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Pre-operative Clinical, Demographic and Urodynamic Measures Associated with Failure to Demonstrate Urodynamic Stress Incontinence in Women Enrolled in Two Randomized Clinical Trials of Surgery for Stress Urinary Incontinence

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Abstract

Aims—The unexpected absence of urodynamic stress incontinence (USI) in women planning surgery for stress urinary incontinence (SUI) is a challenge to surgeons. We examined the prevalence and clinical and demographic factors associated at baseline (pre-operatively) with the unexpected absence of USI among study participants of two multi-center randomized clinical trials of surgery for treatment of SUI.

Methods—Women with stress incontinence symptoms and positive stress tests on physical examination enrolled in two separate clinical trials comparing the autologous fascial sling with the Burch suspension (SISTER trial), and the retropubic mid urethral sling compared to the transobturator mid urethral sling (TOMUS), were evaluated for USI preoperatively. The association of clinical, demographic and urodynamic parameters was examined in women without USI in univariable and multivariable analyses.

Results—Overall, 144 of 1233 women (11.7%) enrolled in the two studies did not show USI. These women had a significantly lower mean volume at maximum cystometric capacity than those with USI (347.5 vs. 395.8 in SISTER, $p = 0.012$), (315.2 vs. 358.2 in TOMUS, $p = 0.003$), and a lower mean number of daily accidents reported on a three day diary (2.2 vs 2.7 in SISTER, $p = 0.030$) (1.7 vs 2.7 in TOMUS, $p < 0.001$). Additionally, those without demonstrable USI were more likely to have POPQ stage III/IV (31.7% vs 14.4% in SISTER, $p = 0.002$), (15.5% vs 6.9% in TOMUS, $p = 0.025$). Severity of SUI as recorded on Urogenital Distress Inventory correlated strongly with the presence of USI in both studies.

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Conclusions—We observed that about one of out eight women planning surgery for SUI does not show USI. Severity of stress incontinence and Stage 3/4 pelvic organ prolapse were strongly associated with the unexpected absence of USI. A diminished urodynamic bladder capacity among women who did not display USI may reflect an inability to reach the limits of capacity during urodynamics, at which these women normally leak.

Introduction

Stress urinary incontinence (SUI) is among the most common forms of urinary incontinence reported by women. Distinguishing the type of urinary incontinence is often difficult, with physical exam, questionnaires, and urodynamic studies often being utilized, either individually or combined to evaluate and categorize the type of leakage. Relying solely on patient history or urinary incontinence questionnaires may lead to an inappropriate diagnosis in certain women,¹ while establishing the presence of urodynamic stress incontinence (USI) may be considered an overuse of an invasive and costly diagnostic tool, with questionable reproducibility.²

USI has been proposed as “the gold standard” for diagnosing stress incontinence in women. However, some women with bothersome symptoms of stress incontinence may not display USI. We previously observed that approximately ten percent women enrolled in a randomized clinical trial of Burch colposuspension versus fascial slings had an unexpected absence of a urodynamic finding of USI, despite reporting pure or predominant symptoms of stress incontinence and having a positive standardized urinary stress test during pelvic exam.³

There are several possible reasons why USI may not be observed in women with symptoms and/or physical exam evidence of stress incontinence. Pelvic floor muscle tone induced by the actual test procedure, partial occlusion of the urethra by the physical presence of a catheter, an inability to recreate the precise inciting event for SUI, and coexisting pelvic organ prolapse all have been suggested as possible reasons for failing to elicit USI in women reporting stress incontinence.⁴ The inability to demonstrate USI in a woman considering surgery for SUI poses a challenge in confirming the correct diagnosis and recommending appropriate treatment.

The clinical significance of failing to observe USI among women with diagnosed SUI is uncertain. The presence of USI has found to be associated improved overall surgical success in the case of pubovaginal sling and Burch, but, interestingly, lower objective success for midurethral slings. Less is known, however, about the clinical and demographic findings in patients who are not found to have USI. Whether this finding is associated with altered severity of SUI, as reported by questionnaire, or other characteristics of women reporting SUI requires study. Furthermore, a better understanding of the characteristics of women with SUI who do not demonstrate USI may provide insight into the mechanism(s) of stress leakage as well as identifying women who should undergo urodynamic testing. We report this secondary analysis, on a broad range of clinical and demographic characteristics and urodynamic study findings in women with SUI enrolled in two randomized clinical trials of surgery who had an unexpected absence of USI.

