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Normal preoperative urodynamic testing does not predict postoperative voiding dysfunction among women undergoing surgery for stress urinary incontinence: Results from a prospective randomized trial comparing Burch colposuspension versus pubovaginal sling

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Abstract

Purpose—Urodynamic studies have been proposed as a means of identifying patients at risk for voiding dysfunction following surgery for stress urinary incontinence We determined if preoperative urodynamic findings predict postoperative voiding dysfunction after pubovaginal sling and Burch colposuspension.

Materials and Methods—Data were analyzed from preoperative, standardized urodynamic studies performed on participants in the Stress Incontinence Treatment Efficacy Trial, in which women with stress urinary incontinence were randomized to undergo pubovaginal sling surgery or Burch colposuspension. Voiding dysfunction was defined as use of any bladder catheter after 6 weeks or reoperation for takedown of a pubovaginal sling or Burch colposuspension. Urodynamic study parameters studied were post void residual urine, maximum flow during non-invasive flowmetry, , maximum flow during pressure flow study (change in vesical pressure at maximum flow during pressure flow study, change in abdominal pressure at maximum flow during pressure flow study and change in detrusor pressure at maximum flow during pressure flow study. The study excluded women with preoperative post-void residual urine volume of more than > 150ml or maximum flow during noninvasive flowmetry of less than 12 ml per second unless advanced pelvic prolapse was also present.

Results—Of the 655 women in whom data was analyzed voiding dysfunction developed in 57 including 8 in Burch colposuspension and 49 in the pubovaginal sling groups. There were 9 patients who could not be categorized and , thus, were excluded from the remainder of the analyses (646). A total of 38 women used a catheter beyond week 6, 3 had a surgical takedown and 16 had both. All 19 women who had surgery takedown were in the pubovaginal sling group. The statistical analysis of urodynamic predictors is based on subsets of the entire cohort, including 579 with preoperative uroflowmetry, 378 women with change in vesical pressure, and 377 with change in abdominal and detrusor pressure values.. No pre-operative urodynamic study findings were associated with an increased risk of voiding dysfunction in any group. Mean maximum flow during noninvasive flowmetry values were similar among women with voiding dysfunction compared to those without voiding dysfunction in the entire group (23.4 vs. 25.7 ml per second, p=0.16), in the Burch colposuspension group (25.8 vs. 25.7ml per second, p=.98) and in the

pubovaginal sling group (23.1 vs. 25.7ml per second, p=0.17). Voiding pressures and degree of abdominal straining were not associated with postoperative voiding dysfunction.

Conclusions—In this carefully selected group, preoperative urodynamic studies did not predict postoperative voiding dysfunction or the risk for surgical revision in the pubovaginal sling group. Our findings may be limited by our stringent exclusion criteria and studying a group believed to be at greater risk for voiding dysfunction could alter these findings. Additional analysis using subjective measures to define voiding dysfunction is warranted to further determine the ability of urodynamic studies to stratify the risk of postoperative voiding dysfunction, which appears to be limited in the current study.

Keywords

urodynamics; urinary incontinence

Stress urinary incontinence is common in the United States and urodynamic studies are often used preoperatively to confirm the diagnosis and severity as well as assess for potential problems which might influence surgical outcome. The International Consultation on Incontinence suggests that UDS be used when the information is expected to alter clinical management and subsequently improve clinical outcomes.[1] Identifying patients at risk for post-operative VD would allow for improved counseling and possibly altered management.

Urinary retention and/or delay in return to normal voiding can occur after surgery for stress urinary incontinence The incidence of persistent urinary retention after PVS ranges from 5% to 20%, with an average time to return to complete emptying of f 1 to 70 days.[234] A large contemporary review of tension-free vaginal tape reported 2.8% to 14% of patients to be in urinary retention or to have obstructive voiding symptoms.[5] Several reports have suggested that a poor detrusor contraction or voiding by valsalva rather than by detrusor contraction (intra-abdominal pressures more than 10 cm. H_2O during voiding and detrusor pressureless than 15 cm. H_20) were associated with impaired postoperative voiding in women who underwent incontinence surgery.[678] Bhatia and Bergman reported that patients using Valsalva voiding were at 12 times greater risk of needing prolonged postoperative catheterization after BC compared to those with normal detrusor voiding.[6] However, others have not shown an association between urodynamic voiding pattern and postoperative voiding dysfunction after a fascial sling operation.2[9] One of these studies suggests that the time to effective voiding primarily depended on the type of surgery performed rather than preoperative urodynamic parameters.[9]

The Urinary Incontinence Treatment Network conducted the SISTEr as a multisite randomized surgical trial that compared the Burch colposuspension and the autologous fascial pubovaginal sling. The trial design has previously been reported. 10The primary outcomes, overall urinary incontinence treatment success and stress incontinence specific treatment success at 24 months followup , were recently published.[11] A secondary aim of the SISTEr trial was to determine the prognostic value of UDS results and to identify which urodynamic parameters predict success after each procedure. We previously examined filling phase urodynamic parameters which could predict successful surgical outcomes. We examined urodynamic parameters including post-void residual volume, noninvasive peak

and mean uroflow rates, the presence and magnitude of the detrusor contraction, and the presence and magnitude of abdominal pressure via the Valsalva maneuver to determine if these can predict voiding dysfunction after stress incontinence surgery.

