

A Randomized Trial of Burch Retropubic Urethropexy and Anterior Colporrhaphy for Stress Urinary Incontinence

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Objective: In a randomized trial, we compared the success of Burch retropubic urethropexy to the modified anterior colporrhaphy for the treatment of genuine stress urinary incontinence.

Methods: Thirty-five patients with stress incontinence were randomly assigned to undergo Burch retropubic urethropexy or modified anterior colporrhaphy. Subjects had preoperative and 1-year postoperative physical examinations, multichannel urodynamic testing, 20-minute pad test, and subjective grading of incontinence severity with questionnaires. Data were evaluated using Fisher exact test, Wilcoxon two-sample test, logistic regression analysis, and analysis of variance.

Results: Objective cure 1 year postoperatively was significantly greater for the women treated by Burch retropubic urethropexy than by modified anterior colporrhaphy (16 of 18 [89%] versus five of 16 [31%], relative risk .15, 95% confidence interval .04, .59). Patients' subjective ratings of incontinence severity 1 year after surgical treatment were significantly lower in women who had Burch retropubic urethropexy.

Conclusion: Burch retropubic urethropexy yields a significantly superior objective cure for genuine stress urinary incontinence than the modified anterior colporrhaphy in a randomized trial. (Obstet Gynecol 1999;93:75-8. © 1999 by The American College of Obstetricians and Gynecologists.)

Many surgical treatments for genuine stress urinary incontinence have been reported, with the goal of elevating and stabilizing the urethrovesical junction in a retropubic position, forming a hammocklike urethral support layer. Burch retropubic urethropexy and modified anterior colporrhaphy are two such surgical treatments.

Anterior colporrhaphy, described by Kelly and Dunn in 1914¹ and later modified by Kennedy,² was the main surgical treatment of genuine stress urinary inconti-

nence for many years. Marked variability in success rates of anterior repair were reported, ranging from 27-91%.³⁻⁸ Alternative anti-incontinence procedures, such as Burch retropubic urethropexy, were developed because of the variable success of anterior repair and the evolution of understanding of urinary incontinence pathophysiology. The cure rates for the Burch procedure are consistent, ranging from 78-95%.^{6,7,9-14} At 5- to 10-year follow-up, the success rate of the Burch procedure declines slightly to 78-89%,^{7,11-13} but the success rate with the anterior repair decreases markedly to 31-37%.^{7,13}

Many objective, retrospective or prospective studies evaluated the success of the Burch procedure and anterior repair by the same operators,^{3,4,8,9,12-14} but only two randomized trials compared the Burch procedure with anterior repair.^{6,10} Both studies found the Burch significantly more successful than anterior repair, yet some authors continue to report considerable success with anterior repair, with cure rates ranging from 75-90%.^{3,4} The purpose of this study was to compare the success of Burch retropubic urethropexy and modified anterior colporrhaphy for treatment of genuine stress urinary incontinence in a randomized trial using multiple questionnaires and objective data.

Methods

After the study was approved by the Human Research Review Committee, eligible women with genuine stress urinary incontinence (defined as urodynamically demonstrated urine loss with cough or valsalva in the absence of detrusor contraction) who wanted operative repair were identified from the Gynecology Clinic at the Women's Health Center, University of New Mexico Hospital. Each had preoperative physical examination with grading of prolapse (grades 0-4)¹⁵ and mobility of urethrovesical

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junction using a cotton-tip applicator, multichannel urodynamic testing including cystometrogram, abdominal leak point pressure, urethral pressure profilometry, and uroflowmetry (Dantec UD 550 MK2; Dantec Medical Inc, Allendale, NJ), 20-minute intensive stress pad testing,¹⁶ and postvoid residual testing. Questionnaires rating incontinence severity, including ordinal scale rating of number of pads used (0 = none, 4 = more than one daily), number of incontinent episodes (0 = none, 6 = with every cough, sneeze, or laugh) and self assessment score (1 = dry, 10 = severe leakage), and overall quality of life according to the Incontinence Impact Questionnaire¹⁷ were administered by research nurses. Women were excluded from the study for incontinence of neurologic origin, detrusor instability, history of previous radical pelvic surgery, pelvic radiation, intrinsic sphincteric deficiency, and history of interstitial cystitis or urethral syndrome. Intrinsic sphincteric deficiency was defined as low abdominal leak point and maximal urethral closure pressures (under 65 and 20 cm of water, respectively) and poor urethral coaptation demonstrated cystoscopically.

After patients gave their informed consent, they were assigned by computer-generated randomization table to undergo Burch retropubic urethropexy or modified anterior colporrhaphy. Everyone except the author performing the randomization was blinded to the procedure until the day of surgery. Surgical procedures were standardized and performed by senior residents under supervision of the two senior authors. The Tanagho modification of the Burch procedure, with two permanent figure eight sutures (0-Ethibon or 0-Prolene; Ethicon Inc, Cincinnati, OH) bilaterally, was used.¹⁸ The modified anterior colporrhaphy was accomplished with two figure eight 0-polyglycolic acid sutures.^{3,4,8} All subjects had suprapubic catheters.

