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ORIGINAL ARTICLE

Patrick J. Culligan · Roger P. Goldberg · Peter K. Sand

A randomized controlled trial comparing a modified Burch procedure and a suburethral sling: long-term follow-up

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Abstract The aim of this study was to compare the long-term results of a modified Burch procedure with a sling procedure for the treatment of stress incontinence with a low-pressure urethra. Thirty-six women with urodynamic stress incontinence, low-pressure urethra, urethral hypermobility and no significant pelvic organ prolapse were randomly assigned to undergo either a modified Burch procedure ($n=19$) or a sling placement ($n=17$). Cure of the stress incontinence (defined as a negative stress test and negative pad-weight test) was the primary long-term endpoint. Secondary endpoints included subjective cure of stress incontinence (defined as no incontinence episodes on a 1-week voiding diary) and voiding function studies. Comparisons of group means were performed with the Mann–Whitney *U*-test, pooled variance *t*-tests and separate variance *t*-tests. Proportions were compared with Fisher's exact test. A logistic regression analysis was performed to control for covariates that differed in our two groups despite randomization. Long-term follow-up (mean = 72.6 months) was available for 82% (28/34) of the original study group. The objective cure rates for the Burch and sling groups were 84.6% and 100%, respectively ($P=0.17$). Mean uroflowmetry rates for the Burch and sling groups were 7.38 and 6.8 ml/s, respectively ($P=0.58$, 95%CI −2.5, 4.4). Mean postvoid residual volumes for both groups were 35 ml ($P=0.97$, 95% CI −23.8, 65.9). Two sling patients (12%) required partial resection of their slings because of erosion. Both patients remained continent. In terms of voiding function and stress incontinence cure, there were no differences between groups undergoing modified Burch or sling procedures for treatment of urodynamic stress incontinence with low-pressure urethra.

Keywords Burch · Sling · Stress incontinence · Urethropexy

Abbreviations *SI* Stress incontinence · *UI* Urge incontinence

Introduction

The surgical treatment of stress urinary incontinence is an example of the close relationship between art and science in medicine. For nearly 100 years, surgeons have struggled to find the ideal treatment algorithm for this condition. Currently two basic approaches, the Burch retropubic urethropexy and the suburethal sling, are regarded as the most effective procedures for long-term success [1], but there is no consensus as to which of them is the better operation. In a recent decision analysis, Weber et al. [2] found the overall effectiveness of Burch and sling operations to be 94.8% and 95.3%, respectively. Although these rates suggest that the Burch and sling procedures are interchangeable, strong opinions exist among experts regarding the relative benefits of each [3, 4]. This debate centers on two basic controversial assumptions [1, 3, 4, 5, 6, 7] (1) slings cause more voiding dysfunction and de novo detrusor instability than do Burch procedures, and (2) Burch procedures do not work as well as slings when used for the treatment of intrinsic urethral sphincter deficiency.

The assumption that Burch procedures are inadequate for the treatment of intrinsic urethral sphincter deficiency stems largely from a 1987 retrospective study [7]. In that report, a group of women with urethral closure pressures ≤ 20 cmH_2O had an objective cure

P. J. Culligan (✉) · R. P. Goldberg · P. K. Sand
Evanston Continence Center, Northwestern University Medical School, Evanston, Illinois USA

Present address: P. J. Culligan
Department of Obstetrics Gynecology and Women's Health, Division of Urogynecology and Reconstructive Pelvic Surgery, University of Louisville Health Sciences Center,
315 East Broadway M-18, Suite 4002, Louisville, KY 40202 USA
E-mail: pculligan@louisville.edu
Tel.: +1-502-6292442
Fax: +1-502-6292444

rate of 46% 3 months after the operation, compared with an 82% cure rate in the group with higher closure pressures. As a follow-up to this retrospective work, we initiated a randomized controlled trial comparing a modified Burch procedure to suburethral slings for patients with urethral closure pressures ≤ 20 cmH_2O. The early outcomes from that trial were reported earlier [8], and now we are reporting the long-term results for the same group of patients.

