A prospective randomized study comparing modified Burch retropubic urethropexy and suburethral sling for treatment of genuine stress incontinence with low-pressure urethra

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OBJECTIVE: The aim of this study was to compare a modified Burch procedure with a suburethral sling for the treatment of stress incontinence complicated by a low-pressure urethra.

STUDY DESIGN: Thirty-six women with stress incontinence, low-pressure urethra, and urethral hypermobility (straining cotton swab angle ≥30°) were randomly assigned to undergo either a modified Burch procedure (n = 19) or a suburethral sling (n = 17). Objective and subjective cure rates at 3 months after the operation were the primary outcome measures. Comparisons of group means were performed with the Student *t* test for independent groups, and proportions were compared with the Fisher exact test.

RESULTS: After the operation the 2 groups had statistically similar cure rates and voiding function. Urethral closure pressure, pressure transmission ratios, and maximum detrusor pressure during voiding were significantly higher in the sling group.

CONCLUSION: At 3 months there were no clinically significant differences between the groups treated with suburethral sling and modified Burch procedures. (Am J Obstet Gynecol 2000;182:30-4.)

Key words: Burch, sling, stress incontinence, urethropexy

Since 1907, when Giordano[1] described the use of a gracilis muscle flap for the correction of stress incontinence, a tremendous number of anti-incontinence procedures have been described. Two of the most widely used procedures for the correction of stress incontinence are retropubic urethropexy as described by Burch[2] and the suburethral sling. The Burch procedure and its various modifications all work by creating a shelf of endopelvic connective tissue and vaginal tissue at the level of the bladder neck and fastening it to the iliopectineal ligament. Many different techniques and materials have been used for sling procedures, but the basic design in all cases involves placement of a nonabsorbable autologous or heterologous piece of material under the urethrovesical junction and anchoring it either to the retropubic structures or the abdominal wall structures or to both. Many factors influence the surgeon's decision as to which technique to use. Because sling procedures have been associated with higher rates of postoperative voiding dysfunction,[3] they are commonly reserved for patients with complicated stress incontinence resulting at least partially from intrinsic urethral sphincteric weakness or damage.

In 1987 Sand et al[4] reported on a subgroup of patients who were found to have an unusually high failure rate after the modified Burch colposuspension. These procedures were performed in a standard fashion that placed minimal tension on the sutures at the time of fixation to the ligament. We found that the group of women with urethral closure pressures ≤20 cm H_2O had a 54% objective failure rate at 3 months after the operation, compared with an 18% objective failure rate in the group with higher closure pressures. We concluded that patients with such "low-pressure urethras" might be better served by sling procedures for the correction of stress incontinence. Since then we have questioned whether the poor success rates described in that study were a result of the minimal tension used when the Burch sutures were secured. Subsequent experience has suggested that tying the Burch sutures more tightly could improve the success rates without causing the voiding dysfunction typically attributed to suburethral slings. The purpose of this study was to evaluate and compare results of a modified Burch procedure with tighter sutures against those of a suburethral sling for the treatment of women with genuine

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Table I. Preoperative characteristics and urodynamic findings of study patients

	Burch group (n = 19)	*Sling group (n = 17)*	*Statistical significance**
Age (y, mean ± SD)	61.3 ± 10.3	60.4 ± 8.5	*P* = .78
Parity (mean ± SD)	2.8. ±.1.8	3.2 ± 1.1	*P* = .49
Maximum urethral closure pressure (cm H_2O, mean ± SD)	12.1 ± 4.6	13.1 ±.4.3	*P* = .48
Pressure transmission ratio (mean ± SD)	0.91 ±.08	0.94 ±.14	*P* = .43
Functional urethral length (mm, mean ± SD)	18.0 ± 6.3	18.1 ± 6.4	*P* = .98
Detrusor instability (No.)	18 (95%)	7 (41%)	*P* = .01
Voiding by Valsalva maneuver (No.)	7 (36.8%)	5 (29.4%)	*P* = .73
Postvoid residual volume (mL, mean ± SD)	25.4 ± 30.1	8.5 ± 4.8	*P* = .03
Maximum flow rate during void (mL/s, mean ± SD)	13.3 ± 5.1	12.3 ± 5.0	*P* = .57
Average flow rate during void (mL/s, mean ± SD)	5.7 ± 2.9	5.3 ± 2.7	*P* = .68
Maximum detrusor pressure during void (cm H_2O, mean ± SD)	20.3 ± 9.5	18.1 ± 6.4	*P* = .54

*Means were compared with the Student *t* test for independent groups. Proportions were compared with the Fisher exact test.

stress incontinence, urethral hypermobility, and low-pressure urethra.

