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Urodynamic Changes Associated with Successful Stress Urinary Incontinence Surgery: Is a Little Tension a Good Thing?

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Abstract

Objectives—The aim of this study is to identify urodynamic changes that correlate with successful outcomes after stress urinary incontinence (SUI) surgery.

Methods—655 women were randomized to Burch colposuspension or autologous fascial sling as part of the multi-center Stress Incontinence Surgical Treatment Efficacy Trial. Preoperatively and 24 months after surgery, participants underwent standardized urodynamic testing which included non-invasive uroflowmetry, cystometrogram and pressure flow studies. Changes in urodynamic parameters were correlated to a successful outcome, defined *a priori* as: 1) negative pad test, 2) no urinary incontinence on 3-day diary, 3) negative cough and valsalva stress test, 4) no self-reported SUI symptoms on the Medical, Epidemiological and Social Aspects of Aging Questionnaire and 5) no retreatment for SUI.

Results—Subjects who met criteria for surgical success showed a greater relative increase in mean Pdet@Qmax (baseline vs 24 months) than women who were considered surgical failures (p = 0.008). While a trend suggested an association between greater increases in bladder outlet obstruction index and outcome success, this was not statistically significant. Other urodynamic

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variables such as maximum uroflow, bladder compliance, and the presence of preoperative or de novo detrusor overactivity did not differ with respect to outcome status.

Conclusions—Successful outcomes in both surgical groups (Burch and sling) were associated with higher voiding pressures relative to preoperative baseline values. However, concomitant changes in other urodynamic voiding parameters were not significantly associated with outcome.

Keywords

Urodynamics; Stress Urinary Incontinence; Burch Colposuspension; Pubovaginal Sling; Obstruction

Introduction

The physiologic mechanism underlying successful stress incontinence surgery remains unclear. While urodynamics testing is often performed to assess postoperative failures; by and large, urodynamics testing is rarely performed in the setting of postoperative successes. Yet in the research setting, post-surgical urodynamic evaluation can measure alterations in bladder storage and emptying function; and may provide insight into urodynamic parameters associated with surgical success, failure, and complications. Analysis of urodynamic parameters after SUI surgery, with stratification of the data based on outcome success or failure, may help clarify which urodynamic parameter(s), if any, are associated with continence.

While there is no clear evidence that effective SUI surgery is “obstructive”, we know that beyond some threshold of urethral resistance, patients can indeed experience clinical bladder outlet obstruction. Prior studies on urodynamic changes following SUI surgery are limited by small, single-institution case series, and lack of standardization of urodynamic protocols, surgical procedures, and outcome measures. Investigators have measured increased urethral resistance after successful Burch colposuspension, while observing no such change in the Burch failure group[1]. Others have noted significant changes in urodynamic parameters suggestive of obstruction after a Burch procedure[2]. Similarly, after pubovaginal sling some investigators have reported decreased noninvasive urine flow rates, elevation of the residual urine volume and increased Pdet@Qmax [3,4] while others have observed no significant changes in these variables after sling.[5,6,7]

The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr), a multi-center, randomized clinical trial utilizing standardized pre/postoperative urodynamics testing, offers us a unique and rich database to examine these same questions. The goals of this analysis were two-fold: 1) to compare urodynamic data from the baseline and 24 month follow-up visits in women who underwent Burch colposuspension or pubovaginal sling, and 2) to determine if these changes correlate with successful surgical outcome.

Methods

The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) was a prospective randomized clinical trial at nine sites conducted through the Urinary Incontinence Treatment Network (UITN) with institutional review board approval at all sites. Details of the study design and primary outcome have been previously reported.[8,9] Briefly, 655 women were randomized to either Burch colposuspension or autologous fascia pubovaginal sling for treatment of SUI. Eligibility required pure or predominant SUI as determined by scores on the Medical, Epidemiological and Social Aspects of Aging Questionnaire (MESA)[11] and a willingness to undergo study evaluations at baseline and 24 months post operatively. The primary outcome, overall surgical success, 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). Various measures were assessed at 6 months post operatively and continued every 6 months until 24 months.

