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Risk Factors For Incomplete Bladder Emptying After Midurethral Sling

Peggy Norton^a, Charles W Nager^b, Toby C Chai^c, Elizabeth Mueller^d, Anne Stoddard^e, Jerry Lowder^f, Edward Varner^g, and Gary Lemack^h for the Urinary Incontinence Treatment Network

^aUniversity of Utah, Salt Lake City

^bUniversity of California, San Diego

^cYale University School of Medicine

^dLoyola University, Chicago

^eNew England Research Institutes

^fUniversity of Pittsburgh Magee-Womens Hospital

^gUniversity of Alabama at Birmingham

^hUniversity of Texas Southwestern, Dallas

Introduction

Voiding difficulties after continence surgery can lead to patient dissatisfaction, urinary tract infection, or the need for sling revision.¹ Such symptoms often are attributed to the effects of the surgery, and urodynamic testing may be utilized to assess the risk of voiding problems. Less is known about the prevalence of such symptoms prior to surgery, and whether the presence of abnormal voiding is predictive of postoperative voiding difficulties.

Synthetic midurethral slings (MUS) have become the predominant incontinence procedure performed for stress urinary incontinence (SUI), and while the “tension-free” positioning of the MUS is thought to decrease the incidence of post-operative incomplete bladder emptying², the problem is not eliminated entirely. The Trial of Midurethral Sling (ToMUS) study was conducted by the Urinary Incontinence Treatment Network (UITN) to compare the transobturator and retropubic approaches to MUS utilizing a randomized equivalence study design³, and although the rate of adverse events was overall low, prolonged voiding difficulty was observed after these surgeries. Data from this large multi-center randomized trial provides a unique opportunity to identify important clinical variables that might impact the development of post-operative voiding dysfunction.⁴ The objective of this study was to determine risk factors for incomplete bladder emptying after retropubic or transobturator MUS, including pre-operative voiding symptoms, clinicodemographic or urodynamic parameters.

Methods

This was a planned secondary analysis of the ToMUS trial whose complete design has been published.³ Inclusion criteria included women 21 years of age or older planning to undergo

surgery for the treatment of predominant SUI with a positive urinary stress test at a bladder volume of 300 mL or less; urodynamic stress incontinence was not required. Women with persistent postvoid residuals (PVR) in excess of 100 mL were excluded from the trial (in the case of Stage 2-4 POP, PVR of up to 500 mL was allowed.) Voiding symptoms were assessed pre-operatively, including descriptors of urinary stream, and voiding accommodation defined as maneuvers to facilitate voiding such as standing or straining. As no validated detailed measure of voiding symptoms existed, investigators designed a tool using questions as outlined in table one. Between April 2006 and June 2008, 597 women were randomly assigned to receive either a retropubic sling (298 women) or a transobturator sling (299 women). Slings were standardized with placement in a midurethral position without tension as determined by the individual surgeon.

Urodynamics

Urodynamic testing, according to standardized protocols, was performed prior to surgery in accordance with International Continence Society recommended Good Urodynamic Practice guidelines.⁵ Preoperative urodynamic test results were interpreted by an investigator other than the study surgeon; the study surgeon remained unaware of the results throughout the study unless unblinding of the results was necessary for the management of postoperative care. Details of the urodynamic protocol have been published.⁶ Non-instrumented uroflowmetry (NIF) was obtained before instrumentation for filling cystometry (CMG), and a voided volume of at least 150 ml was required to be valid. Maximum flow rate (Qmax) during NIF and catheterized PVR were obtained.

Filling cystometry was performed using a dual lumen urethral catheter (8Fr or less) with the patient in the standing position at a fill rate of 50 ml 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. Pressure/flow studies (PFS) were performed after reaching maximum cystometric capacity. Subjects were repositioned to the sitting position and transducer height was adjusted to maintain a level with the symphysis. PFS pressures were measured at baseline (before voiding) and at maximum flow. The difference between pressures at Qmax and baseline pressures were calculated as delta values at Qmax (delta Pves, delta Pabd, and delta Pdet.) Voiding mechanisms were evaluated on review of urodynamic tracing and described as pure or predominant detrusor, pure or predominant abdominal straining, mixed voiding mechanism, or indeterminate/uninterpretable.

Definition of Voiding Groups after surgery

At the time of discharge after surgery, subjects underwent a standardized voiding trial: 300 mL were instilled via an indwelling urethral catheter which was then removed. A successful voiding trial was defined as 150 mL or more voided immediately after filling. Subjects with successful voiding trials were deemed to be self voiding, but clinicians were allowed to recommend catheter use at discharge based on the voiding trial or other mitigating factors such as intraoperative bladder perforation. The primary outcome was adequate bladder emptying at discharge: Subjects who were self voiding at discharge were defined as having adequate bladder emptying, while those who were discharged with an indwelling catheter or clean intermittent self-catheterization were defined as having incomplete bladder emptying at discharge, and are the outcome of interest for this analysis.

