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Changes in Urodynamic Measures Two Years after Burch Colposuspension or Autologous Sling Surgery

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Abstract

Objectives—To characterize urodynamic changes in subjects 24 months after Burch urethropexy and autologous fascial sling surgeries for stress urinary incontinence.

Materials and Methods—In the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr)l, 655 women underwent standardized urodynamics prior to and 2 years after Burch or sling surgery. Paired t- tests were used to compare pre- and post surgery urodynamic measures by treatment group. ANOVA models were fit predicting change in UDS measures controlling for treatment group.

Results—Noninstrumented maximum flow rate decreased 3.6 ml/sec (Burch) and 4.7 ml/sec (sling), p=0.42. Average flow rates decreased [2.4 ml.sec (Burch) vs. 3.8 ml/sec (sling), p=.039]. There was no difference in increases in first sensation (23.3 and 29.3 ml, respectively, p=0.61). There were no differences in reductions in pressure flow study maximum flow rates [(2.3 (Burch)

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and 4.4 ml/sec (sling), p=0.11]. Increased detrusor pressure at maximum flow (Pdet@Qmax), (11.4 cm H_20, p<0.001) was seen only after the sling procedure. Increases in bladder outlet obstruction index (BOOI) occurred after both procedures with greater increases seen after sling (change, Burch +6.27 versus sling +20.12, p=0.001).

Conclusion—The Burch colposuspension and autologous fascial sling procedures were associated with similar decreases in noninstrumented flow rates and the sling was associated with greater increases in Pdet@Qmax and BOOI. These changes suggest that both procedures are effective, in part, because of increased outlet resistance; the sling procedure may be more obstructive.

Keywords

stress urinary incontinence; urodynamics; Burch Coloposuspenion; Pubovaginal sling

Introduction

The mechanism(s) by which surgical treatments improves stress urinary incontinence (SUI) in women remains uncertain. Two likely mechanisms are an increase in urethral resistance[1] and/or relocation of the proximal urethra to a more intraabdominal position to optimize pressure transmission to the proximal urethra.[2] More recently, procedures have emphasized support at the mid-urethra without repositioning the bladder neck or increasing urethral resistance[3]. The findings from urodynamics studies in women undergoing these procedures to assess the changes in urethral and bladder function are inconsistent. There are conflicting reports about whether the Burch colposuspension affects urethral resistance.[2] Likewise with the pubovaginal sling there are reports that it is obstructive and others that it does not change voiding parameters.[4] The data on the mid-urethral sling is similar. Factors that may contribute to a lack of consistent findings include heterogeneity in the subjects, studies including different types of incontinence, variation in the way surgical procedures were performed by different investigators, consideration of different urodynamic measures as outcomes, absence of standardized urodynamic methods and small sample size. Thus, well designed urodynamic studies are needed to help identify the mechanism(s) by which surgery corrects incontinence in women.

Women enrolled in a randomized clinical trial of Burch and autologous slings, the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) underwent standardized urodynamics (UDS) including non instrumented uroflow, cystometrogram and pressure flow studies, prior to surgery and approximately two years later.[5,6] We report urodynamic changes occurring over this time period within and between each surgical treatment group to gain insight into their effect on women with urinary incontinence.

Methods

The design and primary outcome of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr), have been reported previously. [5,6] All women provided written informed consent and a Data and Safety Monitoring Board evaluated study progress and safety. The Institutional Review Boards of the participating organizations approved the study protocol. Briefly, 9 clinical sites randomized 655 women with predominant stress urinary incontinence to undergo either a Burch colposuspension or fascial sling. Eligibility required pure or predominant SUI as determined by scores on the Medical, Epidemiological and Social Aspects of Aging Questionnaire (MESA), a positive bladder stress test with associated urethral hypermobility as measured by Q-tip test and a willingness to undergo study evaluations at baseline and 24 months post operatively. Overall surgical success,

assessed over a two year period of follow-up, was defined as: no self-reported SUI symptoms on the MESA, an increase of less than 15 g in pad weight during a 24-hour pad test, no incontinence episodes recorded in a 3-day diary, a negative urinary stress test (no leakage noted on examination during cough and Valsalva maneuvers at a standardized bladder volume of 300 ml), and no retreatment for stress urinary incontinence (including behavioral, pharmacologic, and surgical therapies).