MATERIALS AND METHODS

Between February 2002 and June 2004, a total of 655 women with stress predominant urinary incontinence symptoms were randomized at 9 clinical sites for participation in SISTEr. Women were considered eligible if they had predominant SUI as defined by higher stress subscores on the MESA,12 a voiding frequency of 12 or less per day, a positive cough stress test, urethral hypermobility, and a post void residual urine volume of 150 mLor less (unless Stage II-IV prolapse was present). Exclusion criteria were evidence of obstructed voiding in the absence of prolapse (women without prolapse with Qmax less than 12 ml per second or detrusor pressure at maximum flow more than 50cm H_2O were excluded), or a medical condition, previous pelvic surgery, or cancer treatment, known to affect bladder or urethral function. The study was approved by the institutional review boards at all participating clinical centers and the biostatistical coordinating center. All patients gave written informed consent before enrollment in the study.

Urodynamics

Preoperative urodynamic testing consisting of a non-instrumented uroflowmetry CMG, and PFS was performed on all patients. A standardized research protocol was developed[13] that followed the International Continence Society recommended Good Urodynamic Practice Guidelines.14The reference urodynamic values for these stress incontinent women have been reported and details of the urodynamic protocol have been published15

The NIF was obtained prior to instrumentation for the CMG and PFS, a voided volume of at least 150 ml was required for it be valid. Maximum flow rate during NIF and catheterizedPVR were obtained. CMG was performed using a dual lumen urethral catheter (8 Fr or less) with the patient in the standing position at a fill rate of 50mL per minute . Simultaneous abdominal pressure monitoring was obtained through a fluid-filled rectal balloon catheter. Pressures were measured using external pressure transducers which were zeroed to atmospheric pressure using the level of the symphysis pubis as the reference height. The presence of involuntary detrusor contractions with or without incontinence was documented and Valsalva leak point pressures were obtained as previously described.[16]

PFS were performed upon reaching maximum cystometric capacity. Patients were repositioned to the sitting position and transducer height was adjusted to maintain them being level with the symphysis pubis. PFS pressures were measured at baseline (before voiding) and at maximum flow (Q_{max}PFS). The difference between pressures at Qmax and baseline pressures were calculated as deltavalues at Qmax (delta Pves, delta Pabd, delta Pdet).

Outcomes Assessment

Evaluation for treatment success was started 6 months post operatively and continued every 6 months until 24 months. The assessment panel included 24-hour pad test, 3day bladder

diary record of leakage and frequency of voiding, bladder stress test at300 ml or greater, self-reported incontinence symptoms on the MESA and whether there was any re-treatment of SUI.

Definition of Voiding Dysfunction

Voiding dysfunction in SISTEr was defined as either the need for surgical revision to improve voiding postoperatively as determined by the treating physician or the need for catheterization due to voiding difficulties at any time beyond 6 weeks after surgery.

Statistical Methods

Descriptive statistics on each UDS measure by voiding dysfunction group overall and by treatment group were conducted, and after checking for normality of the distributions of UDS measures t tests were computed to compare means by group. Otherwise Wilcoxon rank sum tests were used to compare median values. To further investigate differences between voiding groups, separate logistic regression models for each UDS measure where voiding dysfunction is the dependent variable A 5% 2-sided significance level was used for all statistical testing. Analyses were performed using SAS® version 9.1

RESULTS

Of the 655 women enrolled in the SISTEr postoperative data regarding voiding function was available in 646. Of this group, 57 women were noted to have voiding dysfunction as previously defined, 49 in the sling group compared to 8 in the BC group. Of the 57 women 19 required surgical revision, all of whom were in the sling group, at a median time of 41 days from the time of initial surgery. The remaining 38 subjects required catheterization at some point beyond 6 weeks after surgery, although none required revision. We investigated preoperative urodynamic parameters that previously suggested to predict postoperative voiding dysfunction, and found none that were significantly different between those with and without VD (Table 1). Because of missing reliable uroflow values (579 patients with evaluable values), and pressure flow data (378 women with delta Pves and 377 patients with \delta Pabd and delta Pdet values), the number of patients included in the comparisons differed depending on the parameter investigated. When considered as separate groups, again, preoperative urodynamic parameters did not appear to predict an increased risk of developing VD in the sling or BC groups (table 2). Likewise urodynamic parameters did not significantly differ in the group who required a sling revision compared to those with normal voiding.

