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Complications in Women Undergoing Burch Colposuspension Versus Autologous Rectus Fascia Sling for the Treatment of Stress Urinary Incontinence

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Abstract

Purpose—To determine clinicodemographic factors associated with complications of continence procedures, the impact of concomitant surgeries on complication rates and the relationship between incidence of cystitis and method of post-operative bladder drainage.

Materials and Methods—Serious adverse events (SAEs) and adverse events (AEs) of the Stress Incontinence Surgical Efficacy Trial (SISTER), a randomized trial comparing Burch colposuspension to autologous rectus fascial sling, were reviewed. Clinicodemographic variables were analyzed to determine those associated with the development of AEs using logistic regression analysis. Complications were stratified based on the presence or absence of concomitant surgery. Differences in complication rates (controlling for concomitant surgery) and cystitis rates (controlling for method of bladder emptying) were compared using Fisher's exact test.

Results—Blood loss ($p=0.0002$) and operative time ($p<0.0001$) were significantly associated with development of an AE. Subjects undergoing concomitant surgeries had a significantly higher SAE rate (14.2% vs 7.3%, $p=0.01$) and AE rate (60.5% vs. 48%, $p<0.01$) compared to subjects undergoing continence surgery alone. Cystitis rates were higher ($p<0.01$) in the sling versus the Burch group up to 6 weeks postoperatively regardless of concomitant surgery status. Intermittent self catheterization (ISC) increased the rate of cystitis by 17% and 23% in the Burch and sling groups, respectively.

Conclusions—Concomitant surgeries at the time of continence surgery increased the risk for complications. Sling surgery was associated with a higher risk of cystitis within the first 6 weeks

postoperatively. ISC increased risk of cystitis in both groups. The occurrence of complications was associated with surgical factors, not patient-related factors.

Keywords

Burch; sling; complications; randomized clinical trial; urinary incontinence

INTRODUCTION

Complications associated with stress incontinence surgery are poorly characterized. Black and Downs' review of the stress incontinence surgical literature (1) concluded that there was a lack of comprehensive assessment of postoperative complications. Factors thought to impact morbidity include concomitant surgeries, type of post-operative bladder drainage, and clinico-demographic factors such as obesity, diabetes and age. There are very few published studies examining these variables (2,3). A better understanding of specific factors which may impact adverse outcomes may provide surgeons with information with which to better counsel our patients. A detailed analysis of complications recorded prospectively in a large surgical trial has not been previously published.

The Urinary Incontinence Treatment Network (UITN) recently conducted the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr), a randomized trial comparing outcomes from Burch colposuspension versus autologous fascial sling (4). We previously reported no significant difference between the sling and Burch groups in the percentage of patients who had serious adverse events in all complication categories (13% and 10%, respectively). However, there was a significantly higher rate of AEs in the sling group versus the Burch (63% vs. 47%, $p < 0.001$) with the occurrence of cystitis being the primary AE accounting for this difference. However, in this prior publication, detailed analyses of the types of complications were not performed. Further analyses will address whether bladder catheterization could explain increased cystitis events in the sling group, whether differences in complications between sling and Burch surgeries still exist when factoring out concomitant surgery, and whether certain clinicodemographic variables may predict the occurrence of a postoperative complication. Therefore, this study was undertaken to perform a more detailed analyses of the complications data in SISTEr to address these questions.

METHODS

Six hundred fifty-five women with symptoms and signs of stress urinary incontinence (SUI) were randomized to receive an autologous fascia pubovaginal sling or Burch colposuspension as part of the SISTEr trial. Trial design (5) and primary outcomes (4) have been previously published. Adverse events (AEs) and serious AEs (SAEs) were defined by UITN investigators and approved by the Data and Safety Monitoring Board (DSMB) prior to initiation of enrollment in SISTEr (Table 1). All SAEs were reported to the Biostatistical Coordinating Center (BCC) and NIDDK within 72 hours of knowledge of event. The DSMB regularly reviewed summary reports of all AEs and SAEs. A Complications Work Group comprised of four Principal Investigators (PIs) reviewed all complications. The Work Group was masked to site, surgeon and randomization assignment, although for some of the complications, narrative descriptions unintentionally revealed treatment assignment. Event severity was graded utilizing a surgical complication classification system based on the one developed by Dindo et al (6).