Urodynamic measurements prior to surgery (baseline) and after two years included non-instrumented uroflowmetry (NIF), filling cystometry (CMG), and a pressure flow study (PFS) following Good Urodynamic Practice Guidelines.[7] A high inter-rater reliability between local and central reviewers using study-specific standardized interpretation guidelines has been demonstrated. [8]

The NIF was performed first and a volume of at least 150 ml was required for validity after which a catheterized post void residual was obtained. CMG and PFS studies were performed using fluid based external transducer systems which were zeroed to atmospheric pressure with the symphysis pubis serving as the reference height. A dual lumen urethral catheter (8 french or less) and fluid filled rectal balloon catheters were used and bladder filling was performed with a fill rate of 50 ml/min. CMG was performed in the standing position and the following parameters were assessed: first sensation, maximum cystometric capacity (MCC) and the presence of detrusor overactivity (DO) with or without incontinence. Valsalva leak point pressures were assessed at a minimum volume of 200 mL. Detrusor compliance was calculated using the formula Compliance= Volume at MCC/Pdet at MCC. PFS were performed in the sitting position after transducers were repositioned to the level of the symphysis pubis. Voiding parameters included Pves, Pabd and Pdet at PFS baseline and at Qmax. The difference between Pdet at Qmax and PFS baseline was calculated and termed “delta Pdet@Qmax”. The bladder outlet obstruction index (BOOI), was obtained by formulaic calculations: (BOOI = Pdet@Qmax - 2Qmax).[9] While originally designed for measuring obstruction in men, the concept of measuring outlet resistance using this mathematical index of resistance has been used in women.[10] Follow-up UDS was performed at either 24 months after surgery or prior to retreatment for stress incontinence, whichever occurred first.

We analyzed only those women with acceptable UDS measurements at both time points and whose overall surgical success status was ascertained. One sample paired t tests were used to compare pre- and post surgery UDS measures for each surgical treatment group. To investigate whether the differences in pre- and post surgery UDS measures varied by treatment group, ANOVA models were fit to characterize change in UDS measures from baseline to 24 months controlling for treatment group. Change in detrusor overactivity status over time was modeled using repeated measures ANOVA. All analyses were carried out using SAS statistical software (Version 9.1, SAS Institute, Inc. Cary, NC). P-values less than 0.05 were considered statistically significant.

Results

The 655 subjects in the two surgical groups [Burch (n=329), sling (n=326)] were comparable at baseline with respect to demographic, anthropomorphic, clinical, and urodynamic characteristics.[3] The overall surgical success status was known for 520 (79.4%) women; a total of 185 were successes and 335 failures. Thirty-four women received surgical retreatment for stress incontinence and required UDS prior to that retreatment. Of these 34 women, 30 had UDS completed which were performed at a mean of 207 days from their original surgery (range 17-763) including 13 who had their study done at their 2 year mark. No clinically significant differences were seen between those who had their UDS done early

vs the remainder of the subjects with regards to UDS changes or surgical outcome. The number of women with acceptable urodynamic results varied by measure: NIF (n=393; 60%), MCC (n=418; 64%), compliance (n=317; 48%) and PFS (n=178; 27%). Table 1 demonstrates non-instrumented uroflowmetry among all women pre- and postoperatively, stratified by treatment group. Table 2 demonstrates multichannel pre and postoperative urodynamic parameters, also stratified by treatment group.

Non-instrumented uroflowmetry

The Burch and sling groups both had statistically significant reductions in maximum urinary flow rate (3.6 ml/sec and 4.7 ml/sec) and average flow rate (2.4 ml/sec and 3.8 ml/sec), although the reduction was larger following sling than Burch ($p = 0.039$). (Table 1).