Given the subtle differences in maximum flow rate between those with and without VD, this relationship was further explored by creating a logistic regression model (in 464) to predict VD using maximum noninvasive flow. In this model, the Qmax NIF coefficient was not statistically significant (p=.14) with OR.98 and CI (0.95, 1.01). Controlling for BC vs sling and success status in the model did not further improve the performance of any NIF Qmax in predicting VD.

DISCUSSION

The key finding in our study was that in a large group of select women, preoperative urodynamic bladder emptying tests failed to predict postoperative voiding dysfunction. In our study we defined voiding dysfunction as the use of a catheter after 6 weeks postoperatively or the need for a reoperation. . We chose this definitionbecause we believe it is clinically meaningful and represents a burden to the patient. Because of our large number of subjects, 57 of 655 women met this definition of voiding dysfunction (with 9 not able to be categorized). We believe other definitions in the literature that define voiding dysfunction as the need for catheterization after 1 week, or PVR greater than 50ml after 1 week may not be as clinically relevant.

We found that preoperative maximum flow rate (from NIF and PFS studies), changes in vesical, detrusor, and abdominal pressure from baseline to Qmax, and post-void residual volume were clinically and statistically similar in women with and without postoperative voiding dysfunction. In this randomized trial of two incontinence operations the real risk factor for voiding dysfunction was being randomized to the PVS procedure. However, even within the sling group urodynamic values did not predict voiding dysfunction.

There is no generalized agreement about qualitative descriptions of voiding mechanisms. Thus, we used only quantitative measures rather than subjective symptom scoring, measuring changes in pressures from the beginning of the PFS to their values at maximum flow. The change in abdominal pressure provides a quantitative measure of Valsalva effort during voiding. We found that the median change in Pabd for the women who went on to experience postoperative voiding dysfunction was only 1 cm H_2O, indicating that most of the women in this group did not Valsalva significantly during voiding. We also found no difference in mean detrusor pressure for the voiding dysfunction group (17 cm H20) compared to those without voiding dysfunction (16 cm H2O), indicating that a low detrusor pressure was not associated with voiding dysfunction.

Published literature available from some small case series is divided on whether specific urodynamic parameters can serve as prognostic factors for voiding dysfunction after surgery for SUI. Several reports suggest that patients who void with Valsalva will have a delay in return to normal voiding.[6-8] In a small series of 30 women, Valsalva voiding was a risk factor for residuals of more than 50 ml at 7 days after a Burch procedure.[6] In a retrospective study of 50 women with rectus fascia suburethral slings those who had preoperative Valsalva voiding had a 23-day median duration of postoperative catheterization compared to a 14-day median catheterization in the nonValsalva group.[7] In 68 women who underwent a PVS procedure Miller et al found a preoperative absence of a detrusor , contraction in 31% of their subjects, but it was present in all 4 of the subjects who were unable to void at 4 weeks after surgery.16 Lose et al. noted that 42% of women with a detrusor contraction of less than 15 cm H20 had impaired voiding vs 18% of women with normal pressures.17 Variations in methodology and terminology prevent meaningful comparison of those studies with the present investigation.

Most other studies support our finding that there was no relationship between the preoperative maximum flow rate and the presence of postoperative voiding dysfunction. Miller et al found that peak flow rate and preoperative post-void residual were not associated with inability to void at 4 weeks16 Maximum flow rated during nonintubated uroflowmetry was not predictive of delayed return of voiding in 45 women after the Burch procedure.[6] In a series of 101 women undergoing 3 different operations for incontinence there were no nonintubated uroflowmetry or PFS variables that were significantly associated with postoperative return to normal voiding.9 However, in 49 women who underwent fascia lata sling procedures a maximum flow rate during PFS of less than 20 ml per second was associated with a higher rate of requiring more than 7 days to achieve normal voiding. Only 3 of these women seemed to have significant retention and needed surgical re-treatment.2 In that study the voiding mechanism (detrusor, Valsalva, urethral relaxation) was not predictive of delayed return to normal voiding

This is the first prospective study with a large number of women who met a clinically meaningful definition of voiding dysfunction and underwent quality controlled urodynamic studies. Because of our strict insistence on only accepting quality PFS studies with plausible measuring systems at PFS baseline and maximum flow, a significant number of PFS studies were excluded from data capture. Other investigators have noted that 25% of patients could not void during the pressureflow study.[10] These excluded PFS studies were proportionately found in both groupsand, therefore, should not add any bias to our results.

