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Mixed Incontinence: Comparing Definitions in Women Having Stress Incontinence Surgery

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Abstract

Objective—To develop an empirically derived definition of mixed urinary incontinence (MUI) for use in incontinence outcomes research.

Methods—Participants in a randomized trial comparing the fascial sling and Burch colposuspension were assessed using standardized measures including the Medical, Epidemiologic and Social Aspects of Aging (MESA), UI questionnaire, the Urogenital Distress Inventory (UDI), three-day urinary diary and urodynamic studies (UDS). Participants were required to have stress incontinence with a MESA stress subscale score > MESA urge subscale score. Several definitions of MUI were considered. Logistic and linear regression analysis methods were used to predict clinical outcomes based on the different MUI definitions. Analyses were carried out using SAS (SAS Institute, Inc, Cary, NC. Version 9.1). Statistical significance was defined at p-value < 0.05.

Results—In 655 participants, the proportion of women with MUI varied from 8.3% to 93.3% depending on the MUI definition. All definitions were associated with severity as measured by the frequency of incontinence episodes at baseline; however little of the variability was explained by any single definition. No strict cut-off value for these baseline measures was identified to predict clinical outcomes.

Conclusions—These MUI definitions do not adequately categorize clinically relevant UI subgroups. For research reporting, MUI subcomponents of stress and urge UI should be described separately rather than as a single dimension.

Keywords

Urinary Incontinence; Nomenclature; Mixed Incontinence; Stress Incontinence; Urge Incontinence

Introduction

Mixed urinary incontinence (MUI) is a troublesome condition for patients and incontinence specialists because for treatment to be successful, both the stress and urge components of the incontinence need to respond to the therapies. The International Continence Society's standardized nomenclature defined mixed urinary incontinence as "the complaint of involuntary leakage associated with urgency and also with exertion, effort sneezing or coughing (Abrams et al., 2002). The most appropriate definition for mixed incontinence is not known. From a pragmatic standpoint, patients with mixed urinary incontinence and their clinicians want information about the chance of a favorable outcome following their primary incontinence treatment. The clinical consequences of not understanding the role of stress and urge components in MUI include the persistence of urge incontinence after stress urinary incontinence (SUI surgery) which the patient then perceives as surgical failure (Elkadry et al., 2003; Hullfish et al., 2002; Mahajan et al., 2006).

We sought an empirically derived definition of mixed incontinence that could be linked to surgical outcomes. Alternatively, we sought an urge symptom threshold beyond which the risk of persistent urge incontinence is clinically problematic in the setting of MUI pre-operatively.

The Urinary Incontinence Treatment Network recently completed the SISTEr trial which recruited women planning surgery for stress urinary incontinence (SUI). Participants were well-characterized by a variety of validated incontinence instruments and tests. The methods and primary outcomes of the trial have been previously reported (Albo et al., 2007; Tennstedt, 2005). This planned secondary analysis describes our efforts to determine a scientifically sound, clinically useful definition of mixed urinary incontinence in a surgical population.

Methods

This study was approved by the Institutional Review Boards of all nine clinical sites and the biostatistical coordinating center and all participants in both trials provided written consent for research participation. Briefly, the SISTEr protocol randomized 655 women planning SUI surgery to fascial sling or Burch colposuspension procedures. Standardized baseline measures included the Medical, Epidemiologic and Social Aspects of Aging (MESA) incontinence questionnaire (Herzog et al., 1990), the Urogenital Distress Inventory (UDI) (Shumaker et al., 1994) urodynamic studies and a three-day urinary diary. Participants planning surgical correction of stress urinary incontinence symptoms were required to have a MESA stress subscale score higher than their MESA urge subscale score for entry into this surgical trial.

The MESA is a self-reported questionnaire with nine questions on stress incontinence and six questions on urge incontinence. The four response categories range from "never" (0 points) to "often" (3 points), with higher scores indicating more frequent symptoms of incontinence. The UDI is a self-reported questionnaire that measures quality of life impact related to three urinary sub-scales: obstructive symptoms (11 questions), irritative symptoms (6 questions) and stress symptoms (2 questions). If the question is answered affirmatively, then the degree of bother ranging from "not at all" to "quite a bit" is determined. Each sub-scale has a possible range of 0 to 100 and a higher score indicates more urogenital distress. The three-day diary was completed at baseline and at the two-year end point.