Pre and post operative urodynamic testing included non-instrumented uroflowmetry (NIF), filling cystometry (CMG), and a pressure flow study (PFS) using a standardized research protocol[11] that followed ICS recommended Good Urodynamic Practice Guidelines[12]. The NIF was performed first with a volume of at least 150 ml. Post void residual was obtained by catheterization after the NIF was completed. Filling CMG was then performed in the standing position using a dual lumen urethral catheter (8 French or less) at a fill rate of 50mL/min. Simultaneous abdominal pressure monitoring was obtained using a fluid-filled rectal balloon catheter. Pressures were measured using fluid based external pressure transducers which were zeroed to atmospheric pressure with the symphysis pubis serving as the reference height. Cystometrogram parameters including first sensation, maximum cystometric capacity (MCC), and the presence of detrusor overactivity with or without incontinence were annotated. 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 at the level of the symphysis pubis; PFS parameters included Pves, Pabd and Pdet at baseline and at Qmax and Qmax. The difference between Pdet at Qmax and Pdet baseline was calculated and termed “delta Pdet @Qmax”. The bladder outlet obstruction index (BOOI), was obtained by formulaic calculations: (BOOI = PdetQmax - 2Qmax).[13]

Urodynamics studies (UDS) was performed at 24 months after surgery or prior to retreatment for stress incontinence. Thirty-four women had surgical retreatment for stress incontinence and required UDS prior to that retreatment. If the surgical retreatment occurred before the 24 month visit, then the visit prior to surgical retreatment was used as a surrogate for the 24 month UDS measures. One woman was not considered in our analysis because no postoperative UDS measures prior to surgical retreatment (aside from baseline) were available. A urodynamics workgroup provided quality assurance for the urodynamics data.[11]

The aim of this paper was to investigate which changes in UDS measures between baseline and 24 months were related to a successful surgical outcome. Data are reported on those women with analyzable UDS at both time points and a known outcome status. For NIF values, data on n=393 observations were available, for MCC measured by CMG n=418 were available, for compliance measured by CMG n=317 were available and for PFS, data on n=178 were available. Outcome status was known for n=520 women (n=185 successes, n=335 failures).

Analysis of variance (ANOVA) models were fit to assess change in UDS measures from baseline to 24 months by treatment group. To investigate whether the change in UDS parameters for each treatment group varied by success status, statistical models were created which included an interaction term between treatment and success. As an example of an interaction, the change between baseline and 24 months in a particular UDS measure could have varied according to the group it was in; e.g. a measure could decrease between baseline and 24 months in the Burch group but increase in the sling group among successes, but for failures the opposite could be true. A significant interaction between treatment and success ($p < 0.05$) indicates that the changes vary by both treatment and success and warrants further

investigation of the mean changes by treatment and success group. No adjustment for multiple comparisons was explicitly made. All analyses were carried out using SAS statistical software (Version 9.1, SAS Institute, Inc. Cary, NC).

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[9]. Follow-up assessment to measure primary outcome was obtained in 520 women (79%) -- 255 in the Burch group (78%) and 265 in the sling group (81%). Table 1 lists the changes in urodynamic parameters stratified by outcome status alone; Table 2 contained results stratifies by outcome status as well as procedure.

Non-instrumented Uroflometry

The mean NIF Qmax values decreased from baseline to 24 months by 4.4 ml/sec among successes and 3.4 ml/sec among failures, respectively; however, there was no statistically significant difference in the changes by surgical arm or success status. A significant interaction ($p = 0.046$) was detected between surgical group assignment and success status for NIF volume. The mean NIF volume decreased among Burch successes whereas it increased among failures in the Burch group. Conversely, the mean NIF volume increased in women who had undergone a successful sling and decreased in women with unsuccessful slings.

An interaction was also detected for NIF PVR however the p-value did not reach statistical significance ($p =0.09$), indicating that the differences between success/failure and Burch/sling are probably subtle. The mean NIF PVR increased in the failures of both sling and Burch patients, but among the successes, the mean PVR decreased for the Burch group and increased for the sling group.

Cystometrogram

MCC was the only parameter that demonstrated a significant interaction between surgical arm and success status ($p = 0.022$). Specifically, in the Burch group, mean MCC values decreased from baseline to 24 months among successes while they increased among failures. The opposite was true in the sling group: among successes mean MCC values increased, while among failures they greatly decreased. There were no differences in any of the other CMG parameters across both surgical arms in relation to success status.

Pressure Flow Study

Changes in mean Pdet@Qmax between baseline and 24 months in both the Burch and sling groups correlated to successful outcomes; women who achieved successful outcomes had larger increases in mean Pdet@Qmax from baseline to 24 months as compared to women who were classified as failures ($p = 0.008$). Similarly, although not reaching statistical significance, the increases in the mean BOOI values were slightly larger among successes as compared to failures ($p = 0.09$). No significant interactions between the surgical arm and the success status for either the Pdet@Qmax or the BOOI were detected. While both surgical groups demonstrated a decrease in mean PFS Qmax between baseline and 24 months, these decreases were not associated with success status or surgical arm.

Discussion

This large, multi-center randomized surgical trial demonstrates that measures of increased urethral resistance following continence surgery are associated with treatment success.