Material and methods

Patient evaluation before enrollment in the study included a standardized history, physical examination including a directed neurologic evaluation, catheterized urinary specimen for postvoid residual volume determination and culture, cotton swab test, spontaneous uroflowmetry, 24-hour voiding diary, and a standardized multichannel urodynamic evaluation. Patients found to have genuine stress incontinence with urethral hypermobility, a maximum urethral closure pressure of ≤20 cm H_2O in the sitting position, and no significant anterior pelvic support defects were eligible for enrollment. Urethral hypermobility was defined as a maximum straining angle of ≥30° during cotton swab testing. The halfway system[5] was used for the grading of pelvic organ prolapse, and no patient in the study had anterior vaginal wall prolapse below the midvaginal plane. A power calculation was done on the basis of the 54% failure rate reported in the previously mentioned article by Sand et al.[4] It was determined that ≥30 patients (15 in each arm) would need to be enrolled to achieve an 80% power for detecting a significantly lower failure rate in the modified Burch group. It was assumed on the basis of historical data that the sling group in this study would have a cure rate for stress incontinence ≥90%.

Multichannel urodynamic studies included sitting and standing urethrocystometry; urethral closure pressure profiles at rest, while coughing, and during Valsalva maneuver, all at maximum cystometric capacity; and pressure-voiding studies. Abdominal, urethral, and bladder pressures were measured with 8F Mikrotip (Millar Instruments, Inc, Houston, Texas) transducer catheters. Studies were performed with a Urolab 1156 (Life-Tech, Inc, Stafford, Tex) as previously described.[6] Between April 1990 and November 1996, all women reporting to our center who met these inclusion criteria were offered enrollment in the study group, and 37 women were prospectively allocated in a randomized fashion to undergo either a modified Burch retropubic urethropexy or a suburethral sling. All subjects completed institutional review board–approved consent procedures before being enrolled. All subjects agreed to undergo another set of history, physical examination, and urodynamic studies at 12 weeks after the operation. Thirty-six patients underwent operations; the other patient had the procedure canceled after her enrollment because of a significant cardiac risk. Nineteen patients underwent the modified Burch procedure, and 17 patients underwent the sling procedure.

The Burch procedures were performed with four 2-0 polytetrafluoroethylene sutures (Gore-Tex; W.L. Gore & Associates, Inc, Flagstaff, Ariz). Except for the tension placed on the periurethral sutures, the Burch procedures conformed to the principles of the Tanagho[7] modification. When the time came for the tying of the Burch sutures, the subjects were taken out of a Trendelenberg position, and a cotton swab applicator was placed in the urethral meatus to the level of the urethrovesical junction. The sutures were then tied such that the cotton swab made a –10° to –20° angle with the horizontal, as measured with a goniometer. Other than in this study, our standard tension on Burch sutures creates a 0° to –5° angle with the horizontal. The cotton swab standard of –10° to –20° was chosen for this study on the basis of past experience to represent a moderate increase in the tension on the Burch sutures.

All sling procedures were performed as described by Horbach et al[8] with a continuous polytetraflouroethylene (Gore-Tex Soft Tissue Patch; W.L. Gore) strip running from the rectus fascia into the retropubic space and beneath the urethra at the level of the urethrovesical junction. Sling tension was also determined by cotton swab testing. All slings were placed under minimal tension such that the resting angle of the urethra was 0° to 10°. All procedures were performed under the direct supervision of the senior author (P.K.S.).

A suprapubic catheter was placed in all patients, and

Table II. Postoperative characteristics and urodynamic findings of study patients

	Burch group (n = 19)	*Sling group (n = 17)*	*Statistical significance**
Hospital stay (d, mean ± SD)	5.0 ± 1.4	5.1 ± 1.2	*P* = .79
Time to removal of suprapubic catheter (d, mean ± SD)	13.8 ± 16.5	23.3 ± 24.4	*P* = .19
Postvoid residual volume (mL, mean ± SD)	51.8 ± 89.7	31.1 ± 27.0	*P* = .35
Voiding by Valsalva maneuver (No.)	6 (31.6%)	7 (41.2%)	*P* = .73
Maximum flow rate during void (mL/s, mean ± SD)	10.6 ± 5.3	13.5 ± 6.6	*P* = .17
Average flow rate during void (mL/s, mean ± SD)	4.7 ± 3.0	4.8 ± 2.8	*P* = .89
Maximum voiding detrusor pressure (cm H_2O, mean ± SD)	21.3 ± 8.0	28.8 ± 12.3	*P* = .04
De novo detrusor instability (No.)	1 (5.3%)	4 (23.5%)	*P* = .17
Functional urethral length (mm, mean ± SD)	25.7 ± 10.0	27.2 ± 7.3	*P* = .60
Maximum urethral closure pressure (cm H_2O, mean ± SD)	16.4 ± 8.2	39.8 ± 23.0	*P* = .0008
Pressure transmission ratio (mean ± SD)	1.13 ± 0.18	1.54 ± 0.38	*P* = .001