Materials and methods

Between April 1990 and November 1996, all women reporting to our center who met the inclusion criteria were offered enrolment in the study group. Patients found to have urodynamic stress incontinence with urethral hypermobility and a maximum urethral closure pressure of ≤ 20 cmH_2O were eligible. Patients were excluded if they had significant anterior or apical pelvic support defects, defined as descent beyond the midvaginal plane [9]. Thirty-six patients were included. Nineteen patients underwent the modified Burch procedure and 17 underwent the sling procedure. No patients who met the inclusion criteria refused to participate in the study.

A prospective power calculation was performed on the basis of the reported [7] 46% cure rate associated with Burch procedures when urethral closure pressures were ≤ 20 cmH_2O. We did not know whether our modification to the Burch procedure would improve these results, therefore we assumed no benefit for the purposes of the power calculation. Thus the assumed stress incontinence cure rates for the Burch and sling groups were 46% and 92%, respectively. In order to have 80% power to detect this difference, a total of 30 patients (15 in each arm) were required ($\alpha = 0.1$).

A comprehensive urogynecologic evaluation was performed for all patients prior to enrollment in the study, as previously described [8]. Multichannel urodynamic studies were performed with the Urolab 1156 (Life-Tech Inc., Stafford, Texas) as previously described [10]. Randomization was performed the day prior to each operation using a random number table. No blocking or stratification was added to the randomization. Only the study participants were blinded as to group assignment.

The Burch procedures were performed with four 2/0 polytetrafluoroethylene sutures (Gore-Tex; W.L. Gore & Associates, Flagstaff, AZ). Except for the tension placed on these sutures, the Burch procedures conformed to the principles of the Tanagho [11] modification. The Burch sutures for this study were tied moderately tighter than our standard Burch sutures. When the time came for the tying of the Burch sutures, the subjects were taken out of the Trendelenburg 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 swab made a –10° to –20° angle with the horizontal, as measured with a goniometer. Outside of 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 [11], with a continuous polytetrafluoroethylene (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 Burch and sling procedures were performed under the direct supervision of the senior author (P.K.S.).

At 3 months, objective cure of stress incontinence was defined as no leakage of urine during cough or Valsalva maneuver at maximum cystometric capacity with the patient in the sitting or standing position during multichannel urodynamic studies. At 3 months a patient was classified as subjectively cured of stress incontinence if she had no leakage episodes reported during a standardized 24-h voiding diary.

Our initial plan for long-term follow-up of these study patients included 1-year, 3-year and 5-year postoperative urodynamic studies. Unfortunately, only 10 patients returned for their 1-year studies. Therefore, we amended the plan for long-term follow-up in an effort to improve compliance. The Evanston Northwestern Healthcare Human Studies Committee approved this change of plans. They had also approved the original protocol. All subjects provided written consent for the original protocol as well as the modified protocol.

The modified long-term follow-up plan consisted of a voiding diary, pad-weight test, stress test, cotton swab test, and an uninstrumented uroflowmetry test. Long-term objective cure was our primary outcome measure. Objective cure was defined as a combination of no leakage of urine during stress testing at a bladder volume of 250 ml, and a negative pad-weight test as described by Lose [12]. As was the case at 3 months, voiding diaries [13] were used to establish long-term subjective cure of stress incontinence. Secondary endpoints included subjective cure of stress incontinence (defined as having no incontinence episodes on a 1-week voiding diary [13]), cotton-swab testing, postvoid residual volumes and urine flow rates. Independent non-blinded observers (i.e. urogynecology fellows not involved in the original operations) made all of the long-term assessments. The 1-week voiding diary included patient assessment of whether their leakage episodes were stress or urge related. In our analysis, any leakage episodes were then classified as either stress incontinence, urge incontinence or both. The mean number of stress incontinence (SI) and urge incontinence (UI) episodes were then compared between groups.