Cystometrogram

The Burch and sling groups both had significantly increased volume at first sensation, while volume at first urge increased significantly only in the Burch. MCC and bladder compliance were not significantly changed by either surgical procedure and we did not detect significant group differences in any filling phase parameters. When comparing the proportion of women with DO at 24 months among those with no baseline DO in the Burch arm (10/215) to the proportion of women with DO at 24 months among those with no baseline DO in the sling arm (18/239), we find no difference in the proportions (chi-square, $p = 0.20$). In addition, when comparing the proportion of women with no DO at 24 months among those with baseline DO in the Burch arm (19/27) to the proportion of women with no DO at 24 months among those with baseline DO in the sling arm (10/18), we also find no difference in the proportions (chi-square, $p = 0.31$).

Pressure-Flow study

Both groups had statistically significant reductions in maximum instrumented flow rates but this measure did not differ by surgical procedure. Women in the sling group had a statistically significant decrease in voided volume (404.54 vs 349.75 cc $p = 0.003$) unlike the women in the Burch group (421.95 vs 393.10 cc $p=0.088$). The sling group demonstrated a significant increase in Pdet@Qmax (11.4 cm H2O, $p <0.001$) while the Burch group did not (1.7 cm H2O $p =0.39$). Both groups demonstrated an increase in BOOI (Burch 6.27 $p=0.035$ vs. Sling 20.12 $p<0.001$) The change in Pdet@Qmax and BOOI was statistically different between the Burch and sling groups ($p<.0001$and $p=0.01$ respectively).

Discussion

Among women enrolled in a multi-center randomized clinical trial comparing Burch colposuspension with pubovaginal sling both treatment groups demonstrated increased urethral resistance during voiding as represented by significant reductions in non-invasive and instrumented flow rates. There was a significant increase in BOOI noted for each procedure with a greater change noted in the sling group as compared to the Burch colpopexy group. In addition, significant increases in detrusor pressure at maximum flow were demonstrated in the sling group. These findings suggest that while some level of bladder outlet obstruction may occur post-operatively for both procedures the degree of obstruction may be greater in the sling procedure.

Our study is one of the largest, using standardized, Good Practice Urodynamic Guidelines as described by the International Continence Society,[7] in 9 sites across the US. The SISTEr population is a large, well-characterized patient cohort who underwent standardized, quality-reviewed urodynamic testing before and 2 years post incontinence surgery. All study surgeons were documented to fulfill quality assurance parameters for the technical aspects

of the study procedures, in order to assure consistency in performance of these procedures across all clinical sites. An important element was that all surgeons were required to perform the Burch with sutures tied to elevate the anterior vagina to a minimally retropubic position. All surgeons were required to perform the sling so that no visible evidence of angulation of the urethra/bladder neck was visualized at the end of the procedure and no tension was placed on the sling when tied across the midline. Despite the precautions to minimize postoperative bladder outlet obstruction in this trial, we found evidence of increased urethral resistance.

These findings do corroborate previous studies that have noted increases in urethral resistance in both the Burch and sling incontinence procedures. [1,11, 12, 13] Klutke et al reported that increased urethral resistance, as measured by pressure flow studies, was associated with successful Burch urethropexy 1 year after surgery.[1] Bergman et al reported that there were sustained increases in pressure transmission ratio without changes in urethral closure pressure or urethral functional length at 3, 12 and 60 months after Burch colposuspension. [11] Belair et al did not detect changes in static urethral pressure profile parameters or in filling phase parameters in 50 women 3 months following Burch[2]. However, they reported increased detrusor pressures at maximum flow and a decreased maximum flow rate.

In women undergoing fascial slings, similar findings have been reported with decreased non-invasive uroflow rates, increased post void residual volumes, increased detrusor pressure at maximum flow and decreased maximum flow rates.[12,13] Fulford et al performed urodynamic studies on 85 women after a rectus fascia pubovaginal sling between 1992-1996. This group was similar to the SISTEr population in that the patients had mixed incontinence, 41 had undergone previous surgery and over half had hypermobility, while the other half had Type III stress incontinence. There were statistically significant obstructive changes in detrusor pressure at maximum flow rate, maximum flow rate and residual urine volumes. While these results may suggest that such procedures cause an increase in outlet resistance, investigators from other sling studies have reported no significant changes in these urodynamic parameters after surgery.[14, 15]