Materials and Methods

This secondary analysis of women enrolled in two randomized clinical trials, includes those randomized in the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER) and the Trial of Mid-Urethral Slings (TOMUS) trials. The SISTER trial compared the autologous fascial sling with the Burch colposuspension. The TOMUS trial compared retropubic and transobturator mid urethral slings.⁵ Information obtained and tests performed at baseline (pre-operatively) included age, weight, height, BMI, concomitant surgery, Q-tip test, pelvic organ prolapse quantification (POPQ), pelvic muscle strength (Brinks score), full bladder and supine empty bladder stress test, 24 hour pad weight test and three day voiding diary to measure incontinence episodes and symptoms. Self-reported measures included the Urogenital Distress Inventory (UDI), the Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA) with stress and urge subscales, the Incontinence Impact Questionnaire (IIQ) and a question regarding expectation about their upcoming surgery. To qualify for inclusion in the trials, all patients had to leak during a supine stress test (bladder volumes 200–300ml). Patients went on to surgery, regardless of the presence of USI.

Urodynamics

Standardized urodynamic testing, including noninvasive uroflow (NIF), filling cystometry in the standing position, and pressure-flow studies (PFS) were performed on all women prior to surgery in both studies. Urethral pressure profilometry (UPP) was performed in TOMUS but not the SISTER study. To evaluate for USI, Valsalva leak point pressures (VLPP) were measured during filling beginning at a volume of 200 ccs and then again in 100 cc's increments until leakage was demonstrated or capacity was reached. If the patient had reached capacity and had not leaked with valsalva, a cough test was performed. In the SISTER trial, patients with stage 3 or greater prolapse had VLPP testing done with and without prolapse reduction during filling and at MCC. In the TOMUS trial, prolapse reduction testing was not performed. Presence or absence of USI was defined as at least one episode of SUI with a cough or a valsalva maneuver at any point during filling with or without prolapse reduction. Detrusor overactivity and detrusor overactivity incontinence were recorded if present. Maximum cystometric capacity (MCC) was defined as the instilled volume at which the patient had a strong urge to urinate and could accommodate no more fluid. Maximal flow (Q-max) and detrusor pressure at Q-max (Pdet @ Qmax) were also recorded from the PFS.

Statistical Analysis

Descriptive statistics were calculated for each of the studies by USI status to assess differences between these patients. T tests were used to compare means and Wilcoxon rank sum tests were used to compare medians for variables that were skewed (e.g. pad weights, accidents/day and volume at MCC). To investigate which covariates were most likely to independently predict not having USI, multivariable logistic regression models were fit using a two stage process. First, we fit a preliminary multivariable model that included all variables reaching the 0.05 level of significance from separate bivariate models as well as clinically significant variables. Secondly, based on the preliminary multivariable model, variables that did not reach the 0.05 level of significance were deleted to form a “final”

model for the SISTER trial. The same model building technique was repeated for the TOMUS trial. Additional model fitting was done to ascertain whether similar variables could be included in the “final” models for the two trials. Akaike’s Information Criteria (AIC) was used to assess model fit and for model comparison.⁶ Results are presented as odds ratios (with corresponding 95% confidence intervals) to predict women not having USI. Analyses were performed with the use of SAS statistical software, version 9.2 (SAS Institute). This study was submitted and approved by the institutional ethics committee of all 9 participating sites.

