Tension-Free Vaginal Tape versus Laparoscopic Bladder Neck Suspension for Stress Urinary Incontinence

Ching-Chung Liang, MD; Yung-Kuei Soong, MD

Background: Owing to their various advantages, including shortened hospital stays, faster recoveries, and satisfactory outcomes, laparoscopic bladder neck suspension (LBNS) and tension-free vaginal tape (TVT) have become 2 well-known minimally-invasive anti-incontinent procedures. The aim of this study was to demonstrate the outcomes of LBNS and TVT procedures for treatment of stress urinary incontinence.

Methods: From October 1997 to February 2000, 22 women with genuine stress incontinence underwent LBNS, and another 23 women underwent TVT. Estimates of operative time, blood loss, and time to resumption of spontaneous urination were recorded for each group. Surgical results were assessed by urodynamic studies, 1-h pad tests, and voiding diaries.

Results: There were no statistically significant differences between these 2 groups in terms of demographics and blood loss during the operation. When comparing operative time and time to resumption of spontaneous urination, the TVT group had significantly lower values than did the LBNS group for both parameters, at 31.9 ¡ 6.0 vs. 111.7 ¡ 15.6 min and 2.1 ¡ 1.5 vs. 4.0 ¡ 0.9 days, respectively. The cure rate was 86.9% in the TVT group and 86.4% in the LBNS group.

Conclusion: Both TVT and LBNS have been proven effective in treating women with stress urinary incontinence. The TVT procedure, owing to its shorter learning curve, less intraoperative blood loss, and quicker resumption of spontaneous urination, is recommended to treat women suffering from pure stress urinary incontinence. Whereas, in cases that are complicated with concomitant adnexal disease or uterine pathology, LBNS is considered an alternative procedure.

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Key words: laparoscopic suspension, tension-free vaginal tape, urinary incontinence.

Clinically, two common anti-incontinent procedures, retropubic urethropexy and transvaginal needle suspension, have often been used for the treatment of stress urinary incontinence in the absence of a low-pressure urethra.[1,2] Burch colposuspension has gained wide acceptance because of its good long-term outcome as reported by several investigators.[3] However, traditional access to the

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retropubic space requires a large abdominal incision that may be associated with significant postoperative morbidity and prolonged hospitalization.[3,4] In contrast, needle suspension procedures which are usually performed through the vagina have the advantages of lower morbidity, shorter hospitalization, and a good initial rate of success with 1/3 of patients reporting no urine leakage at all during a 10-year follow-up period.[5]

In the past decade, various new techniques and modifications of well-established surgical procedures for treatment of stress urinary incontinence have become available, making surgery less invasive and less complicated. Among them, laparoscopic Burch colposuspension and tension-free vaginal tape are 2 well-known minimally-invasive procedures that claim to have the advantages of shortened hospital stays, fast recoveries, and satisfactory outcomes.[6,7] The aims of this study were to investigate their surgical effects and to draw comparisons between these 2 treatment modalities in terms of success rates, complications, and hospital stay.

METHODS

Between October 1997 and February 2000, 45 patients with a diagnosis of type II stress urinary incontinence undergoing minimally-invasive anti-incontinent surgery were included in this prospective study.[8] They were patients with a clinical incontinence score of moderate or severe.[9] None had intrinsic sphincter deficiency or more than a grade I cystocele according to Baden's grading system, and none had undergone any prior surgical treatment for urinary incontinence.[8,10] Twenty-two patients underwent laparoscopic bladder neck suspension (LBNS), and the other 23 patients underwent a procedure which used tension-free vaginal tape (TVT). Both anti-incontinent procedures were performed by the same well-experienced urogynecologist, who is familiar with these 2 different procedures. The patients were not assigned in a completely randomized fashion because the laparoscopic approach was chosen for patients with associated adnexal disease, uterine pathology, or other indications for abdominal exploration starting from October 1997. The TVT procedure was used in this study for the treatment of urinary incontinence after March 1998. In the LBNS group, 12 patients received adjunctive surgical procedures including lysis of a pelvic adhesion (N=3), ovarian resection (N=3), salpingectomy (N=2), hysterectomy (N=1), myomectomy (N=1), suspension of the uterus (N=1), and bladder repair (N=1). Before we performed the LBNS, all adjunctive operations were completed intraperitoneally. When the blood loss and operative time of the LBNS were determined, those of any adjunctive procedures were not included.