All terminology conformed to that proposed by the International Continence Society [14] except where specifically mentioned. Comparison of group means was performed with the Mann–Whitney *U*-test, pooled variance and separate variance *t*-tests; proportions were compared using Fisher's exact test. A logistic regression analysis was performed to control for covariates, which differed in our two groups despite randomization.

Results

Except for their preoperative postvoid residual volumes and rates of detrusor instability, the two groups were similar prior to the operations as previously reported [8] (Table 1).

The short-term data have already been reported [8]. Briefly, there were no clinically significant differences in the urodynamic parameters of the two groups at the 3-month postoperative interval, and objective cure rates for stress incontinence at that interval were 90% and 100% for the Burch and sling groups, respectively ($P = 0.49$) (Table 2).

Apart from two deceased patients, we were able to obtain long-term follow-up on 82% (28/34) of the original study group. Neither of the deceased had died as a result of surgery. Mean follow-up time was 72.6 months (range 33–116 months). The last follow-up visits for the two deceased patients were at 3 months after surgery, and so they were not included in this report.

The long-term objective follow-up is presented in Table 3. The long-term objective cure rate was 84.6% for the Burch group and 100% for the sling group ($P = 0.17$). There were no differences between the Burch and sling patients in terms of stress testing, pad-weight

testing, straining cotton-swab angle, mean postvoid residual volume, or maximum and mean flow rates.

The long-term subjective follow-up is presented in Table 4. Long-term subjective cure rates were 93% and 84% for the Burch and sling patients, respectively ($P = 0.47$). There were no differences between the Burch and sling patients in terms of nocturia or mean number of urge incontinence or stress incontinence episodes. The sling group had a shorter voiding interval of 2.7 versus 3.2 h in the Burch group ($P = 0.04$; 95% CI 0.23,1.16). Logistic regression analysis demonstrated that preoperative detrusor instability or postvoid residual volumes were not associated with our endpoints of interest.

Two sling patients (12%) suffered partial erosions of their slings. These presented between 3 and 12 months after surgery, and both were successfully managed in the office by resecting the exposed portions of their slings. These patients remained dry after treatment of their erosions, one at 64 weeks and the other at 82 weeks after the erosion.

One sling patient required urethrolysis 5 months post surgery owing to prolonged urinary retention. This patient remained continent 84 months after her original operation. The other two patients in the sling group with urinary retention at 3 months had spontaneous resolution of their retention between 3 and 6 months after surgery.

Comments

To the best of our knowledge there has been no other randomized controlled trial comparing the Burch retropubic urethropexy with the suburethral sling in patients with stress incontinence complicated by urethral closure pressures ≤ 20 cmH_2O.

We found excellent subjective and objective cure rates in both groups. Interestingly, the subjective cure rate in the sling group was 84%, but the objective cure rate was 100%. The opposite situation was found in the Burch group, which had a subjective cure rate of 93% and an objective cure rate of 84%. One possible explanation of this phenomenon relates to our definition of subjective cure (i.e. no incontinence episodes on a 1-week voiding diary). When completing their voiding diaries, patients characterized their leakage episodes as either stress, urge or mixed incontinence; we did not rely on the accuracy of this information to classify patients as 'subjectively cured' in our analysis. Therefore, a woman reporting only urge incontinence episodes on her diary would have been classified as a subjective failure.

A relatively high number of patients in this study were found to have preoperative detrusor instability, and we attribute this finding to the fact that we have a referral practice. We cannot explain the discrepancy in preoperative detrusor instability or postvoid residual volume between the two groups, as randomization was performed without consideration of urodynamic findings. Despite these differences, neither variable was associated with our endpoints of interest in a logistic regression analysis.

Although the sling group reported a shorter voiding interval (3.2 vs 2.7 h, $P = 0.04$ 95% CI 0.23, 1.16), the clinical significance of this difference is questionable.

We did not include Valsalva leak-point pressure assessment in the pre- or postoperative evaluation of these patients, because that measure was described 3 years after the start of this trial.

