weeks. There was no bladder perforation but one sling erosion occurred postoperatively, necessitating débridement and closure of vaginal wound.

The incidence of urinary symptoms, including stress incontinence, frequency, nocturia, and incomplete bladder emptying, were significantly lower following surgery ($P < 0.05$). Postoperative change in voiding hesitancy was not statistically significant ($P > 0.05$; Table 1). No case of urinary retention was found after TBS. The mean straining urethral angle showed a significant decrease from $73.8 \pm 19.4°$ preoperatively to $30.1 \pm 16.4°$ postoperatively ($P < 0.001$; Table 2). A total of 11 patients continued to demonstrate urethral hypermobility (>35°) following TBS; 7 were continent, 2 improved, and 2 failed.

The topography of the BN at rest and during straining, and its mobility assessed by introital ultrasonography pre- and postoperatively are shown in Table 2 and Fig. 3. At rest the postoperative position of the BN was localized more cranially ($P < 0.01$), and no significant difference was noted in the ventrodorsal direction ($P > 0.05$). During straining both ventral and caudal mobility of the BN (δX, δY) decreased significantly following TBS ($P < 0.001$), causing a more cranial and dorsal position of the BN postoperatively ($P < 0.001$). A total of five patients showed BN mobility greater than 10 mm during straining after surgery; one was cured of stress incontinence, one improved and three failed.

The urodynamic parameters obtained before and after TBS, including functional urethral length, maximum urethral closure pressure, and pressure transmission ratio in midurethra revealed significantly greater values following surgery. The relevant values were 3.2 cm (range 2.1–3.9) vs. 2.7 cm (range 1.5–3.2; $P < 0.01$), 94 cmH_2O (range 50–144) vs. 68 cmH_2O (range 36–125; $P < 0.01$), and 78% (range 57–104) vs. 63% (range 42–85; $P < 0.01$), respectively (Table 3). None of the other variables showed significant change from the pre- to the postoperative values ($P > 0.05$). No de novo detrusor overactivity occurred postoperatively.

Table 1 Urinary symptoms ($n=32$)

Symptoms	Preoperation		Postoperation		P^*
	n	%	n	%	
Stress incontinence	32	100.0	5	15.6	< 0.001
Frequency and urgency	18	56.3	2	6.3	< 0.001
Nocturia	16	50.0	5	15.6	< 0.01
Incomplete bladder emptying	13	40.6	5	15.6	0.039
Hesitancy	5	15.6	3	9.4	NS

*McNemar's test

Table 2 Q-tip straining angle, topography of the bladder neck ($n=32$) at rest and during straining, and its mobility assessed by introital ultrasonography before and after surgery. X and Y are the coordinate values of bladder neck (*X-axis* central line of the symphysis, craniocaudal direction, *Y-axis* axis perpendicular to the X axis, ventrodorsal direction, cranial +, caudal −, dorsal +, ventral −, δX bladder neck displacement on craniocaudal direction, δY bladder neck displacement on ventrodorsal direction)

	Preoperation	Postoperation	P^*
Q-tip straining angle (°)	73.8 ± 19.4	30.1 ± 16.4	< 0.001
Rest (mm)			
X	−8.1 ± 11.5	−0.3 ± 6.0	< 0.01
Y	19.5 ± 5.6	20.3 ± 5.2	NS
Straining (mm)			
X	−23.0 ± 10.2	−7.7 ± 6.8	< 0.001
Y	−2.6 ± 10.6	11.6 ± 7.1	< 0.001
Mobility (mm)			
δX	19.8 ± 9.6	8.6 ± 4.2	< 0.001
δY	22.2 ± 9.6	7.3 ± 4.3	< 0.001