Standardized urodynamic studies (UDS) consisting of noninvasive uroflowmetry, filling cystometry, and pressure flow studies were completed preoperatively and 24 months after SUI surgery. A standardized protocol and standardized interpretation guidelines were

implemented based on the ICS Good Urodynamic Practices and Terminology of Lower Urinary Tract Function publications. (Nager et al., 2007) (Schafer et al., 2002) (Abrams et al., 2003) UDS data collection included the presence or absence of detrusor overactivity (and whether or not there was associated leakage) and the presence or absence of urodynamic stress urinary incontinence with respective leak point pressure.

We created several definitions for mixed incontinence with potential clinical utility using baseline measures. Using the MESA instrument, we created three threshold definitions of MUI. The “low threshold” definition was defined as an urge subscale score ≥ 1 (any response of “rarely”, “sometimes” or “often” on one or more urge item); the “intermediate threshold” MESA definition was defined as the sum of the urge score total ≥ 2 ; and the “high threshold” as any answer of sometimes or quite a bit to any urge subscale item.

We also defined MUI with a comparative definition as a relative proportion of urge and stress scores by using the MESA urge and stress subscale scores and converting them to an Index by dividing each subjects subscale score by the maximum possible subscale score. This calculation was necessary to account for the different number of questions in the urge and stress MESA subscales. Recall that all subjects in this study had a MESA stress index > MESA urge index. Three categories were created: pure stress incontinence (Urge index = 0), stress predominant MUI ($0 < \text{Urge index} < \frac{1}{2} \text{ stress index}$) and MUI ($\frac{1}{2} \text{ stress index} \leq \text{Urge index} < \text{Stress index}$). For example, a patient with a MESA stress score of 52% (13/27) and a lesser urge score of 22% (4/18) would be categorized as having stress predominant MUI.

Similar to the MESA definitions, we created three definitions based on the amount of bother for patients experiencing urge incontinence using the UDI. The UDI questions 2 and 3 query “Do you usually experience a strong feeling of urgency to empty your bladder?” and “Do you usually experience urine leakage associated with a feeling of urgency; that is a strong sensation of needing to go to the bathroom?” For participants who responded “yes”, we further queried their degree of bother with the response options of not at all bothersome, somewhat, moderately, or quite a bit. The UDI “low threshold” definition of MUI was defined as: ‘Yes’ to UDI Q2 or a > “not at all” response to UDI Q3. The “Intermediate threshold” UDI definition was defined as UDI irritative symptom subscale score > 20. The UDI comparative definition was based on two UDI subscales: Irritative (UDI-i) and Stress (UDI-s): pure stress incontinence (UDI Irritative symptom scale = 0), stress predominant MUI ($0 < \text{UDI-i} < \frac{1}{2} \text{ UDI-s}$) and MUI (the rest of the cases). Finally, we created a single definition based on the urodynamic findings. MUI was defined as the presence of both urodynamic stress incontinence and detrusor overactivity incontinence.

We evaluated these definitions against the trial's clinical outcome. As originally described, the SISTEr composite outcome criteria was divided into “stress success” (a negative standardized stress test, no SUI re-treatment and no MESA stress UI symptoms) and overall success (stress criteria plus no leakage per 3-day diary and 24-hour pad test). We previously reported that diary failure was more common than pad test failure in the women who did not meet overall success criteria (Albo et al., 2007). Therefore, we used diary as a proxy measure for “non-stress” failures, presumably due to urge incontinence.

Statistical Analysis

Logistic regression analysis was used to estimate association between the study outcomes and different definitions of MUI. We used linear regression analysis to assess the relationship between incontinence episodes per day and each of our measures of MU. Statistical significance was defined by a p-value of <0.05 . All statistical analyses were

carried out using the personal computer version of SAS statistical software (SAS Institute, Inc, Cary, NC. Version 9.1).

Results

Baseline demographics and clinical characteristics of the study sample are presented in Table 1. The mean ($\pm$ SD) MESA total score was 25.8 ($\pm$ 7.4) with mean stress and urge subscale scores of 19.4 ($\pm$ 4.59) and 6.5 ($\pm$ 3.92) respectively. The mean ($\pm$ SD) total UDI score was 151.0 ($\pm$ 48.6). As expected, the prevalence of MUI varied considerably by the MESA (Table 2) and UDI (Table 3) definitions utilized. The proportion of women diagnosed with MUI ranged from a low of 8.3% using only the urodynamic-based definition to a high of 93.3% using the low threshold MESA MUI definition. None of the tested baseline MESA or UDI measures had clear “cut” points by receiver operator analyses to support a scientific definition of MUI. No strict cut-off value for these baseline measures was useful in predicting clinical outcomes.

