Combination of a Tension-Free Vaginal Tape Procedure and Laparoscopic-Assisted Vaginal Hysterectomy for the Treatment of Benign Uterine Disease Associated with Stress Urinary Incontinence

Hsi-Mi Liang, MD; Kuan-Hui Huang, MD; Fu-Tsai Kung, MD;
Chih-Wei Chen, MD; Shiuh-Young Chang, MD

Background: Women undergoing hysterectomy for benign uterine disease (BUD) may experience stress urinary incontinence (SUI). We performed tension-free vaginal tape (TVT) procedure and laparoscopic-assisted vaginal hysterectomy (LAVH) simultaneously and assessed the feasibility and efficacy of TVT performed under general anesthesia and the resultant anti-incontinence effects following the combined procedures.

Methods: Between March, 2000 and March, 2002 inclusively, 63 patients, who suffered from both BUD and SUI, underwent LAVH and TVT. Preoperative evaluation included history-taking, physical examination and ultrasonography. One-hour pad test, multichannel urodynamics and urinary questionnaire were conducted preoperatively and postoperatively. Details about surgical procedures undertaken, hospitalization and urinary problems in the follow-up period were recorded.

Results: 50 patients completed the study with a mean follow-up period of 34 (25-48) months. The mean age was 49 (39-67) years and mean parity 3 (2-6). The mean surgical duration was 163 (95-240) minutes and blood loss 284 (100-1,500) milliliters. Mean duration of hospital stay was 5.5 days and bladder drainage 1.9 days. Three patients suffered bladder perforation and one patient was complicated with excess blood loss. Postoperative urinary problems included transient urine retention, de novo frequency/urgency symptoms and voiding difficultly.

Conclusions: The efficacy of concomitant TVT in LAVH procedure remained satisfactory in treatment of SUI associated with BUD. Both procedures reflect the benefits of less-invasive surgery. So the combination of LAVH and TVT is probably a good alternative for the patient who needs to undergo hysterectomy and anti-incontinence surgery simultaneously.

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Key words: stress urinary incontinence, laparoscopic-assisted vaginal hysterectomy (LAVH), tension-free vaginal tape (TVT).

From the Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Kaohsiung.
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Address for reprints: Dr. Fu-Tsai Kung, Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital. No. 123, Dabi Rd., Niausung Shiang, Kaohsiung, Taiwan, 833, R.O.C. Tel.: (866)7-7317123; Fax: 886-7-7622915; E-mail: ftkung@ksts.seed.net.tw

The genital organs are closely adjacent to the lower urinary tract, embryologically and anatomatically. In clinical practice, benign uterine diseases (BUD) may be associated with lower urinary tract symptoms, including frequency, urgency and stress urinary incontinence.[1-4] According to the study of Parys in 1989, stress incontinence was found in 25% of women who were planning to undergo simple hysterectomy.[1] The combination of simple hysterectomy and anti-incontinence surgery as a single step is probably indicated for women who feature both benign uterine tumors and incontinence problems. A tension-free vaginal tape (TVT) procedure has become a popular technique to use to treat stress urinary incontinence, and appears to have been first described by Ulmsten in 1995.[5] Various groups have claimed the procedure to be minimally invasive, associated with fewer complications than more-conventional techniques, and to reflect an excellent short-term and long-term rate of successful treatment, namely, 84-95% and 84.7% respectively.[6-12]

Toward a goal of minimally invasive surgery, we attempted to perform a combination of TVT and laparoscopic-assisted vaginal hysterectomy (LAVH) for patients who needed to undergo anti-incontinence surgery and hysterectomy simultaneously. Notably, most TVT procedures tend to be carried out under local or regional anesthesia,[5-12] whereas the LAVH procedure should, ideally, be performed under general anesthesia. Therefore, our study aimed to investigate the feasibility of performing TVT concomitantly with LAVH, the feasibility and efficacy of TVT carried out under general anesthesia, and the anti-incontinence effects of such surgical activity, as assessed by application of the one-hour pad test and urodynamic study subsequent to the combination procedures of TVT and LAVH.

