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Symptoms of Combined Prolapse and Urinary Incontinence in Large Surgical Cohorts

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Abstract

Objective—To estimate whether prolapse severity is a major contributor to urinary incontinence severity, as measured by validated incontinence questionnaires.

Methods—We analyzed data from two large female stress urinary incontinence (SUI) surgical cohorts: the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) study (N=655) and the subsequent Trial of Mid-Urethral Slings (TOMUS) study (N=597). All participants completed a standardized baseline assessment including validated measures of symptom severity, quality of life, objective measures of urine loss [Urogenital Distress Inventory (UDI), Medical, Epidemiologic, and Social Aspects of Aging questionnaire (MESA), Incontinence Impact Questionnaire (IIQ) and pad test], as well as the Pelvic Organ Prolapse – Quantification (POP-Q) assessment. Groups were compared using the χ^2 test (categorical measures) or the one-way analysis of variance (continuous measures). Statistical significance was defined at p-value <0.05.

Results—The SISTEr and TOMUS samples were similar for many variables including age (52 vs. 53 years, respectively), nulliparity (9 vs. 12%), prior UI surgery (14 vs. 13%), and prior hysterectomy (31 vs 28%), but other differences necessitated separate analysis of the two cohorts. There was not a statistically significant difference in UDI scores according to prolapse stage in either study population. Patients with prior surgery for POP and SUI had more incontinence symptoms and were more bothered by their UI, regardless of prolapse stage.

Conclusions—Prolapse stage is not strongly or consistently associated with incontinence severity in women who select surgical treatment of stress urinary incontinence. Prior POP and UI surgery is associated with worse UI severity and bother.

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Introduction

Urinary incontinence (UI) is often noted to be associated with the presence of mild to moderate prolapse. However, more advanced prolapse conditions are less predictable in their association with UI (1)(2). Women with more advanced prolapse may have less stress urinary incontinence (SUI) and may be more likely to manually reduce their prolapse to void (3). Many clinicians believe that urinary urgency and urge urinary incontinence (UUI) have some relationship with prolapse severity, though few studies have addressed this (2)(4)(5). The uncertainty of this relationship makes it difficult for surgeons to predict which patients with urgency or UUI will have an improvement in their urinary symptoms after an anatomically successful prolapse repair (6), or conservative management with a pessary.(7) The interaction and relationship between urinary symptoms and prolapse stage remains unclear (8)(9).

This analysis was conducted to evaluate the relationship between POP severity, concomitant POP symptoms, and urinary incontinence symptoms in women scheduled to undergo stress urinary incontinence (SUI) surgery in two large randomized surgical trials (10)(11) We sought to estimate whether prolapse severity, as assessed by the pelvic organ prolapse quantification system (POP-Q)(12)(13), was a major contributor to urinary incontinence severity, as measured by validated incontinence questionnaires(13)(14). We tested the null hypothesis that there is no association between prolapse severity and stress incontinence severity.

Materials and Methods

Participants

We analyzed baseline data from two IRB-approved randomized surgical trials for women undergoing SUI surgery conducted by the Urinary Incontinence Treatment Network (UITN). All participants provided written informed consent. The UITN Stress Incontinence Surgical Treatment Efficacy Trial study (SISTEr) randomized women with predominant SUI to either the pubovaginal sling using autologous rectus fascia or the Burch colposuspension. Between February 2002 and June 2004, 655 women were randomized; the methodology and outcomes of this trial have been previously reported.(15)(11). Between (Enrollment dates), the UITN Trial of Mid-Urethral Slings (TOMUS) study (N=597) compared retropubic versus transobturator mid-urethral slings for SUI (10). For both studies, eligibility criteria included a combination of self-reported symptoms and clinical examination measures. Self-reported SUI symptoms included: duration of SUI symptoms >3 months and a Medical, Epidemiologic and Social Aspects of Aging questionnaire (MESA) stress incontinence symptom score greater than MESA urge incontinence symptom score.(16) Eligibility required confirmed observation of leakage by cough and valsalva stress test at a standardized bladder volume of 300ml. Requirements also included a bladder capacity >200ml and a post-void residual <100cc in patients with pelvic organ prolapse Stage 0-I or ≤500cc in patients with Stage II-IV pelvic organ prolapse as defined by the Pelvic Organ Prolapse – Quantification (POP-Q) system.(12)

Eligibility criteria differed between the two trials. The SISTEr trial allowed concomitant abdominal surgery, whereas the TOMUS trial did not. Both trials allowed concomitant vaginal surgeries. Women who participated in the SISTEr trial or who had a prior synthetic sling for SUI or synthetic mesh placed for vaginal reconstructive surgery were excluded from the TOMUS trial.