Statistical Methods

This analysis was performed on the intention-to-treat population. Descriptive statistics on each UDS measure by bladder emptying 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 bladder emptying groups, separate logistic regression models were fit for each UDS measure and each clinicodemographic measure where incomplete bladder emptying was the dependent variable. A 5% 2-sided significance level was used for all statistical testing. Analyses were performed using SAS® version 9.1. The protocol was approved by the IRBs of the nine study sites and all patients gave consent.

Results

Twelve-month outcomes data on 597 subjects randomized to either retropubic or transobturator MUS have been reported and showed statistical and clinical equivalence for treatment success rates.³ The mean age of the cohort was 52.9 ± 11.2 years, mean BMI was $30.3 \pm 6/9$, while 79/597 (14 %) had had prior surgery, and 151/597 (25 %) had concurrent vaginal surgery for prolapse at the time of sling placement. Of the 597 subjects, 15 did not have a voiding trial prior to discharge due to bladder perforation or other problems. Of the remaining 582 participants, 395 (68%) underwent the midurethral sling as an outpatient procedure and their voiding trial on the same day as surgery, while 187 (32%) underwent a voiding trial on postoperative day #1. The reasons for delayed voiding trial included late surgery for a planned same-day surgery or concomitant procedures with overnight stay.

Four hundred fifty-four of 597 (76%) of subjects were self-voiding at discharge, 114/597 (19%) were discharged with an indwelling urethral catheter and 29/597(5%) were instructed to use intermittent self-catheterization. Three subjects (0.5%) underwent sling loosening or division before 2 weeks post- op. No subjects had a sling release between the second and sixth week, but five additional subjects underwent a sling release between 6 weeks and 2 years postoperatively. By two weeks after midurethral sling, only 38/597(6%) of subjects reported any catheter use, and by six weeks, only 9/597(2%) reported any catheter use. The number of women undergoing sling release was too small to permit any association analysis.

Preoperative voiding symptoms were common and of two types, descriptions of urinary stream and accommodation to facilitate voiding. The most common accommodation was bending forward to void (20.8%); other accommodations were less common, including straining to void (12.4%) and pressing on the bladder (8%); 29% of subjects reported some voiding accommodation preoperatively. Descriptions of urinary stream as abnormal were much more common: only a minority of women described their stream as “steady” at baseline evaluation. Table 1 reports the frequency of “yes” responses to the preoperative voiding symptom questionnaire and using bivariate logistic regression analysis, the odds ratio of incomplete bladder emptying with a “yes” response to each question. Voiding symptoms such as unsteady or slow stream, and voiding accommodations such as straining, bending forward, and pressing on bladder were associated with incomplete bladder emptying at discharge. Retropubic urethral sling was the factor most associated with incomplete bladder emptying at discharge compared to transobturator sling (OR 1.79, 95% CI 1.22-2.62, $p=0.003$). Prior surgery for incontinence, age, higher BMI or concomitant surgery did not increase the likelihood of incomplete bladder emptying at discharge.

All 597 subjects underwent urodynamic testing, but our quality control process requiring high quality, valid and plausible studies meant that not all subjects had valid and plausible values for all urodynamic variables as shown in Table 2, which presents the associations of the UDS factors and incomplete bladder emptying. As expected, Pdet void at Qmax had the fewest evaluable measures. Preoperative urodynamic parameters such as voiding mechanism, detrusor pressure at maximum flow, maximum flow during non-instrumented

and instrumented flow, or post void residual were not associated with incomplete bladder emptying at discharge.

Comment

After surgery, incomplete bladder emptying at time of discharge affects a quarter of women undergoing midurethral sling, but the problem is short-lived. Preoperative voiding accommodation is not commonly reported but is associated with incomplete bladder emptying at discharge. Some accommodating maneuvers that present preoperatively confer almost a 2-fold increase in the risk of incomplete bladder emptying, including straining to void, pressing on bladder to void, and bending forward to void. In contrast, voiding descriptors such as weak urinary stream are common in women planning surgery for stress incontinence but less associated with incomplete bladder emptying. Risk factors include the use of retropubic sling as compared to transobturator sling, but other participant characteristics such as age or prior surgery did not affect the risk of incomplete bladder emptying.

Many studies reporting voiding difficulties after surgery fail to take into account the prevalence of voiding symptoms *prior* to continence surgery, but we found that such symptoms are common, even in women without prolapse or prior continence surgery. Only a small minority of women believed they have a steady stream, and almost three-quarters of women report dribbling. Such preoperative symptoms must be taken into account before ascribing such symptoms to the procedure itself.