METHODS

From March 2000 to March 2002 inclusively, a total of 63 patients featuring urodynamically proven genuine stress incontinence (GSI) underwent TVT in conjunction with LAVH under the indication of BUD. All patients underwent a detailed medical history enquiry, physical examination, urinalysis and sonography prior to surgery. The assessment of pre- and post-operative urinary symptoms included urinary-symptoms questionnaire, a one-hour pad test and multichannel urodynamic studies consisting of free uroflowmetry, filling and voiding cystometry, urethral-pressure profilometry with electromyography. Patient follow-up included completion of a detailed urinary symptoms questionnaire, pelvic examination to evaluate any wound infection or tape rejection, a cough stress test with a comfortably full bladder and the checking of bladder residual urine volume. Repeat one-hour pad test and urodynamic evaluation were performed in the period 6 to 12 months postoperatively. Patients were followed up one week following discharge and then 1, 3, 6 and 12 months postoperatively and again, yearly thereafter. The indications for hysterectomy were fibroids with or without adenomyosis, endometrial simple hyperplasia and carcinoma in situ of the uterine cervix. Those patients who revealed any previous anti-incontinence surgery were excluded from this study.

All patients were admitted to the ward the day prior to surgery. Pre-operative preparation included tape water enema, vaginal douche with povidone-iodine and Talsutin vaginal tablets. A prophylactic antibiotic regimen was prescribed 30-60 minutes prior to surgery, it being delivered as a single dose of a first-generation cephalosporin intravenously . Postoperatively, parenteral cephalosporin and gentamicin were given for two days followed by oral cephalosporin for a further three days. The concomitant surgical procedures were performed under general anesthesia. The LAVH procedure was carried out according to a previously described procedure.[13] In brief, the LAVH procedure was performed incorporating three trocar punctures (one 10-mm infraumbilical and two 5-mm suprapubic incisions) and using Kleppinger forceps with an electrosurgical bipolar unit for hemostasis and desiccation. LAVH, either with or without adnexectomy, was conducted initially, this then being followed by the TVT procedure. The TVT procedure was performed subsequent to the completion of small cystocele repair and then, if deemed necessary, rectocele repair. Cystourethroscopy was also performed subsequent to the insertion of the TVT needle which was used to ensure that the bladder was intact. The tension of the tape was adjusted by the application of suprapubic pressure to attempt to mimic the provocative cough test, with about 300~350 ml distilled water having been instilled into the bladder.

Subsequent to the surgery, bladder catheter was

maintained for 24-48 hours routinely and for a period of one week for cases complicated by bladder perforation. Checking of the postvoided residual urine volume (RU) was conducted by intermittent bladder catheterization following the removal of the Foley. Our criterion for the condition of a satisfactory RU volume was two consecutive RU volume less than 50 ml or 20% of the voided volume. We defined the condition of urine retention as the situation when the RU volume was greater than 100 ml or more than half of the voided volume. We also recorded surgical details such as surgical duration, blood loss, hospital stay, duration of bladder drainage and total number of RU volume checking assays as conducted by intermittent catheterization during hospitalization.

The Student's paired *t*-test was used to compare the differences between urodynamic parameters preoperatively and postoperatively. A difference was considered to be significant statistically when $p < 0.05$.

RESULTS

A total of 63 patients underwent concomitant LAVH and TVT surgery during the study period. Due to the fact that 13 patients were lost to follow up, a final total of 50 patients completed the study with a mean follow-up period of 34 months (range 25-48). Mean patient age was 49 years (range 39-67) and mean parity 3 (range 2-6) (Table 1). Unilateral or bilateral adnexectomy was conducted for 10 of 63 patients. Seven patients underwent anterior and/or posterior colporrhaphy for the correction of small cystorectocele (Grade 1-2). Mean surgical duration and blood loss were 163 minutes (95-240) and 284 ml (100-1,500) respectively (Table 2). Mean duration of bladder drainage, number of intermittent catheterization tests and hospital stay was 45.7 hours (1.9 days; range 20-172 hours), 3.7 tests (range 2-13) and 5.5 days (range 4-17) respectively.