The postoperative course, morbidity, and length of suprapubic catheterization were recorded. One year after surgery, patients were evaluated using all tests performed preoperatively, including multichannel urodynamics.

The perioperative course, subjective and objective cure rates, subjective rating of incontinence symptomatology, and urodynamic indices of the two operative groups were compared at 1 year. Objective cure was defined as absence of urine loss during cough and Valsalva maneuver in the supine and standing positions, with the bladder filled to maximal cystometric capacity. Univariate analysis of binary and ordinal outcome variables were evaluated by Fisher exact test and Wilcoxon two-sample test, respectively. Continuous variables were evaluated using analysis of variance. Logistic regression analysis was used for multivariate analysis of binary outcomes. Statistical analysis was performed using Epi-Info Version 6 (Centers for Dis-

Table 1. Demographic Characteristics

Characteristic	Burch (n = 19)	Anterior colporrhaphy (n = 16)	P
Age (y)	44.5 ± 9.4	53.0 ± 11.8	.02
Parity	3.7 ± 2.1	4.1 ± 1.6	.55
BMI	29.6 ± 3.1	29.8 ± 3.1	.86
Hormonal status			
Premenopausal	14 (74)	5 (31)	.03
Postmenopausal	5 (26)	11 (69)	
Race			
White	6 (32)	4 (25)	.07
Hispanic	13 (68)	8 (50)	
Native American	0 (0)	4 (25)	

BMI = body mass index (kg/m²).

Values are given as mean ± standard deviation or n (%).

ease Control and Prevention, Atlanta, GA), and The Statistical Program/SAS (SAS Institute, Cary, NC) with $P < .05$ statistically significant.

Results

Between August 1994 and February 1997, 35 women participated in the study and completed 1-year follow-up. One woman from each group refused 1-year postoperative multichannel urodynamic testing. The woman from the Burch group completed subjective data only (questionnaires), which indicated a cure, whereas the other woman underwent all other aspects of the evaluation, including objective assessment of cure, which indicated a failure.

Women in the Burch group were significantly younger, and more were premenopausal (Table 1). There were no significant differences in other patient characteristics. Only one patient from the Burch group had previous anti-incontinence surgery, an anterior colporrhaphy. Preoperatively, no significant differences in pelvic organ prolapse, including grade of cystocele and mobility of the urethrovesical junction, subjective or objective rating of incontinence severity, or urodynamic indices, were noted between the groups.

At time of surgery, in addition to anti-incontinence procedures many women had concurrent procedures, including vaginal or abdominal hysterectomy and reparative operations. A significant difference between the two groups was noted in the method of cystocele repair. Anterior colporrhaphy was performed more frequently in the modified anterior colporrhaphy group (16 [100%], versus Burch, 3 [16%], $P < .001$), whereas paravaginal defect repair was more common in the Burch group (8 [42%] versus modified anterior colporrhaphy group, 1 [6%] $P = .02$). The frequency of other procedures was not significantly different between the groups.

Perioperative courses of the groups were similar.

Table 2. Cure at 1 Year

Evaluation of cure	Burch procedure	Anterior colporrhaphy	RR (95% CI)
Subjective	18/19 (95%)	3/16 (19%)	.16 (.04, .58)
Objective	16/18 (89%)	5/16 (31%)	.15 (.04, .59)
Pad weight < 1 g	15/18 (83%)	6/15 (40%)	.28 (.09, .85)

RR = relative risk; CI = confidence interval.

Length of hospital stay, postoperative complications, change in hemoglobin (preoperative minus postoperative hemoglobin), and length of suprapubic catheterization did not differ between the two approaches.

One year after surgery, subjective and objective cure rates of genuine stress urinary incontinence were significantly greater for women treated by the Burch procedure than by modified anterior colporrhaphy (Table 2). This relationship held true after adjusting for age and menopausal status. Subjective and objective ratings of incontinence severity by questionnaires and pad tests were significantly lower in the women who had the Burch procedure (Table 3). Mobility of the urethrovesical junction was significantly less in the Burch group (median 15 [range 0–45] versus 70 [range 10–90] degrees, $P < .001$). No other significant differences in pelvic organ prolapse were noted between the groups postoperatively. Proximal and midurethral pressure transmission ratios were significantly greater after the Burch procedure than the modified anterior colporrhaphy ($102.4 \pm 15\%$ versus $77.2 \pm 23\%$, $P = .001$, and $94.3 \pm 11\%$ versus $75.7 \pm 13\%$, $P < .001$, respectively). No other differences in urodynamic indices were noted postoperatively. Three women from the modified anterior colporrhaphy group and none from the Burch group had urodynamic and cystoscopic findings consistent with intrinsic sphincteric deficiency ($P = .09$). No women had documented detrusor instability, but four (21%) in the Burch group and eight (50%) in the modified anterior colporrhaphy group complained of urgency symptoms several times a week.

