Laparoscopic Burch Colposuspension Versus Tension-Free Vaginal Tape: A Randomized Trial

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OBJECTIVE: To compare the laparoscopic Burch colposuspension with the tension-free vaginal tape procedure (TVT) for efficacy.

METHODS: Seventy-two women from 2 institutions were randomized: 36 to laparoscopic Burch colposuspension and 36 to TVT. Multichannel urodynamic tests were performed preoperatively and 1 year after surgery. A research nurse administered the Urogenital Distress Inventory, Incontinence Impact Questionnaire, and pelvic examinations using the pelvic organ prolapse quantification system preoperatively, and at 6 months, 1 year, and 2 years after surgery. Voiding diaries were collected at 1 and 2 years. Primary outcome was objective cure, which was defined as no evidence of urinary leakage during postoperative urodynamic studies. Secondary outcomes included subjective continence, perioperative and postoperative data, and quality of life.

RESULTS: Thirty-three laparoscopic Burch colposuspension and 33 TVT patients were analyzed with a mean follow-up of 20.6 ± 8 months (range 12–43). Mean operative time was significantly greater in the laparoscopic Burch colposuspension group compared with the TVT group, 132 versus 79 minutes, respectively ($P = .003$). Multichannel urodynamic studies in 32 laparoscopic Burch colposuspension and 31 TVT patients showed a higher rate of urodynamic stress incontinence at 1 year in the laparoscopic Burch colposuspension group, 18.8% versus 3.2% ($P = .056$). There was a significant improvement in the number of incontinent episodes per week and in Urogenital Distress Inventory and Incontinence Impact Questionnaire scores in both groups at 1 and 2 years after surgery ($P < .001$). However, postoperative subjective symptoms of incontinence (stress, urge, and any urinary incontinence) were reported significantly more often in the laparoscopic Burch colposuspension group than in the TVT group ($P < .04$ for each category).

CONCLUSION: The TVT procedure results in greater objective and subjective cure rates for urodynamic stress incontinence than does laparoscopic Burch colposuspension. (Obstet Gynecol 2004;104:1249–58. © 2004 by The American College of Obstetricians and Gynecologists.)

LEVEL OF EVIDENCE: I

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Adoption of minimally invasive surgical techniques for the treatment of stress incontinence by gynecologic and urologic surgeons has increased in recent years. This was initially a result of growing interest in laparoscopic surgery for retropubic colposuspension. However, more recent widespread application of midurethral sling procedures has revolutionized anti-incontinence surgery and has popularized minimally invasive approaches.

In a recent multicenter, randomized trial comparing open Burch colposuspension with the tension-free vaginal tape (TVT) procedure, Ward and Hilton[1] demonstrated similar cure rates at 6 months. The authors cited many advantages associated with the TVT procedure, such as shorter operating time and hospital stay and more rapid return to work and normal activities. Many of these advantages are inherent to minimally invasive surgery in general and would apply to the laparoscopic Burch colposuspension. The purpose of our investigation is to compare the efficacy of the laparoscopic Burch colposuspension with the TVT procedure.

SUBJECTS AND METHODS

This randomized prospective trial was approved by the institutional review boards of the Cleveland Clinic Foundation and Good Samaritan Hospital. All women who were candidates for surgical correction of primary urodynamic stress incontinence were approached for enrollment in this investigation. The patients were recruited from August 1999 through August 2002 and followed up through January 2004.

Clinical evaluation of each patient included a standardized history, gynecologic examination using the pelvic organ prolapse quantification system[2] and the cotton-tipped swab test, neurologic examination, and urinalysis.

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Urodynamic evaluations consisted of uroflometry, cystometrogram with provocation leak-point pressure measurements, and pressure-flow voiding study. A 7F dual-lumen catheter was used to infuse sterile water at room temperature at the rate of 90 mL per minute. Abdominal pressure was measured with a fluid-filled balloon placed in the rectum and connected to a transducer with a 9F catheter. The bladder was filled with the subject sitting in a 45° position, and the patient was asked to Valsalva and cough, starting at a bladder volume of 150 mL and at every subsequent 50-mL increment, until maximum bladder capacity was reached. The lowest intra-abdominal pressure at which water was first noted to escape from the urethra was designated the abdominal leak-point pressure. If the patient did not leak with the catheter in place, the bladder was refilled with 300 mL and a cough stress test was carried out in sitting and standing position with the patient performing Valsalva maneuvers, coughing, and heel bounces. Unless otherwise stated, the methods, definitions, and units conform to standards proposed by the International Continence Society.[3]

Inclusion criteria for this investigation were the following: urodynamic stress incontinence with abdominal leak-point pressures greater than or equal to 60 cm H_2O (or a positive cough stress test if the patient did not leak with the catheters in place); urethral hypermobility defined as maximal straining cotton-tipped swab angle of greater than or equal to 30°; ability to undergo general anesthesia and laparoscopy; no previous anti-incontinence surgery; no detrusor overactivity on urodynamic studies defined by a rise in the true detrusor pressure not due to bladder compliance of more than 15 cm H_2O; no anterior vaginal wall prolapse to or beyond the hymen, and willingness to complete postoperative follow-up and testing.