Few intraoperative complications occurred, they including 3 (6.0%) cases of bladder perforation, and one case of excessive bleeding, this patient also suffering from postoperative vaginal-cuff hematoma. For cases of bladder perforation, the TVT needle was removed and reinserted again. Bladder drainage was maintained for one week post-surgery, after which no problems with micturition or incontinence were noted for any of the patients. The patient that experienced excessive blood loss (1,500 ml) was re-examined, the blood loss being due to pelvic adhesion and the presence of an enlarged uterus which rendered LAVH a difficult procedure. Blood components were transfused intraoperatively for this patient. Five days post-surgery, vaginal-cuff hematoma developed for this patient, and following drainage of this hematoma, the remaining course of this patient's hos-

Table 1. Patient Characteristics and Indications for Hysterectomy

Age (year)	49±6 (39-67)
Parity	3.0±1.0 (2-6)
Hysterectomy indications (N=63)	
Fibroid/adenomyosis (%)	58 (92%)
Carcinoma in situ of cervix (%)	2 (3.2%)
Endometrial hyperplasia (%)	3 (4.8%)
Cystorectocele (Grade 1-2)	7 (11.1%)
Uterine size (cm^3)	249.1±146.8 (65.9-951.9)
Preoperative diagnosis (N=50)	
GSI only (%)	28 (56%)
GSI with sensory urgency (%)	22 (44%)

Abbreviation: GSI: genuine stress incontinence.
Data are presented as mean±SD or number. Values in parentheses are ranges or percentage.

Table 2. Intraoperative and Postoperative Parameters (N=50)

Intra/postoperative parameters	Values
Surgical duration (min)	163.3±36.0 (95-240)
Estimated blood loss (ml)	284.3±230.8 (100-1500)
Preoperative hemoglobulin (g/dL)*	11.9±1.3 (9.4-14.2)
Postoperative hemoglobulin (g/dL)*	10.7±3.8 (7.3-12.8)
Duration of bladder drainage (hours)	45.7±33.7 (20-172)
Number of catheterizations	3.7±2.6
Hospital stay (days)	5.5±2.5 (4-17)
Bladder perforation (patients)	3 (6.0%)
Postoperative complication†	1 (2.0%)
Postoperative urinary problems	
Transient urinary retention	9 (18%)
Re-inserting indwelling catheter	3 (6.0%)
De novo frequency/urgency symptoms	3 (6.0%)
Persistent voiding difficulty	4 (8.0%)

Data are presented as mean±SD or number of cases. Values in parentheses are ranges or proportion (percentage). Statistically compared by means of Student's *t*-test
* $p<0.001$, comparing pre- and postoperative hemoglobulin level
† One patient was complicated by vaginal-cuff hematoma.

pitalization was uneventful. No evidence of any defect in the healing of the vaginal wound or any rejection of the tape was noted for any patient.

Nine (18%) patients experienced immediate postoperative urine retention such that 3 of these patients required an indwelling catheter to remain in place for the subsequent 2 days, because these 3 patients registered a residual urine volume greater than half of the voided volume subsequent to removal of the Foley catheter. These 3 patients also underwent a slight lowering of the TVT tape through the urethra using a Hegar dilator, during their period of hospitalization,[14-15] although no long-term catheterization was necessary. Ten patients complained of voiding difficulty with poor flow during the first postoperative out patient department (OPD) visit (one week following discharge) and 4 of these patients still reported the same complaint during the next follow-up examination, some 6 or more months later, although, at this time, the residual urine volume for these 4 patients was less than 50 ml. Interestingly, the 10 patients experiencing voiding difficulty as noted at the first OPD follow-up were not the same group of patients who demonstrated immediate postoperative urinary retention. Twenty-two patients experienced frequency / urgency symptoms without signs of detrusor instability preoperatively, while 13 patients had their symptoms relieved postoperatively, symptoms persisting for 9 patients. We determined that 2 patients developed de novo frequency / urgency problems, and 1 de novo nocturia (7-8 occasions per night) during the follow-up periods, although no detrusor instability was able to be demonstrated subsequent to the completion of the postoperative urodynamic study. These displayed symptoms for the above-mentioned patients did reveal some range of improvement as a consequence of the supply of appropriate medication.