Before surgery, all patients underwent a thorough urogynecological evaluation including a detailed history, physical examination, urine culture, 1-h pad test, voiding diary, introital ultrasound, water cystometry at a filling rate of 60 ml/min, urine flow measurement, and static and dynamic urethral pressure profiling. The Dantec Monuet Compact six-channel clinical urodynamic investigation system (Dantec Electronics, Skovlunde, Denmark) was used for urodynamic evaluation. All procedures for the preoperative evaluation followed those described in previous literature.[11,12] We objectively assessed surgical outcomes using the same urodynamic investigations, as well as 1-h pad test and voiding diary 6 months postoperatively. A cure was objectively considered to have been achieved if the patient was found to have no leakage of urine at maximum cystometric capacity while the patient performed a Valsalva maneuver or coughed in the sitting position during urodynamic studies, had less than 2 ml on the 1-h pad test, and recorded no urine leakage in their voiding diary. A patient was subjectively considered to have been cured if she reported no loss of urine during any activity with increased intra-abdominal pressure. Each patient was asked to answer a questionnaire regarding urinary problems and life quality via a telephone interview every 6 months after surgery. The duration of the telephone follow-up ranged from 11 to 26 (median, 17.5) months in the TVT group and 14 to 34 (median, 22.8) months in the LBNS group. All terminology conforms to standards proposed by the International Continence Society.[13]

The statistical methods used were the Mann-Whitney test for independent groups and Fisher's exact test for proportional comparisons, with a p value of less than 0.05 regarded as statistically significant.

The LBNS, a modified Burch procedure described by Liu,[14] was performed as follows. The

anterior peritoneum was dissected away from the anterior abdominal wall and the Retzius space was entered. On each side, 1 double-bite with no.1 Prolene suture (Ethicon, Somerville, NJ, USA) was used to raise and pull the anterior vaginal wall forward to Cooper's ligament. The suture was inserted at the level of the proximal urethral and urethrovesical junction and at least 2 cm from the urethra, and was tied using the extracorporeal knot tying technique. Urine in the bladder was continuously drained postoperatively via a Foley catheter for 48 hours. Patients were asked to void spontaneously on the third postoperative day, and the residual volume was assessed with intermittent catheterization every 4 hours. For TVT, the instruments used and surgical procedure applied did not differ than those described by Ulmsten et al.[15] Sterile intermittent catheterization was performed every 4 hours for patients to avoid using an indwelling catheter after surgery. If the post-voiding residual urine amount exceeded 150 ml on postoperative day 2, an indwelling catheter was inserted for 24 hours. The patient then underwent intermittent bladder catheterization again on postoperative day 3. Patients of both groups were discharged from the hospital once the post-voiding residual urine was less than 50 ml or 1/4 of the voided volume. If the patient was unable to void spontaneously on the seventh postoperative day, she was discharged from the hospital and instructed to perform intermittent self-catheterization at home.

RESULTS

In preoperative evaluations, there were no statistical differences between the 2 groups with respect to age, parity, body weight, preoperative 1-h pad tests, frequency of urine leakage, or the interval between the onset and diagnosis of incontinence (Table 1). Clinical evaluation of urinary incontinence showed that 19 (86.4%) patients in the LBNS group and 20 (86.9%) patients in the TVT group demonstrated no perceptible urine leakage. The objective cure rate was 77.3% (17/22) in the LBNS group, 80% (8/10) in the LBNS only group, and 82.6% (19/23) in the TVT group. The objective and subjective cure rates did not significantly differ among them. As shown in Table 2, statistical significance was found for greater blood loss ($p=0.005$), longer operative time ($p<0.001$), and longer time to resume spontaneous urination ($p<0.001$) in the LBNS group than in the TVT group. Two cases in the LBNS with concomitant surgery group were reported to have blood loss exceeding 150 ml. When comparative analyses of the TVT group and the LBNS (LBNS only, N=10) was made, estimated blood loss did not differ significantly between the two ($p=0.19$). In the mean 1-h pad test evaluation, patients in both groups showed satisfactory improvement after the operation, with preoperative 38.5 ml to postoperative 2 ml for the LBNS group and corresponding 34.6 to 0.9 ml for the TVT group.