Tables 4 and 5 report the bivariate results comparing the various MUI definitions compared to SISTEr overall outcomes and stress-specific outcomes, respectively. As expected, women with less urge incontinence have a higher chance of surgical success (alternatively, a lower odds of meeting overall surgical failure criteria) compared to those with mixed incontinence. When the definition allowed three categories, the stress predominant odds ratio was between the odds ratio for the pure stress and the mixed categories.

In regression analysis against incontinence severity only, only three of the MUI definitions (the MESA ratio, UDI intermediate threshold and UDI ratio) were significantly associated with severity; however very little of the variability was explained by any MUI definition: the multiple R^2 ranged from 0.001 to 0.02 (Table 6). By comparison, the two UDI scores achieved $R^2=0.06$ and the two MESA scores had $R^2=0.11$. Keeping stress and urge dimensions separate appears to better reflect severity by incontinence episodes.

Discussion

While the term “mixed incontinence” remains a clinically useful concept there is debate over the utility of its use for outcomes research. As evidenced in this population of women seeking surgical treatment for stress incontinence, the majority of women fell into the category of MUI when using subjective measures to define the condition. Prevalence rates ranged from 50% to 93% depending on the questions used and severity selected; however, when using objective measures only 8% were diagnosed as having MUI on urodynamics. These data illustrate how such wide variations in prevalence rates for MUI can occur. To date, the appropriate MUI definition has not been agreed upon for either research or clinical care.

Investigators are aware of the need to use validated measures, such as the UDI, MESA, urinary diaries or standardized urodynamic testing for research. Unfortunately, despite testing 12 different definitions for MUI using these validated, condition specific, questionnaires and urodynamic findings we were unable to identify a definition that would accurately reflect clinical outcomes. Thus, while it is likely that the majority of incontinent women have multiple urinary symptoms; the utility of a mixed diagnosis using strict symptoms scores becomes vague and non-discriminatory. Based on these findings, we propose that for research reporting, both subcomponents of stress and urge incontinence should be individually described, rather than the current paradigm of a one-dimensional descriptor for multiple incontinence symptoms (stress, mixed or urge).

The complexity of studying MUI may hinge on the lack of consensus for defining the condition. In a single population we have been able to demonstrate many different “prevalence rates” simply by changing the definition. This variation in prevalence rates of MUI due to differences in definition has been reported in a recent study of the participants in the National Health and Nutrition Examination Survey (Vatche A. Minassian, 2008). Overall the prevalence of any MUI was roughly 15%, however if defined as “severe” (more than once per week) only 8% of the population would have been considered having MUI, illustrating the importance of “definition” in the identification of MUI. Similarly, in a population of women with lower urinary tract symptoms, Digesu et al reported urodynamic findings in women diagnosed with mixed urinary incontinence using the King's Health Questionnaire to describe the severity of symptoms (Digesu et al., 2008). Based on the severity, they ascribed predominance of stress vs. urge incontinence. Using that definition, they determined that 59% of incontinent women in their tertiary referral urogynecology center had mixed urinary incontinence and recommended quantifying MUI symptoms by severity of each subcomponent. While we believe this is a step in the right direction, this leaves researchers with difficulty when the frequency of the symptom does not correlate with the bother of that symptom.

The majority of women in our population, regardless of subjective measure used, were classified as having MUI. These rates differ significantly from epidemiologic studies which identify rates of 34% in the NOBLE study of 2735 community dwelling women (Stewart et al., 2003) to as low as 9% in the EPINCONT survey (Hannestad et al., 2000). Differences in prevalence of MUI in community dwelling women not seeking treatment and those undergoing surgery are not surprising as presumably those seeking care and considering surgery have more severe lower urinary tract symptoms.

The limitations of comparing MUI in epidemiologic studies to MUI in clinical settings may also be due, in part, to the fact that they require purely symptom based assessments. Thus, one would expect that evaluations of MUI in clinical samples would be superior as they tend to employ a combination of subjective and objective evaluation. Unfortunately, the variation in prevalence rates for MUI in these settings is equally broad. A recent analysis of MUI in clinical research trials identifies a large gap in the understanding of the pathophysiology and lack of standardization of the condition (Tyagi and Staskin, 2005). Most clinical studies fail to clearly identify criteria used to assess MUI. Those that do report a definition typically take on an “easy” definition which includes any report of urge leakage. Lemak et al identified a MUI prevalence of 26% in 128 women presenting with lower urinary tract symptoms and found that symptoms predicted urodynamic findings less than 50% of the time (Lemack and Zimmern, 1999).