Cystitis was defined as a clinical suspicion of bladder infection that resulted in treatment, either empiric treatment or culture-specific antibiotics. Cystitis events were stratified by post-

operative time intervals as follows: up to 6 weeks, 6 weeks to 3 months, 3–6 months, 6–12 months, 12–18 months, and 18–24 months.

Since cystitis occurred most commonly within 6 weeks postoperatively, we stratified method of bladder drainage over this time period only. Method of bladder drainage for the first 6 weeks after surgery was categorized as: 1) “self-voiding” – never requiring any type of catheter use throughout the 6-week postoperative period, 2), “ISC” – requiring ISC at anytime in the 6-week postoperative period (even if they had Foley or SP tube initially) and 3) “catheter” - requiring a suprapubic or Foley catheter at any time in the 6-week postoperative period and never performing ISC.

To explore the associations of demographic and clinical characteristics with occurrence of an AE, we computed a logistic regression analysis on our summary AE measure. Characteristics of interest included: BMI, age, smoking history, menopausal status/HRT use, presence of diabetes, prior UI surgery, prior prolapse surgery, prior hysterectomy, blood loss during continence surgery (Burch or sling) and operative time of entire surgery. We first tested each characteristic alone in relation to AE occurrence and then computed a multiple logistic regression analysis including all characteristics that were statistically significant in bivariate analysis ($p < 0.05$).

To investigate whether AE's were associated with concomitant surgery, women were stratified with respect to continence procedure performed (Burch or sling) and occurrence of concomitant surgery. The complication rate was calculated as the number of unique subjects developing the complication divided by total number of subjects in that stratum. Differences in complication rates between strata were tested using Fisher's exact test.

Cystitis events were stratified to post-operative time intervals of less than 6 weeks, 6 weeks to 3 months, 3–6 months, 6–12 months, 12–18 months and 18–24 months. Rates of cystitis were determined by dividing number of unique subjects with cystitis (a subject may have had more than one cystitis event) in one time period by the total number of randomized subjects in the Burch colposuspension or sling group. Similarly, rates of cystitis in the 6 week post operative period were computed by surgical treatment for each voiding management category. Differences between types of surgery in rates of cystitis in each category were tested by Fisher's exact test.

RESULTS

Two clinical variables were significantly associated with the occurrence of an AE on bivariate analysis, mean operative time (146 versus 125 minutes, $p < 0.0001$) and mean blood loss (271 ml versus 184 ml, $p = 0.0002$). Operative time and blood loss during surgery were related ($r = 0.50$), so when both were included in a logistic regression analysis, neither was associated with AE. Other clinico-demographic factors such as body mass index, age, smoking history, menopausal status/hormonal replacement therapy use, presence of diabetes, prior urinary continence surgery, prior prolapse surgery, and prior hysterectomy were not associated with occurrence of an AE.

Of the 655 women studied, 275 (42%) received no concomitant surgery. Concomitant surgery rates in the sling and Burch groups are shown in Table 2. Table 3 shows SAEs and AEs stratified by continence surgery alone versus continence surgery with concomitant surgeries. Women who underwent concomitant surgery had significantly higher rates of SAEs (14.2% vs. 7.3%, $p = 0.01$) and AEs (60.5% vs. 48%, $p < 0.01$). The difference in complication rates between the concomitant surgery versus continence surgery alone were due to wound complications requiring surgical intervention in the SAE category (5.3% vs. 0.7%, $p < 0.01$) and GI complications in the AE category (4% vs. 0%, $p < 0.01$). The 22 events in the SAE category

“wound complication requiring surgical intervention” for subjects undergoing concomitant surgery included 8 ventral wall hernias requiring repair, 5 infections requiring operative drainage, 4 hematomas requiring operative drainage, 4 extrusions of vaginal sutures or mesh from abdominal sacrocolpopexies requiring operative removal, and 1 pelvic abscess requiring drainage via interventional radiology procedure. The 15 events in the GI AE category for subjects undergoing concomitant surgery included 11 abdominal pain/ileus, 3 hemorrhoids/anal fissures, and 1 pseudomembranous colitis.