Table 3. Postoperative Subjective and Objective Incontinence Severity

	Burch procedure (n = 19)	Anterior colporrhaphy (n = 16)	P
Pads per wk*	0 (0–4)	3 (0–4)	<.001
Incontinence episodes*	0 (0–6)	4 (0–6)	<.001
Self assessment score*	1 (1–8)	5 (1–9)	<.001
IIQ†	0.32 (0.6)	0.91 (.9)	.04
Pad weight (g)*	0.0 (0–0.1)	4.0 (.3–66.1)	<.001

IIQ = incontinence impact questionnaire.

* Ordinal scale; data expressed as median (full range).

† Data expressed as mean (standard deviation).

* Data expressed as median (interquartile range).

The distribution of large cystoceles preoperatively was equal between groups and was found to be an independent predictor of subjective and objective success. Grades 3 or 4 cystoceles were more likely to result in failure compared with grades 1 and 2 in both groups (ten of 14 [71%] versus five of 21 [24%], $P = .01$). In the modified anterior colporrhaphy group, no successes were noted in women with grade 3 or 4 cystoceles compared with 43% (three of seven) success in those with grade 1 or 2 cystoceles ($P = .06$). Because there were few failures in the Burch group, statistical evaluation of relationship of success to cystocele grade could not be performed. Mobility of the urethrovesical junction was not an independent predictor of objective or subjective success overall or in either group.

Discussion

This study found Burch retropubic urethropexy to be superior to modified anterior colporrhaphy for operative treatment of genuine stress urinary incontinence; however, many gynecologists continue to use modifications of the anterior repair for treatment of genuine stress urinary incontinence. Among the reported advantages of the vaginal approach are decreased morbidity as well as concurrent correction of coexistent pelvic relaxation. Loughlin et al¹⁹ reported 39% fewer hospital days, 50% decrease in blood loss, and lower surgeons' fees for patients undergoing a vaginal repair (needle urethropexy) compared with retropubic urethropexy. We found no differences in perioperative morbidity, including length of hospital stay and change in hemoglobin, when comparing the abdominal with the vaginal route.

Despite our attempts to plicate and elevate the periurethral tissues toward a retropubic position and form a hammocklike urethral support layer, our success rate with the modified anterior colporrhaphy was poor. The only differences found between groups that potentially could affect success rates were age and menopausal status. However, logistic regression analysis showed that these two factors did not influence success rates. The study groups might have varied slightly despite randomization, because of relatively small sample sizes. Given the large discrepancy in success rates between the two groups noted at interim analysis, the data did not support continuation of the trial.

Most women in this study underwent concurrent gynecologic procedures with their anti-incontinence procedures. Other than method of repair of cystocele, the frequency with which other procedures were performed did not differ significantly between groups and is unlikely to have influenced outcome. Preoperative grade of cystocele was an independent predictor of

success in both groups, but urethrovesical junction hypermobility was not. None of the women with significant cystoceles (grades 3 or 4) preoperatively were subjectively cured with modified anterior colporrhaphy. We hypothesize that failure of the modified anterior colporrhaphy resulted from tearing away of the pubocervical adventitia from the tissue at the inferior aspect of the symphysis pubis to which it was sutured. A recent publication noted that with anterior colporrhaphy the vaginal muscularis and adventitia are plicated in the midline, which might further pull the lateral vaginal attachment from the arcus tendineus fascia pelvis at the pelvic sidewall, weakening bladder neck support.²⁰ Similar to previous studies, women who had modified anterior colporrhaphy showed significantly lower postoperative proximal and midurethral pressure transmission ratios than those who had the Burch procedure.^{13,14} Vaginal dissection, necessary for modified anterior colporrhaphy, might contribute to or worsen any preexisting perineal neuropathy.²¹ Intrinsic sphincteric deficiency diagnosed postoperatively in three women from the modified anterior colporrhaphy group might have been secondary to vaginal dissection and resultant neuropathy.

We found superior objective and subjective cure of genuine stress urinary incontinence with Burch retro-pubic urethropexy over modified anterior colporrhaphy, without increased perioperative morbidity or length of hospital stay. On the basis of our findings and the results of two other randomized, prospective trials,^{6,10} retropubic urethropexy should be considered the treatment of choice for genuine stress urinary incontinence over modified anterior colporrhaphy. Given the zero subjective success rate noted with significant cystocele, the modified anterior colporrhaphy should be avoided as a treatment for genuine stress urinary incontinence in these women.

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