RESULTS

The rates of pre-operative USI in the SISTER and TOMUS trials were 91% and 86%, respectively. Table 1 shows study variables for each clinical trial and the demonstration (or not) of USI. In both studies, women who did not show USI had a significantly lower mean volume at maximum cystometric capacity – MCC ($p = 0.012$, $p = 0.003$ for SISTER and TOMUS respectively), and a lower mean number of daily accidents reported on a three day diary compared to women who displayed USI ($p = 0.030$, $p < 0.001$). Women without USI had significantly lower mean UDI stress scores in both studies ($p = 0.013$, $p = 0.004$), higher UDI obstructive scores ($p = 0.041$, $p = 0.042$) and were about twice as likely to have POPQ stage III/IV ($p = 0.002$, $p = 0.025$). POPQ stage III/IV subjects in SISTER had prolapse reduction during UDS and 18.4% (19/103) had No USI, whereas in TOMUS (when prolapse reduction was not performed) these POPQ stage III/IV subjects had a 27.1% (13/48) rate of No USI. ($p = .23$)

In TOMUS, subjects in the no-USI group had a significantly lower mean total ($p < 0.001$), stress ($p < 0.001$), and urge MESA scores ($p = 0.030$). In contrast, women enrolled in TOMUS who did not show USI were more likely to have a significantly higher mean Pdet @ Qmax ($p = 0.001$) and undergo concomitant surgery ($p < 0.001$).

Based on the findings above, multivariable logistic regression models were created to predict absence of pre-operative USI for each study. For example, for SISTER the following variables were considered: UDI stress score, UDI obstructive score, number of incontinence episodes per day from a three day voiding diary, volume at MCC, baseline POPQ stage, and Pdet @ Qmax. Variables no longer significant in the multivariable analysis were removed and the results of the final model are shown in Table 2. Lower UDI stress scores and lower volume at MCC were related to the odds of a woman not having USI. For every 10 unit increase in UDI stress score, the odds of having no-USI decreased by 12% (odds ratio (OR) with 95% confidence interval is 0.88 (0.78, 0.99), $p = 0.028$). Considering volume at MCC, for every 50 mL increase, the odds of no USI decreases by 15% (OR 0.85 (0.76, 0.96), $p = 0.009$). Women with baseline POPQ stage III or IV were over twice as likely to not display USI than subjects with stage 0 or I (OR 2.65 (1.14, 6.16), $p = 0.035$).

For TOMUS the following variables were considered: Pdet @ Qmax, MESA stress and urge scores, UDI stress and obstructive scores, number of accidents per day by diary, volume at MCC, baseline POPQ stage, and concomitant surgery. The results of the model are shown in Table 2. Higher Pdet @ Qmax was positively related to no-USI while number of

incontinence episodes per day, and MCC volume were inversely related to no USI. Specifically, as Pdet @ Qmax increases, the odds of no USI also increases; (OR 1.03 (1.01, 1.06), $p = 0.004$). Regarding number of incontinence episodes per day by diary, for every one unit increase in incontinence episodes/day the odds of no USI decreases by over 25% (OR 0.71 (0.59, 0.86), $p < 0.001$). For volume at MCC, with every 50 mL increase, the odds of no USI decreases by over 20% (OR 0.79 (0.67, 0.93), $p = 0.004$).

To investigate the similarities between SISTER and TOMUS, we created multivariate models for both studies using the same variables including UDI stress score, volume at MCC, POPQ stage, pdet@Qmax and episodes per day. The results of this comparison confirm that the two trials were quite similar in regards to the relationships of the assessed variables with the odds of no USI (not presented). While each relationship did not necessarily reach statistical significance, UDI stress score, volume at MCC and average number of incontinence episodes per day were associated with lower odds of no USI whereas higher POPQ stage and pdet@Qmax were associated with higher odds of no USI.

Discussion

This secondary analysis of women enrolled in two clinical trials of surgery for symptomatic SUI provides a unique opportunity to try to examine how women with symptoms and demonstrable stress incontinence in the office, but without USI may differ from those with USI. These women were more likely to have less stress incontinence symptoms, more obstructive voiding symptoms, fewer daily incontinence episodes, higher stage prolapse, a higher pdet @ Qmax, and a lower MCC compared to women with USI.