When comparing complication rates between surgical groups in subjects who had the continence procedure only (Burch or sling only), the only category noted to be significantly different was genitourinary events (45.4% in sling group versus 28.3% in Burch group, $p<0.01$). Similarly, when comparing complication rates between surgical groups in subjects who had concomitant surgeries, the only complication category noted to be significantly different between the 2 groups was genitourinary events (50% in the sling group versus 34.8% in the Burch group, $p<0.01$).

Differences in cystitis rates between subjects undergoing the sling and Burch procedures were most prominent in the first 6 weeks after surgery (Table 4). After this time period, differences in cystitis rates diminished. Table 5 shows the type of bladder drainage in the first 6 weeks after surgery. Women who had undergone sling procedures and required ISC had the highest rate of cystitis (40%). Cystitis rates differed between the two surgical groups in subjects who were self-voiding ($p<0.0001$) or performing ISC ($p=0.04$). There was no difference in cystitis rates between the surgical groups if an indwelling catheter was used in the first 6 week postoperative period.

DISCUSSION

In this large, multi-center, surgical trial, complications were tracked prospectively and systematically reviewed, providing detailed characterization of complications after autologous sling and Burch continence surgeries. Two clinical variables were associated with AEs on univariate analysis: operative time and blood loss. However, with multivariate analysis, neither variable remained significant. The reason that these two surgical factors were not statistically significant in the multivariate analysis was because they were linearly correlated ($r=0.50$). Therefore, when holding one factor constant in the multivariate model, the other correlated factor does not contribute anything additional to the model. A previous study found no added risks in obese patients undergoing continence surgery (7). Recently, Anger et al published that in the Medicare population, more elderly subjects (>75 years) had higher complications rates (3). The intent of SISTER was to study subjects who were healthy enough to undergo surgery, consequently subjects who had sufficiently severe morbidities would not have been enrolled into the trial. In the entire SISTER population, only 7% (46 subjects) were diabetics, 7% had BMI > 40 (which is the limit considered morbidly obese) and 5% (32 subjects) were over the age of 70 years old (with only 2 subjects ($<1\%$) over the age of 80). This may have decreased our ability to detect an association of these clinical factors with the development of an AE.

Concomitant surgery at the time of the continence procedure was associated with higher rates of both SAEs and AEs compared to the continence surgery alone. Specifically, wound infections that required surgical intervention and gastrointestinal events occurred more frequently in the group that received concomitant surgeries compared to continence surgery alone. These results become especially relevant when one considers that in the SISTER trial, 58% of women underwent concomitant surgery which is a rate that is similar to other studies suggesting that most stress urinary incontinence operations are performed along with another type of surgery, usually prolapse repair (8,9).

While our findings differ with a previous publication suggesting that concomitant continence surgery at time of pelvic prolapse surgery did not increase perioperative complications (10), it is difficult to compare the two studies. Their findings were based on a retrospective review of discharge summaries and did not include complications occurring beyond the perioperative period, whereas we continued to monitor for complications up to 24 months postoperatively. Furthermore, they studied a different population than the SISTER subjects. All of their patients underwent prolapse surgery and only a subset (27%) had concomitant continence surgery. Their study suggests that adding a continence procedure to prolapse surgery does not increase the complication rate. Recently, another group of investigators reviewing Medicare registry information determined that concomitant pelvic prolapse repair at time of sling surgery resulted in higher incidence of post-operative bladder outlet obstruction (11). In our study, because the sum total incidence of pelvic prolapse surgery was similar in both the sling and Burch group (Table 2), the fact that the sling group had higher postoperative retention complications suggest that it was the sling surgery itself rather than the prolapse surgery that resulted in bladder outlet obstruction.