Patients were randomized by a computer-generated randomization schedule, with allocation to either laparoscopic Burch colposuspension or TVT concealed in a sealed opaque envelope. All subjects who underwent laparoscopic Burch colposuspension received general anesthesia. Prophylactic antibiotics were given preoperatively no more than 1 hour before surgery. Each patient was placed in low dorsolithotomy position in Allen stirrups with antiembolic pressure stockings. For the extraperitoneal laparoscopic approach, the distention balloon was used for dissection only in those patients who had no history of laparotomy or did not require concomitant intraperitoneal procedures. If the patient had prior pelvic or abdominal surgery, a transperitoneal technique with sharp dissection was used to enter the space of Retzius after retrograde distention of the bladder with 300 mL normal saline. After dissection of all pertinent landmarks, a total of 4 No. 0 braided polyester, double-armed sutures (Ethibond; Ethicon Endosurgery Inc, Cincinnati, OH) were sequentially passed through the endopelvic fascia/vaginal wall, excluding the vaginal epithelium in a figure-8 fashion, with each end then brought up through Cooper's ligament on the ipsilateral side. Two sutures were placed on either side of the urethra, one at the level of the midurethra and the other at the level of the bladder neck, using the technique modified by Tanagho.[4] Knots were sequentially tied extracorporeally. Gelfoam was placed between both sets of suspending sutures and the sidewall to accelerate scarring and fibrosis. A cystoscopy was performed after intravascular injection of indigo carmine dye to assure bilateral ureteral patency and absence of intravesical sutures. A suprapubic catheter was placed and secured to the skin. All trocar incisions of 10 mm or greater were closed with No. 0 polyglycolic acid suture using the Endoclose needle (US Surgical Corporation, Norwalk, CT).

The TVT procedure (Gynecare Inc, Somerville, NJ) was performed under either local anesthesia with intravenous sedation or under regional or general anesthesia, as indicated, using the upward-pass technique.[5] All patients received prophylactic antibiotics, and patients were placed either in high or low dorsolithotomy position after antiembolic compression stockings were applied. All patients were sterilely prepped and draped. An 18Fr catheter was introduced into the urethra, and the bladder was drained. Two 5-mm incisions were made suprapubically, approximately 3 cm lateral of the midline, just above the pubic bone after suprapubic and retropubic injection of local anesthesia (10 mL of 0.25% bupivacaine on each side). Suburethral and paraurethral injection of local anesthesia was performed at the level of the midurethra. A 1.5- to 2-cm vertical incision was made approximately 1 cm from the external urethral meatus. Sharp dissection of the vaginal tissues was performed, separating the vagina from the urethra and dissecting paraurethrally. The catheter guide was then introduced into the Foley catheter to divert the urethra from the side of trocar insertion. While gripping the needle introducer gently with one hand and guiding the trocar with the index finger of the other hand, the needle tip was used to penetrate the endopelvic fascia with angulation toward the ipsilateral shoulder. The needle then was directed through the space of Retzius, perforating the rectus fascia while aiming toward the ipsilateral suprapubic incision. Cystoscopy was performed after passage of the trocar needle on each side to assure an intact bladder. The needle was advanced with the tape above the abdominal wall and detached from the introducer. The same procedure was performed on the opposite side after the blad-

der was emptied. A cough stress test (local or regional anesthesia) or Crede maneuver (general anesthesia) was performed with 300 mL in the bladder for adjustment of the tape until minimal urine leakage was seen with Valsalva maneuver or cough. The plastic sheath was removed with a right-angle clamp as a spacer between the urethra and tape. The tape was trimmed, and the vaginal incision was closed with No. 2–0 polyglycolic acid suture. A suprapubic tube was placed with the patient in Trendelenburg position.

All patients were discharged according to the same protocol depending on whether the patient underwent concomitant procedures or isolated anti-incontinence surgery. The patient was deemed ready for discharge if she was tolerating a clear liquid diet and oral pain medication and ambulating. Suprapubic tubes were removed under routine clinical protocol when the patient was able to void 150 mL or more consistently without pain, with postvoid residual volumes of 20% or less of the total bladder volume, twice in a row.

The primary outcome of this investigation was objective cure, defined as no evidence of leakage during postoperative urodynamic studies. Secondary outcomes included subjective continence, hospital data and cost, complications, time to achieve normal voiding, data from pelvic organ prolapse quantification and cotton-tipped swab examinations, urinary diaries, sexual function, and quality of life.