The urodynamic finding of detrusor overactivity in these women undergoing surgery for stress incontinence was rare. (Nager et al., 2007) Others have found similarly low rates of DO in women undergoing surgical treatments for prolapse (Foster Sr et al., 2007). In fact, findings of DO in women seeking treatment with MUI symptoms vary widely. Digesu et al reported rates of DO in a population of stress predominant MUI which was similar to our rates (11%), however Lewis et al reported DO rates of 56% in stress predominant MUI population (Lewis et al., 2007). Chou EC et al recently reported lower rates of DO in women with MUI as compared to those with pure urge urinary incontinence suggesting that urge component may be “over diagnosed in patients with SUI who misinterpret their fear of leaking for urge”(Chou et al., 2008). The broad variation in prevalence of MUI using symptoms in a clinical setting raises the question of the utility of urodynamics for securing a diagnosis of mixed incontinence. Alternate theories behind the high rates of MUI have recently been proposed by Minassian et al.(Minassian et al., 2008). They propose two models which could account for the high rates of MUI observed in this population. The

“liability model,” which is based on the concept that the presence of one subtype of incontinence predisposes to the other. The “severity model” postulates that as the severity of UI increases the likelihood of having symptoms of both increases. Both these theories would help explain the high co-occurrence of urge and stress symptoms in our population of women seeking surgical treatment for their incontinence symptoms.

The strengths of our study include the use of several widely used validated instruments and urodynamic testing for the evaluation of urinary incontinence and the ability to compare results for each of these instruments in the same population of women. Limitations in interpreting these results include the fact that all data was collected in a highly select group of women seeking surgery for stress predominant urinary incontinence. Thus, these data may not be generalized to other cohorts of women with differing degrees and types of incontinence.

Our finding that strict definitions using symptoms scores do not adequately categorize patients into clinically relevant subgroups has important ramifications. Both the UDI and MESA categorized nearly all participants into the MUI category despite the clear differences in their predominant symptoms and selected therapies. Given the importance of mixed urinary incontinence as a correlate of incontinence severity and predictor of suboptimal surgical outcome, we recommend that our findings stimulate a scientifically sound definition that is consistent with the clinical importance of this entity.

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Appendix A: Urinary Incontinence Treatment Network Members

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References

- Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A. The standardisation of terminology of lower urinary tract function: Report from the standardisation Sub-Committee of the International Continence Society. *Neurourol Urodyn.* 2002; 21:167–178. [PubMed: 11857671]
- Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, Chai TC, Zyczynski H, Diokno AC, Tennstedt S, Nager C, Lloyd LK, FitzGerald M, Lemack GE, Johnson HW, Leng W, Mallett V, Stoddard AM, Menefee S, Varner RE, Kenton K, Moalli P, Sirls L, Dandreo KJ, Kusek JW, Nyberg LM, Steers W, Urinary Incontinence Treatment N. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med.* 2007; 356(21):2143–2155. [PubMed: 17517855]
- Chou EC-L, Blaivas JG, Chou LW, Flisser AJ, Panagopoulos G. Urodynamic Characteristics of Mixed Urinary Incontinence and Idiopathic Urgent Urinary Incontinence. *Neurourol Urodyn.* 2008; 27:376–378.
- Digesu GA, Salvatore S, Fernando R, Khullar V. Mixed Urinary Symptoms: What are the Urodynamic Findings? *Neurourol Urodyn.* 2008; 27:372–375. [PubMed: 17943988]