Our study is limited by the fact that the results are only applicable to similar groups of women (eg women with dominant stress incontinence, a positive stress test, urethral hypermobility, PVR less than 150ml and a bladder capacity greater than 200ml). These results should not be extrapolated to patients with more complex clinical conditions or to women with preexisting obstructive symptoms. We did exclude women without prolapse who had Qmax less than 12ml per second and pdet more than 50 cm H_2O from participating in our study and, therefore, it is possible that UDS could be of value in this group. We also did not report on qualitative assessments of the voiding mechanism nor did we report on voiding pressure events that did not occur at maximum flow. However, we believe these omissions are unlikely to affect our conclusions. Similarly, voiding symptoms were not included in this analysis and they may be more predictive than urodynamic measures.

CONCLUSIONS

In carefully selected women with stress predominant incontinence preoperative urodynamic nonintubated uroflowmetry values or pressure flow study values were not predictive of clinically meaningful postoperative voiding dysfunction. In similar carefully selected women we have no evidence justify the performance of preoperative urodynamic studies to predict or prevent postoperative voiding dysfunction. Our results further justify the need for a randomized trial of preoperative urodynamics vs none in uncomplicated cases of stress urinary incontinence.

Abbreviations and Acronyms

BC	Burch colposuspension
CMG	filling cystometry
MESA	Medical, Epidemiogical and Social Aspects of Aging Questionnaire
NIF	noninstrumented uroflowmetry
NIF max	maximum flow during noninvasive flowmetry
Pabd	abdominal pressure
Pdet	detrusor pressure
PFS	pressure flow study
Pves	vesical pressure
PVR	post-void residual urine
PVS	pubovaginal sling
Qmax	maximum flow during pressure flow study
SISTEr	Stress Incontinence Surgical Treatment Efficacy Trial
SUI	stress urinary incontinence
UDS	urodynamic studies
VD	voiding dysfunction

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Table 1

Overall preoperative urodynamic results for patients undergoing B C or PVS Dysfunction

	Voiding dysfunction			No voiding dysfunction			P value
	N	Mean or Median	SD or Min, Max	N	Mean or Median	SD or Min, Max	
NIF PVR (ml)	54	10.0	0, 420	525	10.0	0, 275	0.75*
NIF Qmax (ml/sec)	54	23.4	8.4	525	25.7	11.4	0.16
PFS Qmax (ml/sec)	54	21.3	9.1	557	21.4	10.1	0.97
Delta Pves (cm H_2O)	27	20.9	21.0	351	21.9	21.0	0.81
Delta Pabd (cm H_2O)	27	−1	−26, 62	350	0	−28, 100	0.51*
Delta Pdet (cm H_2O)	27	16.9	10.9	350	15.5	11.8	0.54

#Wilcoxon rank sum test since the distribution is not normal and median (range) is reported

* t Test, if variable is normal.

Table 2

Preoperative urodynamic results

	Voiding dysfunction			No voiding dysfunction			P value
	N	Mean or Median	SD or Min, Max	N	Mean or Median	SD or Min, Max	
NIF PVR (ml)	7	10.0	0, 322	287	10.0	0, 275	0.65*
NIF Qmax (ml/sec)	7	25.8	10.6	287	25.7	10.7	0.98
PFS Qmax (ml/sec)	8	22.3	9.8	297	20.3	9.2	0.55
Delta Pves (cm H_2O)	3	25.0	23.5	193	22.2	20.5	0.81
Delta Pabd (cm H_2O)	3	1.0	0, 11	192	0	−24, 91	0.59*
Delta Pdet (cm H_2O)	3	21.0	17.4	192	16.2	11.6	0.48

	Voiding dysfunction	No voiding dysfunction	P value				
	N	Mean or Median	SD or Min, Max	N	Mean or Median	SD or Min, Max	
NIF PVR (ml)	47	10.0	0, 420	238	10.0	0, 220	0.59*
NIF Qmax (ml/sec)	47	23.1	8.1	238	25.7	12.3	0.17
PFS Qmax (ml/sec)	46	21.1	9.0	260	22.6	10.9	0.39
Delta Pves (cm H_2O)	24	20.4	21.1	158	21.6	21.7	0.80
Delta Pabd (cm H_2O)	24	−2.0	−26, 62	158	0.0	−28, 100	0.43*
Delta Pdet (cm H_2O)	24	16.4	10.3	158	14.7	12.0	0.51

rank sum test since the distribution is not normal and median (range) is reported

* t Test if variable is normal