Multichannel urodynamic studies were performed preoperatively and 1 year after surgery. The surgeon who scheduled the procedure interpreted preoperative urodynamic studies. Interpretation of urodynamic studies 1 year after surgery was blinded and performed by the enrolling surgeon and an independent urogynecologist reviewer. A third reviewer resolved any discrepancies between the 2 primary reviewers in the 1-year postoperative urodynamic diagnosis. Urodynamic stress incontinence and detrusor overactivity were defined according to the recommendations of the International Continence Society.[6] Voiding dysfunction was defined as a maximum flow rate of less than 10 mL/second or a post-void residual volume of greater than 100 mL on postoperative urodynamic tests or the need for urethrolysis.

A research nurse administered the Urogenital Distress Inventory,[7] Incontinence Impact Questionnaire,[7] and pelvic examinations using pelvic organ prolapse quantification system and cotton-tipped swab testing, preoperatively, at 6 months, and at 1 and 2 years after surgery. One-week urinary diaries were collected at 1 and 2 years after surgery. Additionally, subjects were asked to score their satisfaction with the procedure on a visual analog scale (VAS) from 0 to 10 at 1 and 2 years postoperatively, with 0 indicating "not at all satisfied" and 10 indicating "extremely satisfied." Procedure cost was calculated by adding total direct and indirect hospital costs (not charges) as determined by the Cleveland Clinic Foundation's cost-based accounting database. Postoperative hospital or patient costs were not included. Cost data could only be obtained for those patients recruited at the Cleveland Clinic Foundation.

Postoperatively, subjective continence status was determined by the subject's responses to specific questions on the Urogenital Distress Inventory. Subjects were considered as having postoperative stress urinary incontinence symptoms if they answered affirmatively to the question "Do you experience urine leakage related to physical activity, coughing, or sneezing?" Subjects were considered as having urge urinary incontinence symptoms if they answered affirmatively to the question "Do you experience urine leakage related to the feeling of urgency?" Subjects were classified as having "any urinary incontinence" if they answered affirmatively to either of the previous questions or to any of the following questions: "Do you experience general urine leakage not related to urgency or activity?" "Do you experience small amounts of urine leakage (that is, drops)?" or "Do you experience large amounts of urine leakage?"

Given a 2-year continence rate of 89% for the laparoscopic Burch colposuspension, we ascertained that 59 patients per group were necessary to detect a 20% difference in continence rates with 80% power and a significance level of .05. Adding 10% potential loss to follow-up, 65 patients were desired for enrollment in each group.

Continuous variables were compared with a 2-tailed *t* test. Categorical variables were compared with the Pearson χ^2 or Fisher exact test, as appropriate. Number of incontinence episodes and number of pads used, as recorded on the bladder diary, as well as Urogenital Distress Inventory and Incontinence Impact Questionnaire scores were compared by repeated measures ANOVA. Within-group comparisons were made with the paired *t* test. Kaplan-Meier survival curves were generated for the development of subjective incontinence symptoms (stress, urge, and any urinary incontinence), and comparisons were made with the log-rank test. The study was performed under the principle of intention-to-treat, so that each patient was analyzed in the group to which she was originally assigned, regardless of what procedure she underwent or if conversion to laparotomy occurred. Statistical analysis was performed using the JMP 5.01 software package (SAS Institute, Cary, NC).