- Elkadry EA, Kenton KS, FitzGerald MP, Shott S, Brubaker L. Patient-selected goals: a new perspective on surgical outcome. *American Journal of Obstetrics & Gynecology*. 2003; 189(6): 1551–1557. discussion 1557–1558. [PubMed: 14710061]
- Foster RT Sr, Barber MD, Parasio MFR, Walters MD, Weidner AC, Amundsen CL. A prospective assessment of overactive bladder symptoms in a cohort of elderly women who underwent transvaginal surgery for advanced pelvic organ prolapse. *Am J Obstet Gynecol*. 2007; 197(1): 82.e81–82.e84. [PubMed: 17618768]
- Hannestad YS, Rortveit G, Sandvik H, Hunskaar S, The Norwegian Epincont study Epidemiology of Incontinence in the County of Nord-Trøndelag. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. *Epidemiology of Incontinence in the County of Nord-Trøndelag. Journal of Clinical Epidemiology*. 2000; 53(11):1150–1157. [PubMed: 11106889]
- Herzog AR, Diokno AC, Brown MB, Normolle DP, Brock BM. Two-year incidence, remission, and change patterns of urinary incontinence in noninstitutionalized older adults. *Journal of Gerontology: Medical Sciences*. 1990; 45(2):M67–M74.
- Hullfish KL, Bovbjerg VE, Gibson J, Steers WD. Patient-centered goals for pelvic floor dysfunction surgery: what is success, and is it achieved? *American Journal of Obstetrics & Gynecology*. 2002; 187(1):88–92. [PubMed: 12114893]
- Lemack GE, Zimmern PE. Predictability of urodynamic findings based on the Urogenital Distress Inventory-6 questionnaire. *Urology*. 1999; 54:461–466. [PubMed: 10475355]
- Lewis JB, Ng AV, O'Connor RC, Guralnick ML. Are there differences between women with urge predominant and stress predominant mixed urinary incontinence? *Neurourol Urodyn*. 2007; 26(2): 204–207. [PubMed: 17078089]
- Mahajan ST, Elkadry EA, Kenton KS, Shott S, Brubaker L. Patient-centered surgical outcomes: the impact of goal achievement and urge incontinence on patient satisfaction one year after surgery. *American Journal of Obstetrics & Gynecology*. 2006; 194(3):722–728. [PubMed: 16522404]
- Minassian VA, Stewart WF, Wood GC. Urinary incontinence in women: variation in prevalence estimates and risk factors. *Obstet Gynecol*. 2008; 111(2 Pt 1):324–331. [PubMed: 18238969]
- Nager C, FitzGerald M, McDermott SM, Wruck L, Kraus S, Howden N, Norton P, Sirls L, Varner RE, Zimmern P, UITN. Reference Urodynamic Values for Stress Incontinent Women. *Neurourol Urodyn*. 2007; 26:333–340. [PubMed: 17315221]
- Schafer W, Abrams P, Liao L, Mattiasson A, Pesce F, Spangberg A, Sterling A, Zinner N, van Kerrebroeck P. International Continence Society. Good urodynamic practices: uroflowmetry, filling cystometry, and pressure-flow studies. *Neurourology & Urodynamics*. 2002; 21(3):261–274. Guideline. *Journal Article. Practice Guideline*. [PubMed: 11948720]
- Shumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health-related quality of life measures for women with urinary incontinence: The incontinence impact questionnaire and the urogenital distress inventory. *Qual Life Res*. 1994; 3:291–306. [PubMed: 7841963]
- Stewart WF, Van Rooyen JB, Cundiff GW, et al. Prevalence and burden of overactive bladder in the United States. *World J Urol*. 2003; 20:327–336. [PubMed: 12811491]
- Tennstedt S. Design of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER). *Urology*. 2005; 66(6):1213–1217. [PubMed: 16360445]
- Tyagi R, Staskin DR. Mixed incontinence: the misclassification of patients and limitations of clinical trials. *Curr Urol Rep*. 2005; 6(6):424–428. [PubMed: 16238915]
- Minassian, Vatche A.; Stewart, Walter F.; Wood, G Craig. Urinary incontinence in women: variation in prevalence estimates and risk factors. *Obstet Gynecol*. 2008; 111(2 Pt 1):324–331. [PubMed: 18238969]

Table 1

Demographics of SISTER population (n=655).

Characteristic	SISTER
Age (yrs) - mean $\pm$ std, range	51.9 $\pm$ 10.3 (27.93, 81.36)
* BMI - mean $\pm$ std, range	30.0 $\pm$ 6.1 (17.72, 53.72)
MESA total score - mean $\pm$ std, range	25.8 $\pm$ 7.4 (4, 43)
MESA stress score - mean $\pm$ std, range	19.4 $\pm$ 4.6 (4, 27)
MESA urge score - mean $\pm$ std, range	6.5 $\pm$ 3.9 (0, 17)
UDI total score - mean $\pm$ std, range	151.0 $\pm$ 48.6 (0, 290.91)
UDI Irritative score - mean $\pm$ std, range	47.8 $\pm$ 25.2 (0, 100)
UDI Stress score - mean $\pm$ std, range	78.0 $\pm$ 21.9 (0, 100)
Race/Ethnicity [n (%)]	
Hispanic	72 (11%)
White, non-Hispanic	480 (73%)
Black, non-Hispanic	44 (7%)
Other	58 (9%)
Missing	1
Education [n (%)]	
Less than High School	54 (8%)
HS/GED	171 (26%)
Some post-HS	262 (40%)
BA/BS	98 (15%)
Graduate degree	70 (11%)
Smoking Status [n (%)]	
Never Smoked	355 (54%)
Former Smoker	207 (32%)
Current Smoker	93 (14%)
** POP-Q Stage [n (%)]	
Stage 0	30 (5%)
Stage I	132 (20%)
Stage II	387 (59%)
Stage III	87 (13%)
Stage IV	19 (3%)