Minor reductions in non invasive and pressure flow maximum flow rates (both non invasive and pressure flow) were noted across the entire cohort, however, only fascial sling patients had significant increases in detrusor pressure at maximum flow (Pdet at Qmax). These urodynamic data, in the context of our clinical observations of more postoperative voiding complications and bladder outlet obstruction requiring surgical revision among sling patients, indicate that the pubovaginal sling procedure increases outlet resistance more than the Burch procedure. These observations may help explain why the Burch procedure is less effective in the treatment of SUI when compared to the more "compressive" sling procedure.[9]

Our data revealed contradictory changes in two important measures of outlet resistance, specifically that urine flow rates (Qmax) did not significantly differ between successful and unsuccessful surgeries for either type of procedure, yet detrusor voiding pressure increases. We observed that Pdet@Qmax was substantially increased in successful sling surgeries (Δ18 cm H2O) as compared to unsuccessful sling surgeries (Δ6 cm H2O). Interestingly, when comparing successful and unsuccessful outcomes in the Burch group, only a slight but statistically significant rise in Pdet @Qmax was noted (3.8 vs. 0.4 cm H2O). These findings suggests that, at least for sling operations, increased outlet resistance as measured by increased detrusor pressure during voiding, is associated with better SUI-specific outcomes. On the other hand, those who underwent a Burch procedure did not see the same degree of rise suggesting other mechanisms may be responsible for its success.

Some investigators have suggested that efficacious SUI surgery is more likely to increase bladder outlet resistance than unsuccessful ones.[14] Our large, uniform dataset findings are consistent with other studies that report increased outlet resistance after incontinence surgery, particularly following fascial sling. Fulford noted fairly substantial increases in Pdet@Qmax (of 14 cm H2O) and reductions in Qmax (11 ml/sec) after pubovaginal sling.[4] Their high SUI cure rate of 97% limits the ability to correlate these urodynamic data with SUI cure and failure. Interestingly, postoperative urge syndrome was associated with more severe increases in outlet resistance, though this was not statistically significant. Mitsui et al noted an 11 cm H2O increase in Pdet@Qmax after sling, but also observed prolonged retention in 28% with 10% requiring urethrolysis.[3] Others, however, have noted no change in pressure-flow data following pubovaginal sling.[6,7]

Some have reported that Burch colposuspension can be obstructive.[15,16] Our data does not suggest the Burch colposuspension significantly changed voiding dynamics. Whether these disparate findings reflect variations in surgical technique, urodynamic interpretation, or patient selection remains unclear.

That we can see increased outlet resistance without concomitant alterations in flow rate illustrates the difficulties in evaluating and describing this complex interaction. To better describe obstruction in men, Lim and Abrams introduced the calculation BOOI (BOOI= PdetQmax - 2Qmax)[13]. Gravina et al subsequently examined various parameters to predict female outlet obstruction and found that a mean BOOI of greater than -8 provided the best sensitivity and specificity.[17] Our data demonstrated a greater increase in BOOI in sling vs. Burch patients, mirroring the observed changes in Pdet@Qmax for the two surgical treatment groups. Although we observed a trend suggesting increased BOOI was associated with surgical success, this did not reach statistical significance.

Several clinical questions of interest are raised by the current analysis. The mechanism of SUI resolution following successful sling surgery may be multi-factorial and heterogeneous. Our findings suggest that increased outlet resistance seen during voiding is associated with surgical cure following fascial sling. However, at least one recent prospective randomized

study of synthetic retropubic and transobturator midurethral slings suggests that voiding pressures are not appreciably altered by these midurethral slings, while success rates remain high.[5] Others have suggested that urodynamic obstruction is not observed in normal voiding after midurethral sling because the mechanism of action is a dynamic kinking of the urethra only during stress maneuvers. Therefore, while pubovaginal slings might rely on compressive forces for their efficacy, it seems as though this type of force is clearly not requisite for all forms of SUI surgery to be effective.

A potential area of confounding is the lack of availability of urodynamics data, specifically the pressure-flow study, from many subjects. The main reasons for this are invalid pressure flow studies mainly due to either technical shortcomings, nonconformance with the standardized urodynamics protocol or implausible data as determined by our urodynamics quality assurance process. We compared patients who had two urodynamic studies to the entire cohort with regard to demographic and urodynamic variables and found that the number of patients returning for both studies was nearly identical between treatment groups. Patients having both studies were more likely to be surgical successes, which certainly could have been a motivating factor for returning for postoperative studies. Symptom severity, bother, and other demographic variables were no different among those returning for studies compared to the entire cohort.