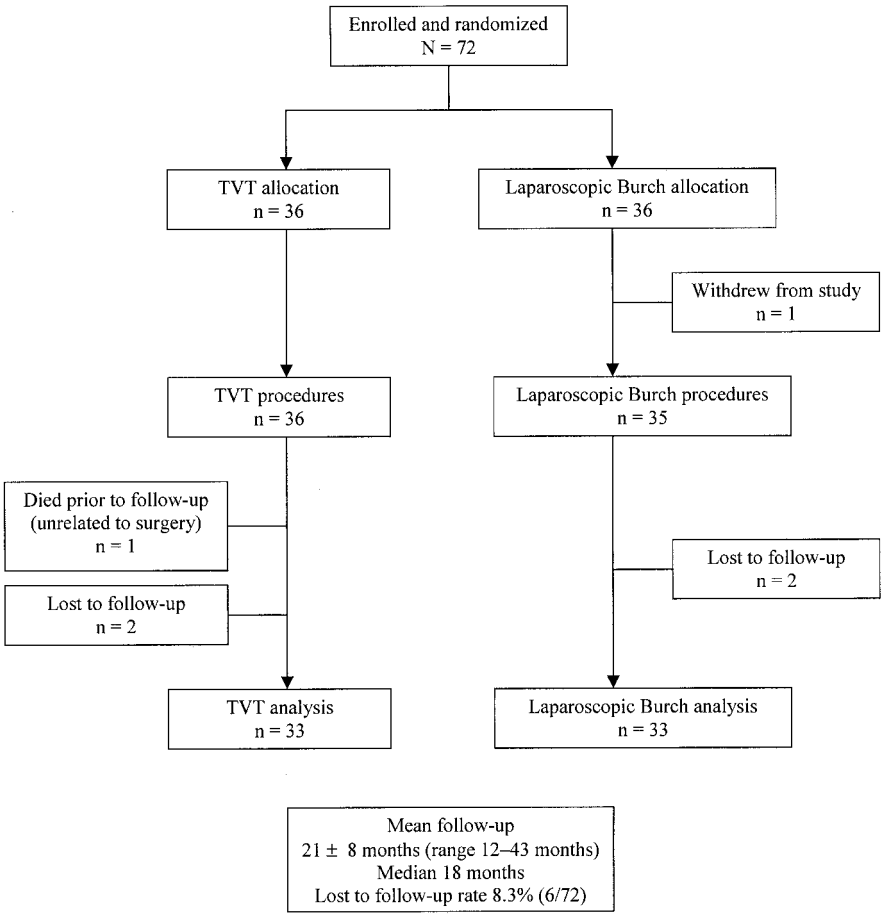

Fig. 1. Flow diagram of subject enrollment and follow-up. Cleveland Clinic Foundation, n = 60; Good Samaritan Hospital, n = 12.
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RESULTS

Allocation of the 72 enrolled patients is shown in Figure 1. Thirty-three patients in each group were analyzed with a mean 20.6 ± 8 months (range 12–43) and median follow-up of 18 months. Loss to follow-up rate was 8.3%. The trial was stopped early because of slow recruitment and lack of funding. The decision to stop the trial was made before statistical analysis.

Demographic data were similar in both groups, as seen in Table 1. Concurrent procedures performed in both groups are shown in Table 2. One fourth of the patients in each group underwent hysterectomy. The only statistically significant difference was that 32% of patients in the laparoscopic Burch colposuspension group underwent lysis of adhesions, compared with 11% in the TVT group.

Hospital parameters and postoperative voiding data are presented in Table 3. The laparoscopic Burch colposuspension group had a significantly greater operating time (defined as incision to incision of all procedures) and a significantly greater isolated procedure time (when either procedure was performed alone). All laparoscopic Burch procedures were performed under general anesthesia. The anesthesia for the TVT procedures included: 19 general anesthesia, 10 regional anesthesia (8 spinal and 2 epidural), and 7 local anesthesia. Estimated blood loss, change in hematocrit, analgesia requirement, hospital stay, and number of days to normal voiding were similar between groups. Total hospital cost was comparable between procedures.

Complications in both groups were not significantly different. One patient in the TVT group required an intraoperative blood transfusion. There were 2 cystotomies in the TVT group, and bladder sutures were detected intraoperatively in 2 patients in the laparoscopic Burch colposuspension group. One patient had incurred bladder sutures during vaginal hysterectomy cuff closure. There was one bowel injury in the laparoscopic Burch group, which was detected and repaired at the time of the primary procedure. Three of the laparoscopic Burch procedures were converted to laparotomy because of severe adhesions in 2 patients and a difficult total laparoscopic hysterectomy in 1 patient. Postoperative complications included 1 hematoma and 1 pelvic

Table 1. Demographic Information by Treatment Group

	Laparoscopic Burch colposuspension (n = 36)	Tension-free vaginal tape (n = 36)	*P*
Age (mean years ± SD [range])	54.8 ± 9.3 (38–76)	53.3 ± 9.5 (40–80)	.50
BMI (mean ± SD [range])	28.5 ± 6.1 (19.8–38.7)	30.1 ± 6.2 (19.1–44.7)	.28
Parity (median [range])	2 (0–5)	2 (0–7)	.79
Menopause status			
Pre-	15 (44)	12 (35)	.07
Post- (no HT)	1 (3)	7 (20)	
Post- (HT)	18 (53)	15 (44)	
Race			
White	33 (94)	30 (88)	.23
Black	1 (3)	4 (12)	
Other	1 (3)	0 (0)	
Occupation			
Sedentary	13 (38)	8 (24)	.73
Light labor	12 (35)	12 (36)	
Heavy labor	4 (12)	5 (15)	
Homemaker	2 (6)	3 (9)	
Unemployed	3 (9)	5 (15)	
Insurance			
Private	33 (94)	30 (91)	.58
Medicare/aid	2 (6)	2 (6)	
Comorbidities			
Diabetes mellitus	0 (0)	0 (0)	1.0
Chronic cough	5 (14)	1 (3)	.19
Chronic obstructive pulmonary disease	1 (3)	0 (0)	1.0
Neurologic disease	1 (3)	1 (3)	1.0
Smoker	4 (11)	5 (15)	.73
Previous hysterectomy	9 (25)	16 (47)	.08
Previous URPS	1 (3)	2 (6)	.61
Anticholinergic therapy	1 (3)	2 (6)	.61