We no longer use polytetrafluoroethylene for sling procedures because of the relatively high rate of local complications reported here and previously by Bent [15]. This fact somewhat undermines the external validity of our findings.

The most obvious shortcoming of this study was its relatively small number of patients. Our strict exclusion criteria (i.e. excluding patients with significant prolapse, fixed urethras or urethral closure pressures greater than 20 cmH_2O), although they allowed for the most

Table 1 Preoperative characteristics and urodynamic findings of study patients

	Burch group ($n = 19$)	Sling group ($n = 17$)	Statistical significance (P value)	95% confidence interval for mean difference
Age (y, median ± SD)[c]	61.3 ± 10.3	60.4 ± 8.5	0.78	NA
Parity (mean ± SD)[b]	2.8 ± 1.8	3.2 ± 1.1	0.49	−1.3, 0.75
Body mass index[b]	21.8 ± 3.7	23.7 ± 5.6	0.23	−5.1, 1.3
Maximum cystometric capacity (mL)[b]	385 ± 63.3	412 ± 99.5	0.33	−82.9, 28.8
Maximum urethral closure pressure (cmH_2O, mean ± SD)[b]	12.1 ± 4.6	13.1 ± 4.3	0.48	−4.1, 1.9
Pressure transmission ratio (mean ± SD)[b]	0.91 ± 0.8	0.94 ± 1.4	0.43	−0.1, 0. 04
Functional urethral length (mm, mean ± SD)[b]	18.0 ± 6.3	18.1 ± 6.4	0.98	−4.4, 4.3
Detrusor instability (no.)[d]	18 (95%)	7 (41%)	0.01	NA
Voiding by Valsalva maneuver (no.)[d]	7 (36.8%)	5 (29.4%)	0.73	NA
Postvoid residual volume (ml, mean ± SD)[a]	25.4 ± 30.1	8.5 ± 4.8	0.03	NA
Maximum flow rate during void (ml/s, mean ± SD)[b]	13.3 ± 5.1	12.3 ± 5.0	0.57	−2.4, 4.4
Average flow rate during void (mL/s, mean ± SD)[b]	5.7 ± 2.9	5.3 ± 2.7	0.68	−1.5, 2.3
Maximum detrusor pressure during void (cmH_2O, mean ± SD)[b]	20.3 ± 9.5	18.1 ± 6.4	0.54	−8.5, 4.7

[a]Separate variance t-test
[b]Pooled-variance t-test
[c]Mann–Whitney U-test
[d]Fisher's exact test

Table 2 Postoperative characteristics and 3-month urodynamic findings of study patients (previously published [7])

	Burch group ($n=19$)	Sling group ($n=17$)	Statistical significance (P value)[a]	95% confidence interval for mean difference
Postvoid residual volume (mL, mean ± SD)[a]	51.8 ± 89.7	31.1 ± 27.0	0.35	−24.9, 67.1
Maximum flow rate during void (ml/s, mean ± SD)[b]	10.6 ± 5.3	13.5 ± 6.6	0.17	−6.9, 1.2
Average flow rate during void (ml/s, mean ± SD)[b]	4.7 ± 3.0	4.8 ± 2.8	0.89	−2.5, 1.2
Maximum voiding detrusor pressure (cmH_2O, mean ± SD)[b]	21.3 ± 8.0	28.8 ± 12.3	0.04	−14.4, −0.6
De novo detrusor instability (no.)[d]	1 (5.3%)	4 (23.5%)	0.17	NA
Functional urethral length (mm, mean ± SD)[b]	25.7 ± 10.0	27.2 ± 7.3	0.60	−7.5, 4.4
Maximum urethral closure pressure (cmH_2O, mean ± SD)[b]	16.4 ± 8.2	39.8 ± 23.0	0.0008	−34.9, −11.9
Maximum cystometric capacity (ml)[b]	398 ± 76.8	444 ± 95.9	0.12	−104.6, 12.5
Pressure transmission ratio (mean ± SD)[c]	1.13 ± 0.18	1.54 ± 0.38	0.001	NA