*Student's t test

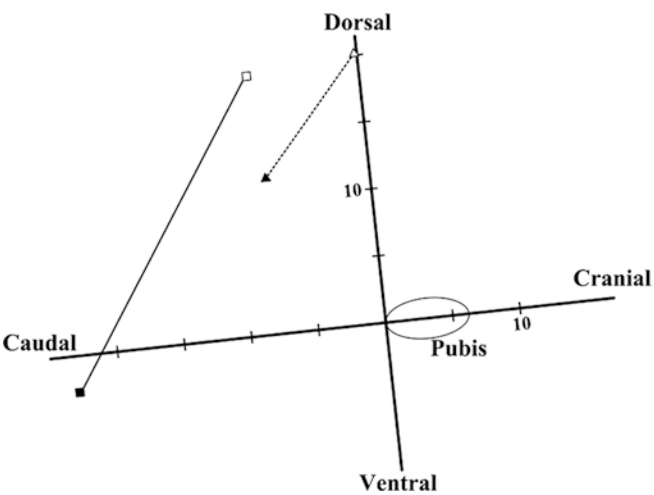

Fig. 3 Bladder neck location of the patients before and after TBS

Table 3 Urodynamic study variables. (*Qmax* maximum flow rate, *RU* residual urine, *Curg* bladder compliance at urgency, *Pdap* detrusor pressure at peak flow, *Vfst* bladder volume at first desire to void, *MCC* maximum cystometric capacity, *FUL* functional urethral length, *MUCP* maximum urethral closure pressure, *PTR* pressure transmission ratio in midurethra) ($n=32$)

Variables	Preoperation		Postoperation		P^*
	Median	Range	Median	Range	
Qmax (ml/s)	18	10–29	23	13–30	NS
RU (ml)	12	0–55	17	0–48	NS
Curg (ml/cmH_2O)	33	5–125	42	6–135	NS
Pdap (cmH_2O)	32	20–56	34	23–61	NS
Vfst (ml)	116	52–161	139	97–268	NS
MCC (ml)	385	278–550	450	302–579	NS
FUL (cm)	2.7	1.5–3.2	3.2	2.1–3.9	< 0.01
MUCP (cmH_2O)	68	36–125	94	50–144	< 0.01
PTR (%)	63	42–85	78	57–104	< 0.01

*Wilcoxon signed rank test

Discussion

Recent surgery for the treatment of genuine stress incontinence has fallen mainly into one of two groups: retropubic urethropexy and pubovaginal sling [1, 2]. The former can correct pelvic anatomy but the reported rate of postoperative voiding dysfunction was up to 16–25% [3]. The TVT may act by mimicking or reinforcing the pubourethral ligament in a tension-free manner, and therefore the incidence of postoperative urinary retention is only about 2–3% [17].

Some studies have proposed that a successful anti-incontinence operation is characterized by the ultrasonographic finding of postoperative elimination of BN hypermobility [18]. By the same token, we found the ventral and caudal mobility of the BN decreased significantly during straining following TBS (Table 2; Fig. 3), accounting for the lower postoperative incidence of stress incontinence and irritative symptoms. No de novo detrusor overactivity was observed after the TBS, less than the 1–2% reported by TVT [19]. This might be explained by the limited cases in our series, which did not have the power needed to compare the rate of de novo detrusor overactivity between the two procedures. In addition, the postoperative position of BN was localized more cranially (Fig. 3) at rest despite the intraoperative tension free manner. This result suggested a difference in sling location between the supine and standing positions and sling migration might occur afterwards.

Considering the Q-tip angle larger than 35° or BN mobility greater than 10 mm during straining as a cutoff value with respect to the postoperative incontinence, the sensitivity and specificity of the former were 80% vs. 74%, and the corresponding figures of the latter were

80% vs. 96%, respectively. Therefore introital ultrasonography appears to be more reliable in predicting stress incontinence than does Q-tip test. In this study the sensitivity and specificity of ultrasonography were slightly higher than that reported in other studies [18]. This may be due to the fact that we observed no case of intrinsic sphincter deficiency (maximal urethral closure pressure $<20\ cmH_2O$), simplifying the pathophysiological events of stress urinary incontinence in our series.