SD, standard deviation; BMI, body mass index (kg/m^2); HT, hormone therapy; URPS, urogynecologic and reconstructive pelvic surgery.
Data are presented as n (%).

abscess in each group. Four patients in the Burch group and 2 in the TVT group had hematocrit levels less than 28%. One patient in the laparoscopic Burch group suffered from a postoperative ileus. One patient in the laparoscopic Burch colposuspension group was readmitted 1 week postoperatively for pulmonary embolism. Another patient in the Burch group was readmitted for pyelonephritis. One patient required conservative man-

Table 2. Concurrent Surgical Procedures Performed

	Laparoscopic Burch colposuspension (n = 35)	Tension-free vaginal tape (n = 36)	*P*
TVH or LAVH	9 (25)	8 (22)	.73
Anterior colporrhaphy	0 (0)	0 (0)	1.0
Posterior colporrhaphy	2 (6)	5 (14)	.24
Culdoplasty or vaginal apex suspension	3 (9)	5 (14)	.47
Lysis of adhesions	11 (32)	4 (11)	.03
Adnexal surgery	5 (15)	4 (11)	.65
Bilateral tubal ligation	2 (6)	0 (0)	.49
Hysteroscopic surgery	1 (3)	1 (3)	1.0
Bladder biopsy	1 (3)	1 (3)	1.0
Laparoscopic cholecystectomy	1 (3)	1 (3)	1.0
Excision of endometriosis	0 (0)	2 (5)	.49
Anal sphincteroplasty	0 (0)	1 (3)	.49

TVH, total vaginal hysterectomy; LAVH, laparoscopic-assisted vaginal hysterectomy.
Data are presented as n (%).

Table 3. Hospital Parameters and Postoperative Voiding Data by Treatment Group

	Laparoscopic Burch colposuspension			Tension-free vaginal tape			
	Mean	95% CI	Range	Mean	95% CI	Range	*P*
Total time in operating room (min)	210	185–234	112–360	141	112–172	55–330	< .001
Total operating time (min)	132	107–156	45–323	79	54–103	22–266	.003
Operating time as isolated procedure (min)	101 (n = 11)	87–115	63–210	42 (n = 18)	36–49	22–78	< .001
Estimated blood loss (mL)	165	93–235	0–950	141	71–294	0–900	.64
Change in hematocrit (%)*	6.5	4.7–7.6	0–14.1	5.2	3.3–7.2	0–19.3	.77
SPT removed (days postoperatively)	4.9	3.5–6.3	0–16	5.2	3.4–7.1	0–19	.77
Patient-controlled analgesia use (h)	10	3.9–16.0	0–39	10	4.5–16	0–44	.97
Hospital time (hours)	33	24–42	6–131	29	19–37	6–96	.86
Cost (U.S. dollars)†	6,368	5,459–7,277	3,556–12,459	6,059	5,149–6,968	3,043–11,215	.63

CI, confidence interval; SPT, suprapubic tube;
Data are presented as n (%).
* Preoperative hematocrit minus postoperative hematocrit. Postoperative hematocrit obtained in the recovery room for patients discharged the day of surgery; for all others the postoperative hematocrit was obtained on the day after surgery.
† Cost data represent total direct and indirect inpatient costs from the subjects recruited at the Cleveland Clinic Foundation only (n = 60).

agement for vaginal erosion of the TVT mesh. Two patients in the TVT group required mesh transection for voiding dysfunction, with one undergoing concomitant bone anchor pubovaginal sling. Two patients in the laparoscopic Burch colposuspension group underwent subsequent collagen injection.

Urinary diary results, Urogenital Distress Inventory and Incontinence Impact Questionnaire scores, and VAS results for patient satisfaction are displayed in Table 4. There was a statistically significant improvement in both groups with respect to number of incontinence episodes, weekly pad use, and percentage of patients using pads at 1 and 2 years after surgery. Improvement in Urogenital Distress Inventory and Incontinence Impact Questionnaire scores was also statistically significant in both groups. Although all parameters improved for both groups, there was no statistically significant difference between groups. Patient satisfaction, as scored on VAS, was high in both groups at 1 and 2 years after surgery and not significantly different between groups.

Table 5 displays multichannel urodynamic study results at 1 year after surgery. There was a greater rate of urodynamic stress incontinence in the laparoscopic Burch colposuspension group: 18.8% versus 3.2%; (relative risk [RR] 1.19, 95% confidence interval [CI] 1.00–1.42, $P = .056$). Although detrusor overactivity was greater in the TVT group, this was not significantly different (19.3% versus 6.2%; RR 1.16, 95% CI 0.96–1.41, $P = .12$). Voiding dysfunction was not different between groups. Pelvic organ prolapse quantification and cotton-tipped swab examinations were also similar in both groups. No patient developed symptomatic pelvic organ prolapse during the postoperative period.