Measures

Baseline demographic data included age, self-reported race/ethnicity, education, and socioeconomic status. Socioeconomic status was measured using the Nam-Powers-Boyd Occupations Status Score (17) that ranks occupations based on educational requirements and expected salary, where a higher score indicates greater status. Body mass index (recorded in kg/m^2) was calculated from measured height and weight. Specific factors related to obstetrical and gynecological history included the number of vaginal deliveries (categorized as 0, 1, and ≥2), prior hysterectomy, and prior urinary incontinence or surgery for pelvic organ prolapse. Prior urinary incontinence and pelvic organ prolapse surgeries included collagen or durasphere injection, open or laproscopic Burch colposuspension, Marshall-Marchetti-Krantz bladder suspension, needle bladder suspension (Raz, Pereyra, Gittes), prior autologous or cadaveric sling procedures (without the use of synthetic materials for TOMUS), anterior repair, posterior repair, and abdominal or vaginal colpopexy.

Definitions of clinical terms and methods of evaluation of participants were uniform across all sites and adhered to standards set by the International Continence Society (18). Subjective pelvic organ prolapse and urinary incontinence symptoms were measured using validated questionnaires: Urogenital Distress Inventory (UDI),(19) Incontinence Impact Questionnaire (IIQ),(19) MESA (total and stress/urge subscales),(16) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Higher UDI and IIQ mean scores indicated increased “bother” and impact from lower urinary tract and urinary incontinence symptoms, respectively.(19) Higher mean MESA scores indicated more frequent symptoms overall and for each incontinence sub-scale (range 0–27 for SUI and range 0–18 for UUI).(16) For a subset of participants who answered affirmatively to questions about sexual activity in the previous 6 months (n = 450 for SISTEr and n = 403 for TOMUS), mean scores on the PISQ-12 were obtained, where higher scores represented better sexual function.(20) Questions used to quantify prolapse symptoms included yes/no responses to the following three questions from the Pelvic Floor Disorders Inventory (PFDI): (1) “Do you currently experience heaviness or dullness in the pelvic area?” (2) “Do you currently experience a feeling of bulging or protrusion in the pelvic area?” and (3) “Do you currently experience bulging or protrusion you can see in the vaginal area?”(21)

Objective measures included a 24-hour pad test (22), POP-Q measurements and bladder volume at the time of a positive stress test. From the POP-Q evaluation, study-certified examiners at each site recorded the overall prolapse stage (stages ranged from 0 to IV) and quantified the POP-Q points for anterior, posterior and apical prolapse.(17) Data are presented as mean values for POP-Q points Aa and Ba (anterior prolapse), Ap and Bp (posterior prolapse), and C (apical prolapse).(17) Certified examiners ascertained the bladder volume at the time of a positive stress test, with either cough or valsalva, in the dorsal lithotomy position in one of two different ways. For the SISTEr protocol, the lowest bladder volume at the time of a positive stress test was recorded. In the TOMUS study, a positive stress test was performed with the bladder empty, with and without prolapse reduction (if present). If the empty-bladder stress test was negative, the bladder was filled to maximum cystometric capacity up to 300 mL with cough or valsalva stress testing repeated. The bladder volume when leakage occurred was recorded (positive stress test).

Data Analysis

SISTEr and TOMUS data were not pooled; rather, statistical testing was conducted separately in each unique study population. Further analyses were performed separately for the two trials. The associations between a set of variables and stage of pelvic organ prolapse were explored using the χ^2 test (categorical measures) or the one-way analysis of variance (continuous measure). For a skewed, continuous measure, median and inter-quartile range

were reported and Kruskal-Wallis test was used. Prolapse stages 0/I and III/IV were collapsed into groups due to small numbers of women in these stages. Similar analyses were done to examine whether symptom levels differ by prior surgical treatment for prolapse and urinary incontinence. Principal component analysis was performed to explore redundancy in the symptom measure and select which measure to pursue further. Statistical significance was defined as p-value < 0.05. Analyses were carried out using SAS (SAS Institute, Inc, Cary, NC. Version 9.2).