The results of a one-hour pad test revealed a substantial reduction in the amount of urine leakage from a mean 36 gm prior to surgery to 0.8 gm subsequent to surgery ($p < 0.0001$; Table 3). Postoperative multichannel urodynamic evaluation revealed significant increase in the volume of first-desire voiding, and reduction in maximal urethral closure pressure at both rest and stress. There did not appear to be any statistically significant differences in other pre- and postoperative urodynamic parameters.

Table 3. Preoperative and Postoperative Urodynamic and One-hour Pad Test Parameters

Parameter	Preoperative	Postoperative	*p*
Pad test (g)	36.0 ± 28.1	0.8 ± 3.6	<0.0001
MFR	20.0 ± 8.9	18.5 ± 10.7	0.497
AFR	8.9 ± 4.3	8.2 ± 5.6	0.326
VV	243 ± 169	224.5 ± 135.6	0.361
RU	21 ± 221.6	13.1 ± 27.9	0.056
FD	135 ± 58.9	155 ± 50.1	0.030
MC	302.5 ± 104.4	321 ± 87.6	0.090
MUCP-R	80.3 ± 28.8	72.9 ± 21.4	0.010
MUCP-S	68.8 ± 25	62.7 ± 19.4	0.007
FUL-R	32.8 ± 7.8	32.6 ± 6.2	0.493
FUL-S	34.8 ± 8.9	34.9 ± 6.3	0.416

Abbreviations: MFR: maximum flow rate (ml/s); AFR: average flow rate (ml/s); VV: voided volume (ml); RU: residual urine volume (ml); FD: first desire (ml); MC: maximum capacity (ml); MUCP-R: maximum urethral closure pressure at rest (cm H_2O); MUCP-S: maximum urethral closure pressure at stress (cm H_2O); FUL-R: functional urethral length at rest (cm); FUL-S: functional urethral length at stress (cm).
Data are presented as mean±SD.

DISCUSSION

Although it is recognized that total hysterectomy may be associated with the occurrence of subsequent urinary incontinence,[16-17] many women are actually sufferers of symptomatic urinary incontinence prior to such surgery,[1-4] with, seemingly, many patients and/or gynecologists really neglecting to deal with such urological symptoms prior to hysterectomy surgery. Most of our study-included patients who visited OPD did so due to menorrhagia and/ or severe dysmenorrhea, rather than stress urinary incontinence or other urological problems. It would appear that most women who suffer from long-term urinary incontinence consider urine leakage to be normal subsequent to their having giving birth or arising as a normal consequence of the aging process.[18] BUD and SUI are two disease entities, but in some patients these two diseases may coexist. Thus gynecologists should enquire regarding and evaluate any urinary incontinence or other lower urinary-tract symptoms that may be present for those patients who are preparing to undergo hysterectomy. In addition, we can distinguish whether any postoperative urinary symptoms that exist were preexis-

tent or whether they had arisen in a de novo fashion as a consequence of the surgical procedure. Furthermore, hysterectomy and anti-incontinence surgery, if necessary, can be performed simultaneously.