Times to development of symptoms for stress and urge incontinence were significantly earlier in the lapa-

Table 4. Urinary Diary, Quality of Life, and Patient Satisfaction Outcomes at 1 and 2 Years After Surgery

	Preoperative		1 Year after surgery		2 Years after surgery		*P* (within group)		
	LBC (n = 35)	TVT (n = 36)	LBC (n = 33)	TVT (n = 30)	LBC (n = 17)	TVT (n = 16)	LBC	TVT	*P* (between groups)
Incontinence episodes/wk	16 ± 13	16 ± 14	0.4 ± 1.6	1.8 ± 5.1	0.3 ± 0.8	0.0 ± 0.0	< .01	< .01	.83
Pads/wk (median [range])	3 (0–10)	3 (1–8)	0 (0–6)	0 (0–3)	0 (0–1)	0 (0–2)	< .01	< .01	.17
Percentage using pads	90	85	30	29	19	25	< .01	< .01	.47
Urogenital Distress Inventory*	40 ± 14	42 ± 15	4 ± 2	6 ± 2	4 ± 2	4 ± 2	< .001	< .001	.69
Incontinence Impact Questionnaire†	144 ± 90	164 ± 95	38 ± 51	49 ± 38	47 ± 49	33 ± 52	< .001	< .001	.93
Satisfaction (0–10)‡	. . .	. . .	8.4 ± 2.9	8.5 ± 2.8	9.0 ± 1.4	8.2 ± 3.4	. . .	. . .	.74

TVT, tension-free vaginal tape; LBC, laparoscopic Burch colposuspension.
Data are presented as mean ± standard deviation, except where otherwise indicated.
* Scores range from 0 to 300, with larger scores indicating greater distress.
† Scores range from 0 to 400, with larger scores indicating greater adverse impact on quality of life.
‡ Visual analog scale of patient's satisfaction with surgery, ranging from 0 (not at all) to 10 (extremely satisfied); only measured postoperatively, so no within-group comparison was done.

Table 5. Urodynamic Test Results One Year After Surgery

	Laparoscopic Burch colposuspension (n = 32)	Tension-free vaginal tape (n = 31)	*P*
Urodynamic stress incontinence	6 (18.8)	1 (3.2)	.056
Detrusor overactivity			
Any	2 (6.2)	6 (19.3)	.12
With incontinence	0 (0)	1 (3.2)	.30
Voiding dysfunction*	5 (14.7)	5 (15.2)	.80

Data are presented as n (%).

* Maximum flow rate less than 10 mL/second, post-void residual volume > 100 mL or urethrolysis performed.

roscopic Burch colposuspension group ($P = .02$ for both symptoms; Figure 2). When assessed postoperatively, 34.5% of patients in the laparoscopic Burch colposuspension group and 23.5% of patients in the TVT group were on anticholinergic therapy, which was not significantly different ($P = .33$). Time to development of any symptoms of incontinence was significantly earlier in the laparoscopic Burch colposuspension group than in the TVT group ($P = .04$; Figure 3).

DISCUSSION

Our trial demonstrates significant subjective improvement and patient satisfaction after both laparoscopic Burch colposuspension and TVT. However, in our hands, TVT resulted in significantly greater subjective cure rates for stress incontinence than the laparoscopic

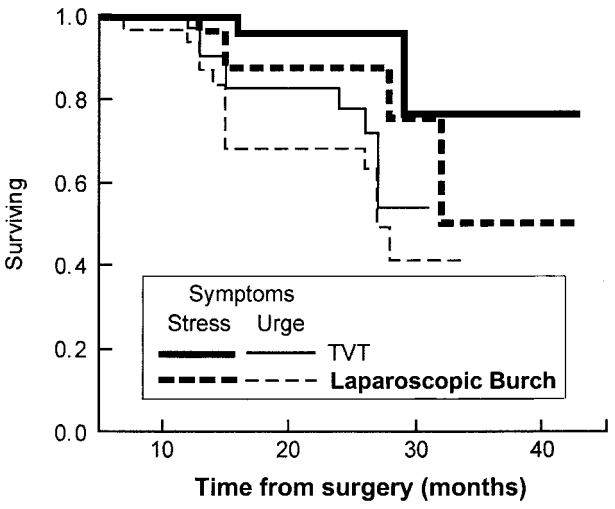

Fig. 2. Kaplan-Meier survival curves for the development of subjective symptoms of stress or urge incontinence after surgery, by procedure. TVT, tension-free vaginal tape; LBC, laparoscopic Burch colposuspension.