*Means were compared with the Student *t* test for independent groups. Proportions were compared with the Fisher exact test.

voiding trials were initiated on postoperative day 1. The suprapubic catheters were removed when postvoid residual volumes remained <100 mL and did not exceed a third of the spontaneously voided volumes for 24 hours. All reported 3-month postvoid residual volumes were determined from catheterized specimens taken within 10 minutes of a spontaneous void. A patient was considered to have an objective cure of stress incontinence if there was no leakage of urine at maximum cystometric capacity while coughing or performing Valsalva maneuvers in either the sitting or standing position during urodynamic studies. Detailed patient questionnaires and histories were used to establish subjective cure rates. A patient was considered to have a subjective cure if she reported no loss of urine during any activity that increases intra-abdominal pressure.

All terminology conforms to that proposed by the International Continence Society[9] except where specifically mentioned. Comparison of group means was performed with the Student *t* test for independent groups. Proportions were compared with the Fisher exact test.

Results

Before the operation there were no statistical differences between the 2 groups with respect to age, parity, maximum urethral closure pressure, pressure transmission ratio, functional urethral length, voiding mechanism, urinary flow rates, detrusor pressure during voiding, or urinary retention. There were significantly more patients in the Burch group with detrusor instability before the operation (95% vs 41%; *P* = .01), and the Burch group also had a higher average postvoid residual volume before the operation (25.4 ± 30.1 mL vs 12.3 ± 5.0 mL; *P* = .03; Table I).

In the Burch group 7 patients had undergone a total of 8 previous anti-incontinence procedures before enrollment; these included 4 needle procedures, 3 Marshall-Marchetti-Krantz procedures, and 1 anterior colporraphy. In the sling group 9 patients had previously undergone a total of 10 anti-incontinence procedures; these included 2 needle procedures, 5 Marshall-Marchetti-Krantz procedures, and 3 anterior colporraphy procedures.

As Table II shows, there were no statistical differences between the 2 groups with respect to length of postoperative hospital stay, duration of postoperative suprapubic catheterization, postvoid residual volume, voiding mechanism, maximum or average flow rates during voiding, de novo detrusor instability, and functional urethral length. After the operation the sling group had significantly higher maximum detrusor pressures with voiding (*P* = .04), maximum urethral closure pressure (*P* = .0008), and pressure transmission ratio (*P* = .001). Among the 18 patients in the Burch group with preoperative detrusor instability, 11 (61%) had persistent detrusor instability at 3 months. The patient in the Burch group who had not been found to have detrusor instability before the operation demonstrated de novo detrusor instability after the operation. In the sling group all 7 subjects with preoperative detrusor instability had persistent detrusor instability at 3 months. Four patients in the sling group (24%) demonstrated de novo detrusor instability at 3 months (Table II). Each of the 3 patients in the Burch group with preoperative urinary retention had persistent retention at 3 months. Although no patients in the sling group had preoperative urinary retention, 3 were found to have retention at 3 months after the operation.

After the operation the maximum detrusor pressure during voiding in the sling group (28.8 ± 12.3 cm H_2O; *P* = .04) was significantly higher than that in the Burch group (21.3 ± 8.0 cm H_2O). There were no significant differences between the 2 groups in postoperative maximum and average flow rates during voiding studies. Postoperative postvoid residual volumes were similar between the 2 groups, as were the numbers of patients found to use a Valsalva maneuver when voiding. No statistical difference in functional urethral length was found

Table III. Objective and subjective cure rates at 3 months

	Burch group (n = 19)		*Sling group (n = 17)*		
	No.	*%*	*No.*	*%*	*Statistical significance**
Objective cure	17	90	17	100	$P = .49$
Subjective cure	18	95	17	100	$P = 1.00$

Patients were considered to have an objective cure if they had no leakage of urine at maximum cystometric capacity while coughing or performing the Valsalva maneuver, either sitting or standing. Patients were considered to have a subjective cure if they reported no urine loss during any activity that increased intra-abdominal activity.
*Statistical analysis was done with the Fisher exact test.

between the 2 groups at 3 months, but both maximum urethral closure pressures ($P = .0008$) and pressure transmission ratios ($P = .001$) were significantly higher in the sling group (Table II).