Urodynamic testing is often recommended prior to surgery for stress urinary incontinence, in part to assess the risk of voiding dysfunction after surgery.⁷ In the SISTER trial, a randomized trial of autologous fascial sling versus Burch colposuspension by the Urinary Incontinence Treatment Network, we found no preoperative urodynamic parameter that was predictive of the need for prolonged continuous or intermittent catheterization in either Burch or sling patients, although most of the voiding dysfunction occurred in the sling group.⁸ In the current study we found that urodynamic variables do not predict incomplete bladder emptying although a dysfunctional pre-operative voiding pattern may confer an increased risk. Thus, two large surgical trials (SISTER and TOMUS) have failed to show the utility of preoperative urodynamics to predict the potential voiding difficulties in women undergoing surgical management of stress urinary incontinence. This differs from smaller studies supporting the use of such testing,⁹ but is similar to findings reported by Lowenstein et al using the obstructive portion of the Pelvic Floor Distress Inventory.¹⁰

Limitations of the study include inability to compare the voiding outcomes of this study with previous studies by our group: Because voiding dysfunction was less severe after MUS, we used incomplete bladder emptying prior to discharge after continence surgery for our analysis. This is in contrast to the UITN randomized trial SISTER, in which voiding problems were more common post-operatively, and the definition of postoperative voiding dysfunction was the need for a catheter at any after six weeks postoperatively, or the need for surgical revision to improve voiding.¹¹ Thus, the two trials cannot be compared directly. Another limitation is the lack of a validated instrument to characterize voiding symptoms in detail. Finally, women with incomplete bladder emptying prior to surgery were excluded from the study, so these results are applicable to women who do not have persistent postvoid residuals greater than 100 mL prior to planned surgery.

Conclusion

Incomplete bladder emptying at discharge after mid-urethral sling surgery is common, especially after RMUS, but of short duration. Risk factors include preoperative voiding symptoms like straining, bending, and slow stream, but urodynamic and clinicodemographic variables did not predict incomplete bladder emptying after MUS. This information can be used to better counsel patients before and after these common incontinence procedures.

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Table 1
Preoperative voiding accommodation, or description by subject : Frequency and Odds Ratios for incomplete bladder emptying at discharge (n=597)

Incomplete Bladder Emptying at Discharge				
Yes (N=143)	No (N=454)	Total (N=597)	P-value	OR (95%CI)
Responding "yes" to Voiding Accommodation n(%)				
Strain to urinate				
25 (17.5)	49 (10.8)	74 (12.4)	0.04	1.75 (1.04--2.96)
Bend forward to urinate				
41 (28.7)	83 (18.3)	124 (20.8)	0.008	1.80 (1.16--2.77)
Lean back to urinate				
12 (8.4)	23 (5.1)	35 (5.9)	0.14	1.72 (0.83--3.55)
Stand up to urinate				
7 (4.9)	11 (2.4)	18 (3.0)	0.14	2.07 (0.79--5.45)
Press on your bladder				
21 (14.7)	27 (5.9)	48 (8.0)	0.001	2.72 (1.49--4.98)
Push on the vagina				
9 (6.3)	14 (3.1)	23 (3.9)	0.09	2.11 (0.89--4.99)
Do anything else				
9 (6.3)	14 (3.1)	23 (3.9)	0.09	2.11 (0.89--4.99)
Responding "yes" to Voiding Description n(%)				
Steady stream				
30 (21.0)	61 (13.4)	91 (15.2)	0.03	1.71 (1.05--2.78)
Slow stream,				
48 (33.6)	103 (22.7)	151 (25.3)	0.009	1.72 (1.14--2.60)
Spurting, spraying				
44 (30.8)	162 (35.7)	206 (34.5)	0.28	0.80 (0.54--1.20)
Hesitating stream				
47 (32.9)	122 (26.9)	169 (28.3)	0.17	1.33 (0.89--2.00)

Incomplete Bladder Emptying at Discharge				
	Yes (N=143)	No (N=454)	Total (N=597)	P-value OR(95%CI)
Dribbling	99 (69.2)	325 (71.6)	424 (71.0)	0.59 0.89 (0.59-- 1.35)

Table 2

Association of incomplete bladder emptying at discharge with urodynamic factors: frequencies or means and results of bivariate logistic regression

	Incomplete Bladder Emptying at Discharge			
	Yes (N=143)(%)	No (N=454)(%)	Total (N=597)(%)	P-value
Voiding mechanism				
N	99	352	451	0.16
Pure or predominant detrusor	53 (53.5)	223 (63.4)	276 (61.2)	reference
Pure or predominant abdominal	15 (15.2)	38 (10.8)	53 (11.8)	0.77 (0.25–2.31)
Mixed	27 (27.3)	69 (19.6)	96 (21.3)	1.65 (0.96–2.81)
Indeterminate/uninterpretable	4 (4.0)	22 (6.3)	26 (5.8)	1.66 (0.85–3.24)
Pdet at Qmax in cm H2O				
N	85	316	401	
Mean (SD)	17.9 (14.7)	19.7 (12.7)	19.3 (13.2)	0.25 0.99 (0.97–1.01)
Qmax on non-instrumented uroflowmetry in mL/sec				
N	128	422	550	
Mean (SD)	23.5 (11.1)	25.5 (12.6)	25.0 (12.3)	0.11 0.99 (0.97–1.00)
Qmax on Pressure Flow study in mL/sec				
N	128	428	556	
Mean (SD)	20.8 (11.1)	22.5 (10.7)	22.1 (10.8)	0.12 0.98 (0.97–1.00)
Post-Void residual after non-instrumented uroflowmetry in mL				
N	379	502		
Mean (SD)	25.3 (32.4)	23.6 (45.1)	24.0 (42.3)	0.71 1.00 (1.00–1.01)