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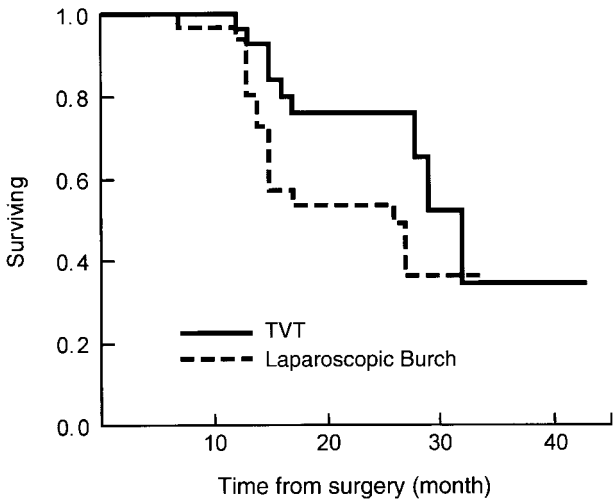

Fig. 3. Kaplan-Meier survival curve for the development of any urinary incontinence symptoms after surgery, by procedure. TVT, tension-free vaginal tape; LBC, laparoscopic Burch colposuspension.

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Burch colposuspension. Additionally, substantially more subjects demonstrated urodynamic stress incontinence during urodynamics 1 year after surgery in the laparoscopic Burch colposuspension group than in the TVT group (absolute risk increase 15.6%, $P = .056$). Multiple outcome measures were analyzed, which confirmed the superior efficacy of the TVT procedure.

There are 2 comparative studies in the literature thus far comparing TVT with laparoscopic retropubic procedures. In a prospective randomized trial comparing TVT (23 patients, mean follow up 11.3 months) and laparoscopic Burch urethropexy (23 patients, mean follow-up 13.5 months), Ustun et al[8] showed 82.6% success in both groups, defined as subjectively dry at follow-up with negative stress tests and urodynamic evaluation at 3 months after surgery. Longer operative times, hospital stay, and duration of catheterization, as well as 3 conversions to laparotomy were reported in the laparoscopic Burch group. In a prospective nonrandomized study comparing TVT (23 patients, median telephone follow-up 17.5 months) with single-stitch laparoscopic bladder neck suspension (22 patients, median telephone follow-up 22.8 months), Liang and Soong[9] showed 86.9% cure versus 86.4% subjective cure, respectively. When assessing objective cure by urodynamics studies, 1-hour pad test, and voiding diary at 6 months, TVT was associated with an 82.6% cure versus 77.3% in the laparoscopic group. Operative time and time to resumption of spontaneous urination was significantly lower in the TVT group.

Both TVT and laparoscopic Burch colposuspension have been compared to the gold standard open Burch colposuspension. Two randomized trials comparing the results of TVT to open Burch colposuspension showed similar objective and subjective cure rates from both procedures.[1,10] Moehrer et al[11] systematically reviewed laparoscopic colposuspension using the Cochran Incontinence Review Group's controlled trials registrar. Meta-analysis of 5 randomized trials (Burton G. A three-year prospective randomized urodynamics study comparing open and laparoscopic colposuspension [abstract]. Neurourol Urodyn 1997;16:353-4), (Carey M, Rosamilia A, Maher C, et al. Laparoscopic versus open colposuspension: a prospective multicentre randomized single-blind [abstract]. Neurourol Urodyn 2000;19:389-91), (Summitt RL, Lucente VL, Karram MM, Shull BL, Bent AE. Randomized comparison of laparoscopic and transabdominal Burch urethropexy for the treatment of genuine stress incontinence [abstract]. Obstet Gynecol 2000;95: S2)[12,13] and 3 "quasi-randomized" trials[14–16] demonstrated that subjective perception of cure showed no difference between open and laparoscopic colposuspension. When one poor-quality trial[13] was excluded from the analysis for objective cure, the cure rate for stress urinary incontinence was lower for the laparoscopic compared with the open colposuspension procedure (RR 0.91, 95% CI 0.82–1.01), with 8% more failures for laparoscopy compared with open procedures. Based on a single trial, the reviewers concluded that 2 stitches placed on each side of the bladder neck are better than one.[14] Overall, the authors concluded that the evidence for laparoscopic Burch colposuspension is limited by short-term follow-up and small numbers; therefore, valid conclusions are difficult to make.

Nilsson et al[17] published long-term objective results of the TVT procedure for primary stress urinary incontinence from a Nordic multicenter trial of 90 subjects. At a median follow-up of 56 months, 85% of patients were objectively and subjectively cured, 10.6% were improved, and 4.7% were regarded as failures. There were no cases of mesh erosion or permanent retention. Regarding laparoscopic colposuspension, there are no long-term studies comparable to those for TVT. Cure rates range from 69% to 100%,[18] with longest mean follow-ups of 34 months (subjective cure rate of 69% reported by Lobel and Davis[19]) and 24 months (objective cure rate of 89% reported by Ross[20]).

There are many strengths in this randomized clinical trial. An experienced research nurse obtained preoperative and postoperative questionnaire and physical examination data, thereby removing the potential bias that might occur when outcomes are obtained by the operating surgeon. Two surgeons who were blinded to the participant and procedure reviewed the postoperative urodynamic testing results. Follow-up of all patients (except those who chose not to or were unable to return) was at least 1 year, and mean follow-up in all patients was 21 months. Satisfaction rates were equally high between groups, which supports the use of both procedures as acceptable surgical treatment for primary urodynamic stress incontinence.