Intraoperative complications were limited to 1 cystotomy in a patient who underwent a Burch procedure. This cystotomy was recognized during the operation and repaired without incident. Two patients in the sling group and 4 patients in the Burch group underwent concurrent procedures in addition to the anti-incontinence operation. In the Burch group these procedures consisted of a ventral hernia repair, a tubal ligation, removal of a Bartholin duct cyst, and a posterior colporraphy. Two patients in the sling group underwent concurrent posterior colporraphy.

No patients were unavailable for follow-up at the 3-month mark. There were no statistical differences between either the subjective or objective cure rates at this interval. The Burch group was found to have a subjective cure rate for genuine stress incontinence of 95% (18/19) and an objective cure rate of 90% (17/19) at 3 months (Table III).

At 3 months no patients in either group had urethral hypermobility or significant pelvic organ prolapse. No patients in the sling group had erosion of the sling material through the vaginal epithelium.

Comment

Despite the fact that nearly 200 different operations for the correction of stress incontinence have been described, few prospective randomized comparative trials exist in the literature. To the best of our knowledge there has been no other prospective randomized trial to compare the Burch retropubic urethropexy with the suburethral sling in patients with genuine stress incontinence, urethral hypermobility, and low-pressure urethra. To our knowledge the only other prospective randomized trial comparing the Burch and sling procedures was published by Enzelsberger et al[10] in 1996 and did not include any patients with preoperative detrusor instability or low-pressure urethra. Those authors reported no significant differences in cure rates between the 2 groups at 32 and 48 months. In their study neither functional urethral length nor maximum urethral closure pressure was significantly different in either group after the procedure. The pressure transmission ratios of both groups in their study increased significantly after the operation, and residual urine volumes of >100 mL were found in 13% of the patients in the sling group and 3% of the patients in the Burch group ($P < .05$). These authors did not report the rates of de novo detrusor instability in the Burch and sling groups.

Nine other prospective randomized comparative studies involving the open Burch procedure and none involving the sling procedure were found in a comprehensive MEDLINE search combined with a review of all available reference lists.[11-19] In these 9 reports success rates for the Burch procedure were reported to be between 82% and 91% for 6 months to 5 years. As with all other anti-incontinence procedures, cure rates for both the Burch and sling procedures have been reported to decline with time.

Retrospective reviews of both sling and Burch procedures report similar success rates. Because of the higher complication rates associated with slings, these procedures are generally reserved for patients with special risk factors complicating stress incontinence. Such risk factors include but are not limited to previous failed incontinence procedures, chronic obstructive pulmonary disease, and intrinsic sphincteric deficiency of the urethra.[20] Although no efforts were made to exclude such patients from our study group, the only such risk factors present in our patient population were previous operations and low-pressure urethra. We no longer use polytetrafluoroethylene for our suburethral slings because of the relatively high rate of local complications reported by Weinberger and Ostergard.[21]

One patient in the Burch group had severe urinary retention both before and after the operation, so the postvoid residual volumes reported are slightly skewed by this outlier. If we had excluded this patient from the mean comparison before the operation, there still would not have been a significant difference between the 2 groups. A relatively high number of patients in this study were found to have detrusor instability, and we attribute this finding to the fact that we have a referral practice.

The most obvious shortcomings of this study are the small patient numbers and short follow-up interval. Our

strict inclusion criteria made recruitment for this study relatively difficult, and we do not have enough patients to fully assess the postoperative voiding dysfunction in the 2 groups. However, when one considers that the poor success rates in the low-pressure urethra group originally reported by Sand et al[4] were also 3-month results, our findings are more encouraging. Before enrollment of patients in this study a power calculation was performed that called for 30 subjects to show a 40% difference in cure rates between the 2 groups. These figures were based on the cure rates previously reported by Sand et al.[4] The lack of statistical significance may be because of the unexpectedly high cure rate for the Burch group. With time the cure rates for each group are sure to decline, and they may do so at different rates. Long-term objective follow-up data are being collected for all patients and will be reported. Our short-term data suggest that the modified Burch procedure as described here with sutures tied at slightly greater than normal tension may be equivalent to the suburethral sling for the population of patients with stress incontinence who have urethral hypermobility and a low-pressure urethra.

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