[a]Separate variance t-test
[b]Pooled-variance t-test
[c]Mann–Whitney U-test
[d]Fisher's exact test

Table 3 Long-term objective follow-up

	Burch group ($n=15$)	Sling group ($n=13$)	P value	95% confidence interval for mean difference
Positive stress test (no.)[d]	15.4%	0%	0.17	NA
Positive pad test (no.)[d]	7.6%	0%	0.39	NA
Straining cotton-swab angle[c]	−1.0° (−18°, + 22°)	−3.18° (−20°, + 15°)	0.62	NA
Mean PVR (ml)[b]	35	35	0.97	−23.8, 65.9
Maximum flow (ml/s)[b]	15.36	14.80	0.85	−3.7, 7.7
Mean flow (ml/s)[b]	7.38	6.80	0.58	−2.5, 4.4
Objective cure of stress incontinence (n0.)[d]	84.6%	100%	0.17	NA

[a]Separate variance K-test
[b]Pooled-variance t-test
[c]Mann–Whitney U-test
[d]Fisher's exact test

Table 4 Long-term subjective follow-up

	Burch group ($n=15$)	Sling group ($n=13$)	P value	95% confidence interval for mean difference
Mean daily UI episodes[b]	0.33	0.31	0.93	−2.1, 2.0
Mean daily SI episodes[a]	0	0.15	0.12	−0.6, 0.3
Mean daily nocturia episodes[b]	1.25	1.19	0.87	−1.1, 1.1
Voiding frequency (hours between voids)[b]	3.2	2.7	0.04	0.23, 1.16
Subjective cure of stress incontinence (no.)[d]	93%	84%	0.47	NA

[a]Separate variance t-test
[b]Pooled-variance t-test
[c]Mann–Whitney U-test
[d]Fisher's exact test

statistically valid study design, made patient recruitment difficult. On first glance, our study could be dismissed because of the possibility of a type II statistical error; however, our enrolment exceeded the requirements of our power calculation, which called for 15 patients in each arm. That power calculation was based on our retrospective study [7] in which the 3-month objective cure rate was found to be 46% when patients with maximum urethral closure pressures ≤ 20 cmH_2O underwent a standard Burch procedure. At the start of this study there was no other information available regarding surgical cure rates among patients with maximum urethral closure pressure values ≤ 20 cmH_2O.

We chose not to use 'intent to treat' analysis for this paper, because that technique is designed to deal with the potential bias associated with differential loss to follow-up between groups. We had no such differential loss to follow-up. We had four patients who were lost to follow-up in each arm. Therefore, we have no reason to believe that attrition affected the two groups differently.

The ideal scientific approach to a trial of Burch versus sling procedures for patients with poor urethral sphincter function would have been to have standard tension placed on the Burch sutures. Given the poor results in the above-mentioned study, however, we felt that doing so would not be prudent. Therefore, we decided to alter the Burch procedures for the purposes of this study by tying the sutures with a moderately increased amount of tension (cotton-swab angle –10° to –20°). Interestingly, the intraoperative differences in cotton-swab angle between the two groups did not persist. Nevertheless, the small increase in intraoperative

tension seems to have substantially improved the cure rates in the Burch group without changing the voiding function between the two groups.

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Editorial comment

The authors have to be congratulated on their effort to provide evidence-based results. They used different techniques to perform the Burch procedure from used in the 1987 paper, and compared it to another technique they no longer use. Their power calculation is based on unsatisfactory results reported in 1987 for the Burch colposuspension. These results made the difference in outcome, thereby decreasing the number of subjects needed for the study. In addition, they did not report results as ITT. In spite of these shortcomings the study provides clinically useful data that can be built on for future research. I find it interesting that the super-Burch is good for low-pressure urethras, contrary to the belief that excessive tension can lead to ISD.