We found that more pronounced prolapse was about twice as common in women who did not display USI than those who did. Prolapse can produce urethral kinking and obstruction which poses a challenge for urodynamic testing, and the optimal method for prolapse reduction is not known.⁷ This effect may be compounded by the presence of a urethral catheter.⁸ Prolapse reduction is commonly performed during urodynamic testing, and our study does suggest that without prolapse reduction the diagnosis of no USI may be more likely. We found a lower rate of No USI (18.4%) in our SISTER subjects with advanced prolapse when prolapse reduction was performed during UDS than we did in comparable TOMUS subjects when no prolapse reduction was performed during UDS (27.1%), though this difference was not statistically significant. It may be that prolapse reduction during UDS is more important during urodynamics in subjects without symptoms of stress incontinence; prior studies document that only 4% of subjects with prolapse and without symptoms of stress incontinence will demonstrate USI without prolapse reduction even though 27% will demonstrate it with prolapse reduction.⁹ Prolapse and its related urethral obstruction are the likely reason these subjects had a higher pdet@Qmax and may explain why the subjects had fewer daily incontinence episodes.

The finding that women without USI had a lower MCC is interesting. It is well known that in any given individual with SUI, stress incontinence is more common at higher bladder volumes and the odds of eliciting it are increased at higher volumes. We may not have elicited USI because, despite the standardized approach to measure MCC, we did not “push”

the patients to high enough volumes to elicit USI. It is also possible that the act of artificial filling during urodynamics alters the sensory threshold, such that the normal volume at which women leak is not reached – another potential artifact of urodynamic testing. These findings emphasize the possible importance of reaching full MCC to increase the sensitivity of USI detection.

The strengths of our study include detailed characterization of a very large population of 144 subjects with symptoms and signs of stress incontinence without urodynamic stress incontinence. A potential limitation of our study is that we conclude that advanced prolapse poses a 2 fold risk for not demonstrating USI, though prolapse reduction maneuvers were performed only in the SISTER study. We believe this does not affect our conclusion because: 1) there were very few (13) subjects in TOMUS with advanced prolapse who had No USI (and thus reducing them would have uncovered very few, if any cases of USI) and 2) the rates of no USI for this TOMUS group were not significantly different than those overall in SISTER (including those reduced and non-reduced).

Overall, our findings may be reassuring for clinicians who recommend SUI surgery based on history, physical and office testing demonstrating SUI, despite the unexpected absence of USI. Women who meet our study criteria for stress incontinence surgery despite a lack of urodynamic evidence for USI appear to have similar surgical outcomes. In the SISTER trial, women without USI had a tendency for higher failure rates¹⁰ while in the TOMUS trial women without USI had a tendency for lower failure rates¹¹ suggesting that the impact using contemporary treatments for SUI (MUS) might be negligible. Indeed, recent guidelines have suggested that patients with demonstrable SUI and minimal voiding dysfunction or urgency symptoms may proceed to surgery without urodynamics,¹² though clearly characterizing the group of patients who might be best served by preoperative urodynamics requires further clarification.

Conclusions

In conclusion, we have found that women with stress incontinence symptoms and demonstrable office stress incontinence, but without USI, are more likely than their counterparts with USI to have more obstructive symptoms, fewer incontinence episodes, more prolapse, higher voiding pressures, and lower bladder capacities. Our previous results do not suggest that they have worse surgical outcomes after midurethral sling. An ongoing multicenter trial will further evaluate the utility of routine use of urodynamics prior to SUI surgery.¹³