Traditional Burch colposuspension reveals better long-term cure rates for SUI than do other anti-incontinence surgical procedures,[19,20] the Burch procedure sharing the same abdominal incision wound as abdominal hysterectomy. Thus, in the past, Burch colposuspension was often performed concomitantly with hysterectomy through an abdominal approach.[21-23] Unfortunately, patient voiding difficulty following Burch colposuspension would appear to be common, with such a symptom being noted for up to 22% of patients at long-term follow-up.[20] Considering the notable benefits of endosurgical procedures and particularly for those that are able to use the same route of approach, it seems logical to suggest that LAVH and laparoscopic Burch colposuspension (LBC), if necessary for a patient, should be carried out simultaneously. It should be recognized, however, that the surgical technique for LBC is more skill-dependent and requires a definite and longer learning curve for the surgeon to master the procedure.[24] Thus, considering the above-mentioned advantages (in the content of introduction) of TVT compared to more-conventional analogous surgical modalities, for the purposes of concomitant anti-incontinence surgery with LAVH, we recommend that TVT is a better choice than is the case for LBC in conjunction with LAVH.

In a previous study, we reported data pertaining to the LAVH procedure, they including mean surgical duration (134 min), blood loss (260 ml) and hospital stay (4.9 days),[13] and, according to a review of the relevant literature, we have determined that, for TVT, corresponding parameter range values are, respectively, 22-45 min, 34.5-300 ml and 1-3 days.[6,10,14,25] For the present study, the parameter values for surgical duration, blood loss and hospital stay for the concomitantly conducted surgical procedures of LAVH with TVT were, respectively, 163 min, 284 ml and 5.5 days. Although the postoperative hemoglobulin level did drop statistically significantly from the pre-surgical level (11.9 g/L to 10.7 g/L), there appeared to be little clinical significance for such a combined surgery-induced blood loss resulting in mild anemia. The incidence of bladder perforation for our patient sample (6.0%) was similar to figures that had been previously reported for a number of studies (0.8~9.6%).[7,10,11,14,26] Bladder drainage was retained for one week for our patients that suffered from bladder perforation so as to attempt to avoid the likelihood of further complication, however, as reported in some previous studies, bladder drainage was retained for only 2 days for those cases featuring bladder perforation without any serious problem appearing to arise.[2,8,28,29] Cognizant of such results we will attempt to reduce the duration of bladder drainage for those cases featuring bladder perforation, and hopefully thus, shorten future hospital stays.

In 1996, Ulmsten et al. reported that the TVT procedure should be carried out under local anesthesia, such that a provocative stress test may be conducted intraoperatively in order for surgeons to be able to adjust the tension of the tape.[6] Under general anesthesia, however, carrying out the intraoperative coughing stress test is not possible. In 2001, Haab et al reported that the rate of post-operative voiding difficulty was greater for patients who did not undertake the cough stress test as a part of the TVT procedure.[26] So one of our main concerns was how to adjust the tape into a “tension-free” position, and maintaining its continence function under general anesthesia. For the combined surgical procedures, if general anesthesia is indeed necessary, the surgeon conducting a brisk and vigorous Crede maneuver, or with the help of anesthesiologist, attempting to stimulate the patient to trigger a cough reflex may be able to demonstrate an appropriate alternative procedure to duplicate the cough test. Four (8%) patients in our study reported that they had experienced symptomatic voiding difficulty for a period of 6 or more months during follow-up period, the data being similar to those previously reported (4.3~8.6%).[10,11,14,26] From our initial experiences with these surgical techniques, we found that when TVT was performed under general anesthesia, the tape needed to be placed under the mid-urethra as loosely as possible. If the tape is inserted too tightly and obstructs the urethra, a Hegar dilator can be used to lower the tape through the urethra gently so as to attempt to avoid urethral damage within the first week subsequent to surgery.[14,15] Neither release of the tape nor urethrolysis during follow-up was needed for any of the patients participating in the present study. The appli-

cation of intraoperative ultrasonography surveillance may be useful whilst placing the tape in situ in order to avoid elevating the urethra and, thus, to attempt to minimize the likelihood of postoperative voiding difficulty and urine retention.[15]