Conclusion

We believe that this data provides additional insight into the possibility of various mechanisms for surgical cure of SUI with and without increases in outlet resistance. Despite the limitations in dichotomously classifying “obstruction” in women; this large-scale, uniformly collected dataset demonstrates that the successful SUI surgery patient experiences a measurable change in voiding function. Objective, albeit imprecise urodynamic measures strongly suggest a relative increase in urethral resistance occurs as a consequence of SUI surgery.

Appendix A

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Table 1

Means (standard deviations) of NIF, CMG and PFS urodynamic measures at baseline, 24 months and the difference of the two by success status (success/failure).

	Success					Failure					
	n	**Baseline**	**24 Months**	**Difference: 24 Mos – Baseline**	**P-value (change over time)***	**n**	**Baseline**	**24 Months**	**Difference: 24 Mos – Baseline**	**P-value (change over time)****	**P-value (time by success status interaction)*****
NIF Qmax	150	24.53 (10.19)	20.12 (9.32)	-4.41 (11.61)	<0.001	216	26.02 (12.41)	22.65 (12.34)	-3.37 (13.83)	<0.001	0.45
NIF Volume	150	320.12 (156.10)	324.77 (146.93)	4.65 (192.46)	0.77	216	311.69 (138.80)	308.93 (135.16)	-2.76 (153.83)	0.79	0.68
NIF PVR	150	27.79 (35.85)	31.01 (44.39)	3.23 (54.23)	0.47	216	25.05 (34.37)	33.24 (45.47)	8.19 (47.54)	0.012	0.35
MCC	165	411.18 (146.95)	412.10 (122.11)	0.92 (125.14)	0.92	222	390.08 (128.17)	377.51 (125.63)	-12.57 (141.13)	0.19	0.33
Compliance	125	30.71 (196.42)	48.11 (155.53)	17.40 (266.59)	0.47	168	73.57 (175.90)	43.85 (130.19)	-29.72 (225.89)	0.09	0.10
PFS Qmax	72	19.72 (7.38)	16.70 (7.72)	-3.03 (7.87)	0.002	96	21.50 (9.71)	18.11 (9.03)	-3.39 (9.14)	<0.001	0.79
Pdet@Qmax	71	15.56 (11.93)	26.62 (23.41)	11.06 (23.10)	**<0.001**	95	19.45 (10.64)	22.60 (13.80)	3.15 (15.46)	**0.050**	**0.009**
BOOI	71	-24.07 (19.12)	-6.91 (31.21)	17.16 (31.15)	<0.001	95	-23.56 (23.79)	-13.82 (24.39)	9.74 (25.17)	<0.001	0.09

* P-value associated with test of change between baseline and 24 months (among successes).

** P-value associated with test of change between baseline and 24 months (among failures).

*** P-value associated with test of whether mean change between baseline and 24 months differs by success/failure status

Table 2

Change in UDS values from baseline to 24 months are presented by failure status and surgical arm.

	Success				Failure						
	Burch		Sling		Burch		Sling		P-values		
	n	Mean (sd)	n	Mean (sd)	N	Mean (sd)	n	Mean (sd)	Interaction*	Success vs. failure	Burch vs. sling
NIF Qmax	66	-3.7 (10.4)	84	-5.0 (12.5)	123	-3.0 (13.9)	93	-3.8 (13.8)	0.85	0.52	0.43
NIF Volume	66	-6.0 (193.48)	84	13.0 (192.4)	123	20.5 (147.1)	93	-33.5 (157.8)	**0.046**	0.58	0.34
NIF PVR	66	-6.8 (41.3)	84	11.1 (61.65)	123	8.4 (39.9)	93	8.0 (56.3)	0.09	0.26	0.10
MCC	69	-4.0 (118.6)	96	4.5 (130.14)	119	13.0 (125.7)	103	-42.1 (152.4)	**0.022**	0.29	0.09
Compliance	54	32.7 (298.1)	71	5.8 (241.4)	89	-22.8 (222.8)	79	-37.52 (230.5)	0.83	0.09	0.47
PFS Qmax	36	-3.0 (6.4)	36	-3.0 (9.2)	48	-2.2 (9.4)	48	-4.6 (8.8)	0.38	0.79	0.37
Pdet@Qmax	35	3.8 (23.3)	36	18.1 (20.9)	48	0.4 (16.8)	47	6.0 (13.5)	0.13	**0.008**	**<0.001**
BOOI	35	9.9 (31.5)	36	24.2 (29.5)	48	4.7 (25.6)	47	14.8 (24.0)	0.63	0.09	**0.005**

* between success vs. failure and Burch vs. sling