Results

The total study group of 1252 included the 655 women in SISTEr and the 597 women in TOMUS. The majority of participants were Caucasian and vaginally parous. The groups were similar when looking at many variables (Table 1). The SISTEr participants had higher scores for severity measures incontinence (UDI and IIQ) and a slightly higher median pad weight compared to the TOMUS participants. Neither the MESA subscale scores nor the MESA total scores were different between the groups. The proportion of women with the various prolapse stages differed between the 2 groups, as women with Stage III and Stage IV represented 16% of the SISTEr population compared to 8% of the TOMUS population. Table 2 displays the symptom measure values according to prolapse stage. The symptoms of “feeling” or “seeing” a vaginal bulge were related to prolapse stage in both groups ($p<0.0001$). However, the relationship of prolapse stage to the various measures of incontinence severity and bother was not uniform in the 2 study groups, and UI symptom severity was not consistently related to the prolapse stage overall. There were no statistically significant differences in UDI scores. Pad weight differed among the prolapse groups in SISTEr ($p<0.0001$) but not in TOMUS. There were statistical differences in the MESA scores for the various prolapse stages ($p=0.05$ and $p<0.001$ for SISTEr and TOMUS, respectively), but the differences in the SISTEr population were small, raising questions about the clinical significance of this finding. There was no difference in the IIQ score for bother among the three prolapse stages in the TOMUS study, but the IIQ score was found to differ according to prolapse stage in the SISTEr ($p=0.03$). Finally, the existence of a “cumulative” or additive symptom effect was not clearly demonstrated. In TOMUS subjects, feeling or seeing a vaginal protrusion was associated with a higher IIQ score ($p=0.01$), this relationship was not observed in the SISTEr population.

In both cohorts, women who had undergone prior POP or UI surgery had worse UI severity as measured by UDI, IIQ, and MESA (Table 3), but the proportion of women with prior POP/UI did not differ by prolapse stage.

When the interdependence among symptoms of incontinence and prolapse symptoms were analyzed by a principal component analysis for the individual studies, two distinct dimensions were found. In one dimension for SISTEr and TOMUS, the UDI, IIQ, and MESA scores had the highest coefficients, thus representing incontinence severity (data not shown). Pad weight was found to be a weak measure of incontinence severity in both of these study populations. In the second dimension, seeing or feeling a vaginal protrusion was the strongest variable and most likely represented prolapse (data not shown). Pelvic heaviness or dullness was found to be too non-specific to distinguish between either dimension.

Discussion

The most important finding in this study is that prolapse stage is not strongly or consistently associated with incontinence severity in women who select surgical treatment of stress urinary incontinence. The large cohort of over 1200 well-characterized women undergoing

SUI surgery is the largest study to date evaluating the relationship of prolapse stage and SUI. As expected, prolapse symptoms increased with increasing anatomic prolapse stage. However, a similar relationship was not found for all symptoms urinary incontinence as measured by the UDI and IIQ according to increasing prolapse stage. The only urinary incontinence symptom measure to show a trend toward reduced scores with increasing prolapse stage was the MESA. These differences in urinary incontinence symptom measures and prolapse highlight the different ways in which validated measures characterize urinary incontinence and impact in terms of prolapse stage. Other variations in the relationship of incontinence symptoms and prolapse may have been highlighted if incontinence symptoms had been further characterized by predominant type.

Symptoms of seeing or feeling a bulge appear to be reliable screening question for detection of pelvic organ prolapse, and this approach has been used in other epidemiologic studies (23). While the presence of these symptoms increased significantly with prolapse stage, we found that approximately one third of participants with Stage II POP felt a bulge, but only approximately one in five saw a bulge. The correlation between symptoms and anatomical prolapse stage in women with Stage III/IV prolapse was more consistent, with approximately 65% seeing and feeling a bulge; however, nearly one third of these women did not have symptoms of prolapse despite the loss of anatomic support. Multiple other authors have highlighted their findings that the relationship between symptoms and anatomy is poorly understood (8,9). Pelvic organ prolapse cannot be defined dichotomously and the current POPQ staging system may not reflect the degree of symptom bother. Many investigators believe that increasing prolapse severity negates the utility of the validated pad test, due to anatomic distortion of the urethra. However, no significant differences were seen among pad weights with increasing prolapse stage for either trial.