The post-operative urodynamics data regarding the more minimally invasive midurethral slings (MUS) is also inconsistent. One group of investigators showed no changes in Pdet@Qmax post MUS up to 3.5 years post-operatively.[16] Another study showed significantly increased Pdet@Qmax 1-year after TVT from 15 to 19 cm water although the authors concluded that this was not clinically significant.[17] In this same study, however, Qmax from non-instrumented uroflow appeared to have a more clinically relevant decrease from 29 cc/sec to 16 cc/sec. In a study by Lin[18] sequential assessment of urodynamic parameters in women with SUI before and after TVT operation revealed dramatic improvement in UPP parameters at 6 months after TVT operation that persisted at 12 months postoperatively. In contrast, the urodynamic parameters of uroflowmetry and filling and voiding cystometry were not significantly different before and after TVT operation. Further studies examining the urodynamic effects after MUS surgery will hopefully clarify this area.

In addition to the increase in urethral resistance secondary to the anatomic changes from surgery there may be physiologic changes due to surgery responsible for the observations of increased volume at first sensation and the trend towards greater volume at first urge. For instance changes in sensation and volume parameters during filling may be related to disruption or injury to urethral and bladder neck nerves during the dissection required when performing these two procedures. These nerves may play a role in bladder storage and emptying through various neural reflexes and some element of bladder afferent function

may be altered postoperatively. It has been hypothesized that an open bladder neck may allow urine to enter the proximal urethra causing stimulation of urethral afferent receptors which then reflexively activate bladder efferents. Procedures that close the proximal urethra may prevent stimulation of afferent receptors and thereby contribute to the improved urgency and urgency incontinence symptoms observed after surgery for SUI.

The data presented are consistent with increased outlet bladder resistance after both Burch and slings. Slings result in more increased outlet resistance compared to the Burch procedure. A future ability to better determine the degree of urethral resistance increase required at time of surgery relative to the reported degree of SUI may help increase surgical success and minimize postoperative complication of obstruction and voiding dysfunction. The long term implications of this fixed increased urethral resistance, if any, remains uncertain.

Our study has a number of strengths including a large sample size, uniform inclusion criteria for entry into the trial, standardization of both surgical procedures across performance sites, uniform procedures for urodynamic measures with rigorous quality control. However, our findings need to be considered within the context of several limitations of this investigation some of which are fairly significant including the lack of availability of urodynamic data from many subjects, specifically pressure flow data as well as a low incidence of detrusor overactivity, and absence of urethral pressure studies.

The main reasons for the low number of subjects with urodynamic data were; invalid pressure flow studies mainly due to technical problems, noncompliance with the standardized urodynamics protocol or implausible data as determined by our urodynamics quality assurance process. The standardization process for our UDS procedures including the quality assurance process has been described.[8] This process evolved as we discovered problems especially with the PFS during our first quality assurance checks which ultimately left 385 patients with valid baseline UDS and 293 patients with valid UDS at 24 months. Furthermore, there were patients who had valid studies at one time point but not the other. Ultimately, this yielded 180 patients for inclusion in our analyses which were nearly equally allocated between the 2 surgical arms with 91 in the Burch and 89 in the sling. In addition, we performed additional analyses on several parameters (demographics, measures of severity, baseline urodynamic measures) to confirm that the patient populations were still equally distributed in the 2 arms after the high loss of subject data. Our findings confirmed that these groups remained equally characterized and we did not feel that any bias was encountered (data not shown))

The low incidence of detrusor overactivity at baseline is likely related to our strict inclusion and exclusion criteria which may not accurately reflect the general population of women with SUI. Lastly, since our inclusion criteria required the presence of urethral hypermobility, it is unclear if patients with intrinsic sphincter deficiency would have similar changes in urodynamic parameters after the same procedures.

Conclusion

Urodynamic changes were seen in women 2 years after both the Burch colposuspension and Pubovaginal sling with autologous fascia. While both procedures were associated with similar decreases in flow rates, the sling was associated with greater increases in Pdet@Qmax and BOOI. These changes imply that both procedures are effective, in part, because they increase outlet resistance though the sling procedure may be more obstructive.