There are several limitations to this investigation. First, the sample size is small, and desired enrollment was not met. A larger, sufficiently powered study would address a wider scope of associated complications with both procedures and define the specific indications for each procedure. When comparing groups, the number of complications was not statistically different because of the small sample size; however, the complications associated with TVT proved more serious in nature. We did find a clinically significant difference between the 2 procedures in our primary outcome and a statistically significant difference in some of our secondary outcomes. This is primarily because the magnitude of the differences between the 2 procedures was considerably greater than we initially estimated in our a priori sample-size calculation. For instance, the relatively large difference in subjective continence between groups was unexpected and contributed to our ability to detect significant differences with fewer subjects enrolled. So, although we did not meet our intended sample size, the magnitude of the differences that we found was large enough to make the results of this trial valid. The significant difference in cure rates does not necessarily imply that TVT is a superior procedure to the laparoscopic Burch colposuspension because patient satisfaction was equally high in both groups. It does seem that the patients in the laparoscopic Burch group were subjectively happier than their urodynamic studies indicated. Most patients in the Burch group had significant improvements in number of urine leakage episodes and Urogenital Distress Inventory and Incontinence Impact Questionnaire scores. The discrepancy in objective cure and subjective improvement may be a reflection of the tolerance of the incontinence symptoms by the patients in this group.

It is also worth noting that this study was not stopped because of an interim analysis of the data. The criteria used for stopping a trial early based on the results of an interim statistical analysis that suggests the superiority of one intervention of the other are purposefully stringent and require *P* values much less than .05 to account for multiple testing of the data. We planned no interim analysis for this trial, and our results are likely not dramatic enough to have warranted trial stoppage using traditional criteria. Rather, our trial was stopped because of lack of funding and continued slow recruitment (only

half of the intended sample size had been recruited during a period that was twice the intended duration of our study). Statistical analysis was not performed until the decision to stop the study had been made and subject follow-up completed.

When comparing our study with previously published series of TVT or laparoscopic colposuspension, there are a few differences that are noteworthy. The 81% cure rate for stress incontinence for the laparoscopic colposuspension was similar to past studies. However, the 97% cure rate for TVT was higher than most studies of this procedure. This high cure rate, combined with a higher rate of voiding dysfunction, suggests that we may be adjusting the TVT tape with a higher amount of tension than other groups. In addition, the majority of TVT procedures were performed under general anesthesia in this investigation, which may affect tension adjustment of the sling. Also, uniform application of suprapubic tubes in both groups could have affected the number of days to normal voiding because our criteria for suprapubic tube removal may have been more stringent than in previously published TVT studies. Finally, conversion rate to laparotomy was higher than in other laparoscopic colposuspension series but similar to that of Unstun et al[8] All investigators in this trial had individually performed more than 80 laparoscopic Burch procedures before commencement of the trial. The conversions tended to be for reasons related to intraperitoneal surgery, not because of an inability to do the laparoscopic colposuspension. The technique of laparoscopic colposuspension was standardized and was identical to the open technique of the primary surgeon.

In our investigation, patients in the Burch group underwent significantly more adhesiolysis procedures, which is common when performing colposuspension by the intraperitoneal route as we did in most cases. This may be one of the factors that contributed to the longer total operative time associated with the laparoscopic Burch colposuspension when compared with the TVT procedure. Given the greater operative time and lower cure rate associated with laparoscopic Burch colposuspension, is the steep learning curve for acquisition of laparoscopic suturing skills required to perform laparoscopic Burch colposuspension worthwhile? Laparoscopic surgery enthusiasts (practicing or in training programs) would deem suturing skills essential when performing any advanced laparoscopic procedure, specifically laparoscopic myomectomy, laparoscopic sacral colpopexy, uterosacral ligament-vaginal apex suspension, and culdoplasty. Circumstances in which laparoscopic Burch colposuspension may be the procedure of choice, in spite of the superiority of TVT, include the following: the patient desires future pregnancy (because TVT is contraindicated by the manufacturer in this circumstance); the patient requires concomitant laparoscopic surgery, such as a paravaginal defect repair or gynecologic adnexectomy; the patient has an unrepaired inguinal hernia, has suspected bowel adhesions in the suprapubic area, or has a femoral-femoral bypass graft that would make the blind passage of TVT trocars into the retropubic space undesirable; or the patient does not desire or is allergic to polypropylene mesh.[21]

In summary, the TVT procedure resulted in significantly greater subjective cure rates for urodynamic stress incontinence than did the laparoscopic Burch colposuspension in our hands. However, patients in both groups were extremely satisfied with surgery after 2 years of follow-up.

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