The median values of maximum flow rate increased from 18 ml/s preoperatively to 23 ml/s postoperatively; this insignificant difference revealed no obstructive effect of TBS. Moreover, TBS decreased the movement of BN beyond the intra-abdominal cavity by stabilizing the BN during stress in its suspended resting position. The sling provides a stable support of urethrovesical junction at rest and dynamic compression of the urethra during straining. As expected, we found significant increases in functional urethral length, maximum urethral closure pressure, and pressure transmission ratio (around midurethra) after TBS. Karram et al. [20] evaluated ten stress-incontinent women receiving transvaginal fascia lata sling to support the urethrovesical junction and obtained similar results. Most studies, however, have shown the enhancement of urethral pressure transmission but not static urethral pressure profilometry after TVT or Burch operations [7, 21, 22]. Therefore the curative mechanism of TBS appears to differ from that of other surgeries.

Bump et al. [23] ever proposed that optimal correction after BN surgery was defined as a pressure transmission ratio of 90–110% and a Q-tip test 5–20°. The corresponding figures of our study were 78% and 30°, belonging to the inadequate correction of their criteria. However, TBS reached the subjective and objective cure rate of 84.4% and no women with urinary retention necessitating catheterization following TBS. Of course, the limited number of cases makes it hard to confirm the significance of these findings over the retention rate of 2.8% reported for TVT [17]. In the report of Hilton et al. [21] maximum flow rate decreased from 29 to 17 ml/s after the sling procedure, indicating too much tension on the sling instead of a tension-free nature. The higher the tension, of course, the more likely the continence is achieved, but an untoward effect of voiding dysfunction may occur postoperatively. By the same token, we believe BN should be stabilized rather than elevated as much as possible during retropubic urethropexies.

As with TVT procedure, TBS was proposed for the correction of genuine stress incontinence. In our study, however, 13 of the 51 women (25.5%) with stress urinary incontinence had coexisting genital prolapse. Therefore all patients were operated on under epidural anesthesia, allowing them with minimal discomfort, especially during the repairs of pelvic floor defects. Previous studies have also shown that the efficacy and safety of the TVT procedure do not depend on the method of anesthesia [24]. TBS has the advantage that concomitant prolapse surgery can be performed easily using the same vaginal incision, whereas TVT needs two separate wounds. Fortunately, no bladder perforation was noted in our series, possibly related to no patients having an anti-incontinence procedure before TBS. One patient (3.1%) experienced sling erosion into the vagina, similar to the erosion rate of other studies [25].

In our series, TBS restored sufficient outlet resistance to prevent urinary leakage during straining, instead of urethral obstruction, as evidenced by increased values in urethral pressure profilometry but no change in maximum flow rate postoperatively. It is unclear whether those women with intrinsic sphincter deficiency could benefit from this procedure. More categorical studies may characterize the patients with various types of urinary incontinence more thoroughly.

Despite the short-term follow-up and limited cases, the results of our study suggest that TBS can be recommended for the treatment of genuine stress incontinence without intrinsic sphincter deficiency. Whether the placement of TVT tape on BN or midurethra is more physiological remains controversial. More prospective randomized trials and long-term follow-up will be helpful to understand how a procedure creates compensatory changes to achieve continence.

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Editorial comment

The paper challenges the concept that to be successful a TVT must be placed at the midurethra. Recent reports tell us that even when thought to be placed at the midurethra, often a TVT is closer to the bladder neck, yet it remains successful. This contribution reports on a select group of patients who had the tension-free tape placed knowingly at the UVJ rather than the traditional midurethra location. Unfortunately, this case series provides the weakest type of medical evidence, and no serious conclusions can be drawn from it. It should lead to a prospective, randomized study of the two techniques with objective outcome reporting. Only then can a truly scientific conclusion be made.