Appendix A

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Table 1

Non-instrumented flowmetry values before and after surgery. The final column denotes if the post-surgical differences were significantly different in the 2 surgical groups.

	Burch (n=206)				**Sling (n=187)**				**Burch vs. Sling**
	Pre	**Post**	**Difference: Post – Pre**	**P**	**Pre**	**Post**	**Difference: Post - Pre**	**P**	**P value**
Qmax	25.15 (10.26)	21.53 (10.56)	-3.62 (12.55)	<0.001	25.58 (12.45)	20.91 (11.68)	-4.67 (13.05)	<0.001	0.42
Qaverage	12.77 (5.76)	10.42 (5.42)	-2.35 (6.46)	<0.001	13.38 (6.96)	9.63 (5.49)	-3.75 (6.89)	<0.001	0.039
Time to Qmax	11.27 (8.59)	14.94 (21.99)	3.67 (22.21)	0.019	12.16 (11.24)	13.44 (14.92)	1.28 (16.37)	0.29	0.23
Void Volume	316.87 (152.04)	322.72 (145.44)	5.84 (160.94)	0.60	312.54 (131.59)	301.84 (125.88)	-10.70 (173.28)	0.40	0.33
PVR	25.51 (35.31)	28.39 (41.41)	2.88 (41.76)	0.32	26.50 (33.35)	35.41 (46.87)	8.91 (57.43)	0.035	0.23

Table 2

Results of urodynamic testing before and after surgery. The final column denotes if the post-surgical differences were significantly different in the 2 surgical groups.

	Burch					**Sling**					**Burch vs Sling**
	n	**Pre**	**Post**	**Difference: Post – Pre**	**P**	**n**	**Pre**	**Post**	**Difference: Post – Pre**	**P**	
First sensation	205	145.64 (95.40)	168.90 (92.61)	23.26 (117.33)	0.005	213	141.32 (93.15)	170.58 (103.72)	29.26 (123.61)	<0.001	0.61
First urge	204	260.88 (130.34)	281.47 (117.02)	20.58 (141.16)	0.039	212	265.27 (140.20)	284.91 (130.51)	19.64 (159.84)	0.075	0.95
MCC	204	389.61 (132.77)	392.61 (122.89)	3.00 (122.88)	0.73	214	405.62 (136.78)	389.62 (128.34)	-16.00 (141.79)	0.10	0.14
Compliance	155	53.52 (181.68)	49.15 (140.92)	-4.37 (250.03)	0.83	162	64.89 (187.38)	39.58 (144.91)	-25.31 (241.10)	0.18	0.45
Qmax	91	20.32 (7.86)	18.06 (8.12)	-2.25 (8.21)	0.010	89	21.25 (10.05)	16.82 (8.51)	-4.42 (9.76)	<0.001	0.11
Voided volume	91	421.95 (161.44)	393.10 (148.57)	-28.85 (159.53)	0.088	89	404.54 (141.57)	349.75 (144.14)	-54.79 (167.68)	0.003	0.29
Pdet@Qmax	90	20.46 (10.35)	22.19 (18.46)	1.73 (19.09)	0.39	89	15.85 (12.16)	27.30 (17.62)	11.44 (17.69)	<0.001	<0.001
BOOI	90	-20.34 (19.76)	-14.08 (27.80)	6.27 (27.73)	0.035	88	-26.65 (24.26)	-6.53 (25.80)	20.12 (27.79)	<0.001	0.001

Table 3

Detrusor overactivity pre and post operatively; overall, by treatment group Burch and Sling

Overall:				
		24 Month DO		
Baseline DO		**Yes**	**No**	
	Yes	16	29	45
	No	28	426	454
		44	455	499
Burch:				
		24 Month DO		
Baseline DO		Yes	No	
	Yes	8	19	27
	No	10	205	215
		18	224	242
Sling:				
		24 Month DO		
Baseline DO		Yes	No	
	Yes	8	10	18
	No	18	221	239
		26	231	257