In the laparoscopic group, the most frequent

Table 1. Preoperative Characteristics of Study Patients

	LBNS (N=22)	TVT (N=23)	$p^{\dagger}$
Age (yr)	46.5 ¡ 9.6	45.8 ¡ 9.1	0.65
Parity	3.0 ¡ 1.6	2.7 ¡ 1.0	0.37
Body weight (kg)	60.4 ¡ 11.8	64.2 ¡ 9.8	0.43
Pad test (ml/h)	38.5 ¡ 38.7	34.6 ¡ 30.7	0.68
Frequency of leakage (no. of times/day)	2.7 ¡ 1.0	2.7 ¡ 1.6	0.85
Duration of incontinence (months)	51.9 ¡ 41.2	47.1 ¡ 34.1	0.57

Abbreviations: LBNS: laparoscopic bladder neck suspension. TVT: tension-free vaginal tape.
†: Statistical analysis was performed using the Mann-Whitney test.

Table 2. Operative and Postoperative Data

	LBNS (N=22)	LBNS only (N=10)	TVT (N=23)	$p^{\dagger}$
Blood loss (ml)	150.2 ¡ 126.2	83.9 ¡ 55.0	59.5 ¡ 48.3	p1<0.001 p2=0.19
Operative time (min)	144.3 ¡ 33.1	111.7 ¡ 15.6	31.9 ¡ 6.0	p1<0.001 p2<0.001
Time+ (day)	4.9 ¡ 1.5	4.0 ¡ 0.9	2.1 ¡ 1.5	p1<0.001 P2=0.002
Pad test (ml/hr)	2.0 ¡ 2.4	1.7 ¡ 1.6	0.9 ¡ 1.4	p1=0.76 p2=0.48

Abbreviations: LBNS: laparoscopic bladder neck suspension; TVT: Tension-free vaginal tape; LBNS only: LBNS without concomitant operation
†: Time to resume spontaneous urination
p1: comparative analysis of TVT and LBNS was done with Mann-Whitney test.
p2: Comparative analysis of TVT and LBN only was done with Mann-Whitney test

complications were urgency (N = 2) and incomplete bladder emptying (N = 2). De novo detrusor instability was evident in 1 patient, while 2 other patients complained of urgency after surgery, but without apparent detrusor instability according to urodynamic studies. Urinary tract infection was found in 1 patient. In the TVT group, 2 patients with preoperative detrusor instability had persistent urgency at 6 months, but none of them demonstrated de novo detrusor instability after surgery. No major intraoperative complications occurred in either group except for 1 bladder injury inflicted during the laparoscopic procedure, which was repaired immediately by laparoscopy.

DISCUSSION

Our study demonstrates favorable clinical outcomes using 2 different minimally invasive approaches for treatment of stress urinary incontinence. Vancaillie and Schuessler first reported the use of LBNS in 1991.[16] Since that time, this procedure has gained popularity because of its several advantages, including reduced hospital stay, shorter catheterization time, and faster recovery. Theoretically, the colposuspension techniques used in both the open and the laparoscopic groups approached the same anatomical space and applied the same principle, therefore the continence rates should be similar. However, most urologists or urogynecologists do not perform enough laparoscopic procedures to allow them to achieve the level of proficiency of experienced laparoscopists. Given that laparoscopic suturing and knot tying are some of the most challenging skills for the surgeon to master, the operative time for LBNS is longer than that for open procedures.[6,17] Additional shortcomings of LBNS are possible injury to visceral and vascular structures such as the bladder. In previous reports, there were 1% to 10% injury rates of ureters or bladder during LBNS, which are higher than for traditional Burch procedures.[1,4] Fortunately, those bladder injuries can usually be recognized intraoperatively and successfully repaired by laparoscopy or open exploration. To minimize the risk of bladder injury, the authors suggest filling the bladder with 100 to 200 ml of normal saline to delineate its boundaries during dissection.

The reported effectiveness of LBNS ranged from 58% to 97% in short-term assessments of continence rates.[14,18-22] Studies reporting a high success rate might have applied looser criteria, for example, patients who showed improvement after the operation, but did not quite meet the strict criteria of dry or social continence being deemed as having successful treatment. In our study, we used the more-stringent criteria to define the objective cure in incontinent patients. Nineteen of 22 (86.4%) patients were clinically normal, and 77.3% were objectively cured; these rates are comparable to those found in other open and laparoscopic series.[2,6,18, 23,24] However, early resolution of stress urinary incontinence following surgical procedures does not guarantee long-term cure. At present, most data are inconclusive and are sometimes discouraging. Lobel and Davis found that 86% of patients were dry at 1 year, but only 69% of patients reported clinically normal continence when followed up for an average of 34 months.[25] Das reported data indicating that only 40% of patients were continent 3 years after LBNS.[26] Conversely, McDougall and Portis reported that the continence rate for LBNS stabilized at 75% at 4-year follow-up.[27] Two single-bite sutures resulted in a significantly higher objective short-term cure rate than did a single double-bite suture on each side of the urethra, as indicated in a recent report.[22] Nevertheless, whether their ultimate results significantly differ remains to be seen during long-term follow-up since the laparoscopic paired single-bite suturing is technically more difficult to master. Although reduced catheterization time is one of the advantages of LBNS in comparison to other open procedures, patients undergoing the Burch procedure in our hospital had longer hospital stays than that described in previous reports because our protocol requires continuous bladder drainage via an intraurethral catheter for 48 hours after the operation.[18,23,24] On top of that, increased operative and anesthesia times further contributed to their extended stay. Nowadays, authors are revising the protocol to remove the intraurethral catheters on the second postoperative day and discharge patients as early as possible.