Approximately 1 in 3 women in SISTER trial had at least one episode of cystitis in the first 6 weeks after surgery. Of note, all patients received antibiotics at the time of surgery as this is standard of care, however, the type of antibiotic given was not standardized. During this time period, the cystitis rates were higher in the sling group than Burch group regardless of whether concomitant surgery was performed or the method of postoperative bladder emptying mechanism. The cumulative cystitis rate in the sling group at 3 months postoperatively was 35%. This 35% rate is comparable to the 33% previously reported for 3 months postoperatively in a retrospective study evaluating complications in a group of Medicare patients undergoing sling procedures (2). While the mean age of their group was not stated, by definition, the age of entire group was >65 years of age with 65% between 65–74 years of age. With advanced age, there may be an inherent increased risk of voiding and/or detrusor dysfunction which may increase the risk of cystitis. Cystitis rates in the SISTER trial occurring between 12 and 24 months postoperatively were similar for the two groups with a rates of 16% for Burch and 18% for the sling group (Table 4). These rates are twice as high as that reported for an otherwise healthy female population of similar age range. In a prospective study of 1017 menopausal women aged 52–75 years, there were 138 culture defined symptomatic bacterial cystitis events over a 24-month period which equate to a cystitis rate of 7% over a 12-month period (12),

One possibility for the higher cystitis rates in the SISTER population may be due to the definition of cystitis. Urine cultures were not required when cystitis was clinically suspected. Therefore, some cases of “cystitis” may have been due to non-bacterial lower urinary tract inflammation or urethral irritation rather than acute bacterial infection. The definition of cystitis was made a priori to manage these symptoms as in clinical practice where patients are often treated empirically without a urine culture during the postoperative period. Consequently, it is possible that the increased incidence of “cystitis” events detected in the sling group is due to more urethral and bladder irritation by the sling as compared to the Burch. Future studies should attempt to differentiate irritative bladder symptoms from infectious and non-infectious causes to better clarify the true extent of postoperative symptomatic bacterial cystitis.

The strengths of this analysis are that in the SISTER trial SAE and AE data were collected prospectively and robustly as part of a large randomized surgical trial. Quality controls included a pre-defined list of adverse events to monitor. Cross-checks of related variables on study forms were performed at every visit and patients were also queried about office visits made outside of their follow-up time points. Furthermore, a Complications Work Group reviewed, categorized and graded all complications in a blinded fashion utilizing a validated surgical complications instrument (6).

The findings from this study should be compared to minimally invasive suburethral synthetic slings. While complication rates from minimally invasive synthetic slings have been published, there is not a systematic analysis such as the one presented here for Burch and sling. We will have the ability able to compare complications from SISTER with complications from our currently active trial, TOMUS (Trial of Midurethral Slings). TOMUS is a prospective randomized trial comparing outcomes of retropubic versus transobturator placed minimally invasive slings. There will be internal consistency in comparing the complications between SISTER and TOMUS because the data will have been processed and analyzed in a similar prospective manner by the same multi-institutional group.

A comprehensive review of our complication rates over a 2 year period after sling and Burch surgeries is important to report. This data can be used as a reference for other types of continence surgeries. While minimally invasive polypropylene slings have been popularized recently, the FDA recently released a public health notification regarding serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence (<http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html>). The complications of the Burch and sling procedures must be balanced against the potentially more serious complications in minimally invasive slings.

CONCLUSIONS

Development of complications in women undergoing pubovaginal slings or Burch colposuspensions was associated with surgical factors and not patient-related factors. Concomitant surgeries increased the complication rates in women undergoing continence surgery, specifically wound and GI events. The most frequent complication after continence surgery was cystitis. Subjects who underwent slings, as compared to Burch colposuspensions, had significantly higher rates of cystitis during the first 6 weeks postoperatively. ISC increased risks of cystitis in both Burch and sling subjects. This data can assist the clinician during preoperative counseling in the discussion of these risks in women undergoing continence surgery with or without concomitant surgery.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix

APPENDIX A: Urinary Incontinence Treatment Network Members

STEERING COMMITTEE

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Table 1**Concomitant Surgery**