This analysis also highlighted important differences in urinary symptom severity affecting women with prior POP/UI surgery. Prior hysterectomy did not appear to be a factor for increasing prolapse stage in the TOMUS trial, but was a significant factor for the SISTEr trial despite no difference in hysterectomy rates between the two groups. Interestingly, similar findings were reported by FitzGerald et al. in that a history of pelvic surgery had an effect on the relationship between prolapse stage and severity of pelvic symptoms. (24)

The relationship between patients' measured symptoms and symptoms both prior to and following initial surgery are known for the SISTEr trial, but remain pending at the time of this manuscript for the TOMUS trial (11). As proposed by FitzGerald et al, it is also unknown whether women with prior pelvic floor surgery have different expectations or different thresholds for symptom bother. Or perhaps women who need repeat pelvic floor surgery have differences in underlying pathophysiology, such as connective tissue. Conclusions about this finding are difficult to make and further study is necessary.

A major strength of this analysis is the large, well-characterized cohort of women undergoing SUI surgery at multiple centers. The use of validated instruments for urinary incontinence symptoms and standardized anatomic characterization of the prolapse stage further strengthens our findings. The relationship of incontinence symptoms and prolapse may have been highlighted if incontinence symptoms had been further characterized by predominant incontinence type, although no differences were seen in the MESA stress and urge subscales scores for either trial (Table 1). The small number of women with Stage III or Stage IV prolapse limited our ability to analyze symptom severity in this category of more advanced prolapse. This could be partially explained by the fact that women undergoing abdominal prolapse repairs, such as sacrocolpopexy, were allowed in the SISTEr trial, but were excluded from the TOMUS trial. In addition, the heterogeneity of the two cohorts prevented us from pooling these data. However, in doing separate analyses in each of the

surgical cohorts, common themes related to self-reported measures of incontinence symptoms and prolapse symptoms were found in the principal component analysis. An important limitation of this analysis is that only women who volunteered for research participation were included. In addition, most participants received care in tertiary care settings.

Our findings suggest that prolapse stage is not a proxy for estimating the severity of urinary incontinence, which should be assessed and treated separately. Clinicians can use this information to counsel patients with SUI and prolapse. In addition, the discrepancy between prolapse symptoms and anatomic prolapse stage deserves additional study in order to refine our understanding of symptom thresholds and indications for treatment, as well as to better integrate symptoms within the quantification of prolapse stage.

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Table 1

Demographics of SISTEr and TOMUS patients

Characteristic	SISTEr (N=655)	TOMUS (N=597)
Age – Mean (SD)	51.9 (10.3)	52.9 (11.0)
Race/ethnicity		
Hispanic	72 (11%)	71 (12%)
Non-Hispanic Whites	480 (73%)	473 (79%)
Non-Hispanic Blacks	44 (7%)	17 (3%)
Non-Hispanic Other	58 (9%)	36 (6%)
Missing	1	0
Education		
1:<HS	54 (8%)	35 (6%)
2:HS/GED	171 (26%)	149 (25%)
3:>HS	262 (40%)	217 (36%)
4:BA/BS	98 (15%)	101 (17%)
5:Grad/Prof	70 (11%)	95 (16%)
SES (occupational score)	56.9 (24.6)	59.4 (22.8)
Vaginal Deliveries		
0	58 (9%)	70 (12%)
1	76 (12%)	100 (17%)
>=2	521 (79%)	427 (71%)
Prior UI surgery		
Yes	93 (14%)	79 (13%)
No	562 (86%)	516 (87%)
Missing	0	2
Prior Hysterectomy		
Yes	201 (31%)	168 (28%)
No	454 (69%)	427 (72%)
Stage of Prolapse		
Stage 0	30 (5%)	51 (9%)
Stage I	132 (20%)	216 (36%)
Stage II	387 (59%)	282 (47%)
Stage III	87 (13%)	36 (6%)
Stage IV	19 (3%)	12 (2%)
Pad weight loss – Median (25^{th} percentile, 75^{th} percentile)	15.3 (5.6,47.5)	12.5 (6.0,33.5)
Bladder volume at time of positive stress test – Mean (SD)	176.2 (117.8)	164.6 (134.4)
MESA total – Mean (SD)	25.8 (7.4)	25.6 (7.5)
MESA stress subscale – Mean (SD)	19.3 (4.6)	19.3 (4.6)
MESA urge subscale – Mean (SD)	6.5 (3.9)	6.3 (4.0)
UDI total – Mean (SD)	151.0 (48.6)	134.6 (45.5)
IIQ total – Mean (SD)	171.4 (101.3)	151.5 (97.4)
PISQ total at baseline sexually active only [mean (SD)] (N=447 for SISTEr and N=403 for TOMUS)	31.6 (7.0)	32.81 (7.1)