In 1995, Ulmsten et al. devised a TVT procedure to treat female stress urinary incontinence that simply entailed loose positioning of a piece of Prolene tape in the area of the mid-urethra.[15] Subsequent changes in paraurethral connective tissue induced by the tape can improve paraurethral colla-

gen properties, which may reconstruct or reinforce the pubourethral ligament and the suburethral vaginal hammock. Unlike various bladder neck suspension procedures, TVT has not been found to suffer a reduction in continence rates over time.[28,29] Because the implanted Prolene tape is not absorbed over time, it may be justifiable to assume that the results are permanent.[30] Recently, Ulmsten reported encouraging results of a 3-year follow-up study of TVT for the correction of female stress urinary incontinence, showing a cure rate of 86%.[29]

Our results agree with reports of other workers using the same TVT technique. In all those studies, cure rates of TVT were reported to be around 85%, and other advantages of the procedure were minimal blood loss, shorter operative times, the option of local anesthesia, shorter hospital stays, and faster recoveries.[15,28,31-33] A prospective multicenter study of TVT showed that the cure rate was 91%, operative times were short, and complications were few. In the majority of centers, surgeons without specific training in urogynecologic surgery were involved, and their results were as good as those of the more experienced.[31] Although operative time and blood loss may be reduced after practicing enough laparoscopic procedures, and hospital stay may be shortened after optimizing postoperative care, the shorter learning curve and lower incidence of complications remain the two main advantages of TVT which laparoscopic techniques lack.

In conclusion, both LBNS and TVT were effective in treating women with stress urinary incontinence according to short-term follow-up results. The fact that all the anti-incontinent procedures were performed by a single senior urogynecologist obviated the need for technical bias adjustment. As for the durability of both procedures, more long-term studies need to be conducted. The authors recommend performing TVT for treatment of pure stress urinary incontinence and LBNS as an alternative when there are other indications for abdominal exploration, such as concomitant adnexal disease or uterine pathology.

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腹腔鏡膀胱頸懸吊術與無張力性陰道懸帶術使用在婦女應力性尿失禁病患之比較

梁景忠　宋永魁

背 景： 由於住院天數短、恢復快、治癒效果佳，腹腔鏡膀胱頸懸吊術與無張力性陰道懸帶術是目前被很多醫師採用的尿失禁手術。本研究的目的在比較此兩種微侵襲性尿失禁手術的效果。

方 法： 自1997年10月到2000年2月，由同一名婦女泌尿科醫師針對應力性尿失禁（膀胱頸過度下降）進行手術，其中22名採用腹腔鏡膀胱頸懸吊術，另外23名採用無張力性陰道懸帶術，並且分析病患的手術時間、失血量、回復自己解尿的時間，術後以尿動力學檢查，一小時棉墊測試與解尿日誌爲評估。

結 果： 手術時間與回復自己解尿的時間，在無張力性陰道懸帶術群 (31.9±6分鐘，2.1±1.5天) 統計學上有意義較短於在腹腔鏡膀胱頸懸吊術群 (111.7±15.6分鐘，4±0.9天)。治癒率在無張力性陰道懸帶術群是86.9%，在腹腔鏡膀胱頸懸吊術群是86.4%，兩者並沒有統計學上的意義。

結 論： 腹腔鏡膀胱頸懸吊術與無張力性陰道懸帶術應用在婦女尿失禁的治療，追蹤都有不錯的治癒率。因爲學習時間、手術時間，以及回復自己解尿的時間都比腹腔鏡膀胱頸懸吊術短，無張力性陰道懸帶術被建議用在單純尿失禁的手術上；至於合併有婦科病灶需要探腹時，可以考慮採用腹腔鏡手術。

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關鍵字：腹腔鏡懸吊術，無張力性陰道懸帶術，尿失禁。

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