	Burch N=329	Sling N=326
None	145 (44%)	130 (40%)
Enterocoele repair	29 (9%)	24 (7%)
Abdominosacrocolpopexy	24 (7%)	26 (8%)
Uterosacral ligament vault suspension	41 (12%)	29 (9%)
Anterior colporrhaphy	11 (3%)	47 (14%)
Vaginal paravaginal repair	1 (<1%)	11 (3%)
Abdominal paravaginal repair	46 (14%)	12 (4%)
Standard posterior colporrhaphy	14 (4%)	14 (4%)
Defect-directed posterior repair	37 (11%)	40 (12%)
Vaginal hysterectomy	28 (9%)	27 (8%)
Abdominal hysterectomy	51 (16%)	47 (14%)
Oophorectomy	59 (18%)	46 (14%)
Hernia repair	3 (1%)	1 (<1%)
Sacrospinous ligament vault suspension	1 (0%)	0 (0%)
Iliococcygeus vault suspension	1 (0%)	0 (0%)
Other	55 (17%)	56 (17%)

Note: an individual subject may have had more than one of the concomitant procedures, so the numbers will not add up to the sample size

Table 2
Complications Stratified to Continence Surgery Alone Versus Continence Surgery with Concomitant Surgery

	Continence surgery alone N=275	Rate (%)	Continence with concomitant surgery N=380	Rate (%)	P value *
SAEs	N of events (no. of unique patients)		N of events (no. of unique patients)		
Genitourinary	19 (17)	6.2	33 (29)	7.6	0.54
Pelvic Pain	0 (0)	0	2 (2)	0.5	0.51
Vascular/hematologic: bleeding	1 (1)	0.4	3 (3)	0.8	0.64
Wound - surgical intervention	2 (2)	0.7	22 (20)	5.3	<0.01
Gastrointestinal	0 (0)	0	2 (2)	0.5	0.51
Pulmonary: atelectasis	0 (0)	0	1 (1)	0.2	1.00
Anesthetic	0 (0)	0	1 (1)	0.2	1.00
Total SAEs	22 (20)	7.3	64 (54)	14.2	0.01
AEs					
Genitourinary	206 (100)	36.4	302 (162)	42.6	0.12
Vascular/hematologic	3 (3)	1.1	11 (11)	2.9	0.17
Wound	48 (47)	17.1	92 (81)	21.3	0.19
Gastrointestinal	0 (0)	0	15 (15)	4.0	<0.01
Pulmonary	5 (5)	1.8	14 (14)	3.7	0.24
Neurologic	4 (4)	1.4	7 (7)	1.8	0.77
Cardiovascular	1 (1)	0.4	1 (1)	0.3	1.00
Allergic	1 (1)	0.4	1 (1)	0.3	1.00
Constitutional	0 (0)	0	3 (3)	0.8	0.27
Dermatologic	3 (3)	1.1	3 (3)	0.8	0.70
Total AEs	271 (132)	48.0	449 (230)	60.5	<0.01

* Note: P-value is Fisher's Exact test comparing percentage of unique patients with SAE/AE.

Table 3
Cystitis Rates Postoperative Periods Stratified to Treatment Group (Burch versus Sling).

Post-operative period	Burch N=329		Sling N=326		p-value
	# events	# subjects (% total randomized)	# events	# subjects (% total randomized)	
Up to 6 weeks	39	33 (10)	91	78 (24)	<0.0001
6 wk to 3 mo	29	27 (8)	43	36 (11)	
3 to 6 mo.	26	25 (8)	39	34 (10)	
6 to 12 mo.	35	29 (9)	47	40 (12)	
12 to 18 mo	32	24 (7)	33	27 (8)	
18 to 24 mo.	45	28 (9)	37	32 (10)	
Total	206		290		

Table 4
Pattern of voiding management within 6 weeks postoperatively by treatment group.

Post-operative period	Burch		Sling		p-value
	Total n	# with UTI (%)	Total n	# with UTI (%)	
Self- voiding	183	11 (6)	138	23 (17)	<0.0001
ISC	44	10 (23)	94	38 (40)	
Catheter	94	12 (13)	87	16 (18)	
Total	321	33 (10)	319	77 (24)	0.0003*