Significant difference in particular preoperative and postoperative urodynamic-parameters have been reported for some previous studies,[9,10,27,30,31] but not for others.[6,12,15] Even though some studies have reported some examples of significant differences between preoperative and postoperative urodynamic parameters, to the best of our knowledge, it would appear that no uniform alterations to urodynamic parameters is likely to be observed according to the literature consulted.[9,10,27,30,31] According to the new Integral Theory, TVT restores continence by correcting the inadequate urethral support from the pubourethral-vesical ligaments and the suburethral vaginal wall.[32,33] This rather new continence-restoring mechanism creates a dynamic urethral kinking of the midurethra during stress but, in principle, elicits no disturbance to bladder-neck and urethral function at rest. The positive transmission ratio, urethral closure pressure and urethral resistance at stress are all parameter values that are expected to increase subsequent to the completion of the TVT procedure. In our study, a significant reduction in postoperative maximum urethral closure pressure at both rest and stress were noted as compared to pre-surgery values. This result appears somewhat difficult to explain and further investigation incorporating a rather large study with a long-term follow up to clarify this unexpected observation is clearly warranted. Decrease in postoperative resting urethral closure pressure has been reported in the previous study.[30] In 2000, Wang explained this phenomenon was due to impairment of the intrinsic sphincteric mechanism resulting from injury to the parasympathetic and sympathetic nerve components during the needle insertion

In conclusion, the efficacy of concomitant TVT in LAVH procedure remained satifactory in the treatment of SUI associated with BUD. Both surgical procedures gained benefits from being less-invasive procedures as compared to their more-conventional open-surgery antecedents. Therefore, the combination of LAVH and TVT is probably a good alternative for the patient who needs to undergo hysterectomy and anti-incontinence surgery at the same time. A larger analogous study incorporating a long-term follow up is still currently proceeding in our medical center.

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合併腹腔鏡子宮全切除術及無張力性尿道中段懸吊術治療同時患有良性子宮疾病及壓力性尿失禁患者

梁西米 黃寬慧 龔福財 陳智偉 張旭陽

背 景： 由於良性子宮疾病而需要接受子宮全切除術的病患可能同時合併有壓力性尿失禁的困擾。在考慮同時能以微創手術處理此兩項問題，所以我們評估同時進行腹腔鏡子宮全切除術及無張力性尿道中段懸吊術之可行性，及無張力性尿道中段懸吊術在全身麻醉下進行之可行性及術後效果評估。

方 法： 從2000年3月至2002年3月期間，共63位同時患有良性子宮疾病及壓力性尿失禁患者接受腹腔鏡子宮全切除術合併無張力性尿道中段懸吊術治療。病患術前評估包括病史、理學及超音波檢查，另外術前及術後均接受一小時棉墊測試、尿動力學檢查及泌尿道症狀問卷，我們亦詳細記錄手術中、住院中及術後解尿等各項細節問題。

結 果： 最後共50位病患完成本研究，平均術後追蹤時間爲34個月，平均年齡49歲，生產次數爲3。手術時間及失血量分別爲163分鐘及284毫升，住院時間5.5天，尿管放置時間爲45.7小時。3位病患有膀胱穿孔及1位失血過多之併發症，術後泌尿道症狀包括暫時性尿滯留、頻尿/急尿症狀及解尿困難。

結 論： 使用腹腔鏡子宮全切除術合併無張力性尿道中段懸吊術來治療患有良性子宮疾病及同時有壓力性尿失禁患者，結果是令人滿意的，而且兩者均有微創手術的好處。根據我們的研究結果如病患同時需要接受子宮切除術及壓力性尿失禁手術時，腹腔鏡子宮全切除術合併無張力性尿道中段懸吊術是很好的另一種選擇。

(長庚醫誌 2005;28:166-73)

關鍵字： 壓力性尿失禁，腹腔鏡子宮全切除術，無張力性尿道中段懸吊術。

長庚紀念醫院　高雄院區　婦產部
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索取抽印本處：龔福財醫師，長庚紀念醫院　婦產部。高雄縣833鳥松鄉大埤路123號。Tel.: (07)7317123; Fax: (07)7322915; E-mail: ftkung@ksts.seed.net.tw