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Table 1

SISTER and TOMUS study variables by study and USI status

Variable	SISTER (N=644)			TOMUS (N=589)		
	USI (n=584)	No USI (n=60)	p-value	USI (n=505)	No USI (n=84)	p-value
Age (n, SD) [‡]	51.9 (10.3)	51.6 (9.6)	0.88	53.0 (10.8)	51.9 (12.0)	0.40
Brinks score [‡]	9.0 (2.1)	9.1 (1.9)	0.53	8.8 (2.0)	8.5 (2.3)	0.21
BMI (kg/m ²) [‡]	30.0 (6.2)	29.8 (5.7)	0.79	30.3 (6.6)	30.2 (7.0)	0.94
Mean MUCP [‡]	N/A	N/A	N/A	67.0 (33.0)	74.1 (29.4)	0.08
NIF max flow [‡]	25.5 (11.2)	24.4 (10.9)	0.50	25.3 (12.2)	22.6 (10.9)	0.08
PFS Qmax [‡]	21.4 (10.0)	21.0 (10.4)	0.80	22.3 (11.1)	20.4 (9.3)	0.16
Pdet @ Qmax [‡]	18.9 (12.6)	21.7 (11.3)	0.23	18.5 (12.6)	25.0 (15.5)	0.001
MESA total score [‡]	25.9 (7.3)	24.9 (8.5)	0.29	26.0 (7.4)	23.0 (8.0)	<0.001
MESA Stress score [‡]	19.5 (4.5)	18.3 (4.9)	0.06	19.6 (4.4)	17.7 (5.4)	<0.001
MESA Urge score [‡]	6.5 (3.8)	6.6 (4.5)	0.84	6.4 (4.0)	5.4 (3.7)	0.03
UDI total score [‡]	151.6 (49.1)	149.5 (43.8)	0.75	135.5 (45.9)	128.2 (42.8)	0.18
UDI Irritative score [‡]	48.1 (25.2)	46.2 (23.9)	0.58	41.8 (25.8)	37.4 (22.0)	0.14
UDI Stress score [‡]	78.9 (21.8)	71.5 (21.7)	0.01	75.3 (20.7)	68.1 (24.8)	0.004
UDI Obstructive score [‡]	24.7 (21.6)	30.7 (22.4)	0.04	18.4 (17.6)	22.8 (22.1)	0.04
Average number of incontinence episodes per day [*]	2.7 (0.0–26.0)	2.2 (0.0–13.3)	0.03	2.7 (0.0–25.7)	1.7 (0.0–10.0)	<0.001
IIQ total score [‡]	171.5 (102.3)	175.2 (89.3)	0.78	153.8 (97.7)	134.7 (91.1)	0.09
Volume at MCC (mL) [‡]	395.8 (137.1)	347.5 (139.4)	0.01	358.2 (121.5)	315.2 (119.3)	0.003
Q-tip max straining angle [‡]	60.7 (18.5)	56.5 (17.2)	0.09	46.0 (20.7)	46.8 (21.2)	0.73
Pves @ Qmax [‡]	58.5 (24.0)	57.9 (23.0)	0.90	55.8 (24.9)	60.8 (35.3)	0.21
Detrusor overactivity (Yes) [‡]	53 (9.1)	7 (12.1)	0.46	57 (11.4)	12 (14.3)	0.44
DO-Incontinence (Yes) [‡]	32 (5.6)	4 (7.1)	0.64	33 (6.8)	8 (9.8)	0.33

Variable	SISTER (N=644)			TOMUS (N=589)		
	USI (n=584)	No USI (n=60)	p-value	USI (n=505)	No USI (n=84)	p-value
POPQ stage [‡]			0.002			0.02
0/1	149 (25.5)	10 (16.7)		231 (45.7)	32 (38.1)	
2	351 (60.1)	31 (51.7)		239 (47.3)	39 (46.4)	
3/4	84 (14.4)	19 (31.7)		35 (6.9)	13 (15.5)	
Concomitant surgery	344 (57.2)	38 (63.3)	0.36	111 (22.0)	39 (46.4)	<0.001

Bolded values indicate that the difference between the USI and no USI groups was statistically significant (p < 0.05).

Data presented as:

- [‡] Number (%);
- [‡] Mean (SD);
- ^{*} Median (Range)

Table 2

Multivariable logistic regression models for prediction of absence of baseline USI.

SISTEr		
Variable	OR (95% CI) *	p-value
UDI stress score (for each 10 unit change)	0.88 (0.78, 0.99)	0.028
Volume @ MCC (for each 50 unit change)	0.85 (0.76, 0.96)	0.009
POPQ stage		0.035
0/1	Reference	
2	1.24 (0.59, 2.63)	
3/4	2.65 (1.14, 6.16)	
TOMUS		
Pdet @ Qmax	1.03 (1.01, 1.06)	0.004
Average number of incontinence episodes per day	0.71 (0.59, 0.86)	<0.001
Volume at MCC (for each 50 unit change)	0.79 (0.67, 0.93)	0.004

* Unless otherwise indicated, odds ratios presented are for each 1 unit change in the variable considered (e.g. for every 1 unit change in pdet@Qmax, OR is 1.03).

The AIC for the SISTEr model was 0.68 and for the TOMUS model was 0.75.