* BMI = body mass index is defined as weight in kilograms divided by square of height in meters.

** POP-Q Stages are defined as follows: Stage 0 is no support loss, in Stage I support, the vagina does not advance below 1 centimeter above the hymen, in Stage II support, the most advanced portion of the vagina is within 1 centimeter above (inside) the hymen, and one centimeter below (outside) the hymen. In Stage III support, the most everted portion of the vagina is beyond Stage II, but not within the distance defined by total vaginal length minus two centimeters. In Stage IV support, the most advanced portion of vaginal support loss is within the total length of the vagina minus two centimeters.

Table 2

MESA-based definitions of “mixed incontinence” in SISTER population (N=655).

Definition of MUI by MESA	Stress (N, %)	MUI (N, %)
Low threshold MUI definition: any answer ≥ 1 on urge subscale (rarely, sometimes, quite a bit)	Pure Stress 44 (6.7%)	611 (93.3%)
Intermediate threshold MUI definition: Total urge score > 2 (Urge index $> 11\%$):	Stress predominant 116 (17.7%)	539 (82.3%)
High threshold MUI definition: any answer ≥ 2 (Sometimes, quite a bit)	Stress predominant 134 (20.5%)	521 (79.5%)
Comparative MESA definition (score converted to a percentage based on the number of items)	Pure stress 44 (6.7%) Stress predominant 281 (42.9%)	Mixed 330 (50.4%)

Table 3

UDI-based definitions of “mixed incontinence” based on women who reported baseline urge incontinence in SISTER population (N=655).

Definition of MUI by UDI	Stress (N, %)	MUI (N, %)
Low threshold MUI definition: ‘No’ to QC2, or ‘Yes’ to QC2 and ‘No’ to QC3 or Response to QC3a>”not at all”	Pure Stress 254 (39%)	397 (61%)
Intermediate MUI definition: UDI Irritative Symptom Scale>20	Stress predominant 114 (17.5%)	Mixed 538 (82.5%)
Comparative UDI definition (score converted to a percentage based on the number of items)	Pure stress 29 (4.5%) Stress predominant 182 (28%)	Mixed 438 (67.5%)

Table 4

Bivariate association of each MUI definitions compared with SISTER failure outcomes: SISTER Failure using 5 criteria for “overall” surgical failure (negative stress criteria plus no leakage per 3-day diary and 24 hour pad test).

Definition of MUI	n	Odds Ratio	95% C.I.	p-value
UDI (question 2), definition based on question 3 bother response				
No vs Yes	518	0.53	0.36 - 0.78	0.001
MESA intermediate threshold:				
No vs Yes	520	0.31	0.19 - 0.49	<.0001
Comparative MESA				
pure stress vs. mixed	520	0.27	0.13 - 0.55	<.0001
Stress predominant vs. mixed		0.52	0.35 - 0.76	
UDI mid				
No vs Yes	519	0.47	0.3 - 0.75	0.002
Comparative UDI				
Pure stress vs. mixed	517	0.31	0.12 - 0.78	0.01
Stress predominant vs. mixed		0.66	0.44 - 0.99	

Table 5

Bivariate analysis of each MUI definitions with SISTER stress-specific outcomes: SISTER Failure using 3 stress criteria outcomes (a negative standardized stress test, no SUI re-treatment and no MESA stress UI symptoms).

Definition of MUI	N	Odds Ratio	95% C.I.	p-value
UDI (question 2), definition based on question 3 bother response				
No vs Yes	541	0.65	0.44 - 0.94	0.02
MESA intermediate:				
No vs Yes	543	0.40	0.25 - 0.65	0.0002
Comparative MESA				
Pure stress vs. mixed	543	0.43	0.21 - 0.87	0.003
Stress predominant vs. mixed		0.59	0.41 - 0.84	
UDI intermediate				
No vs Yes	542	0.51	0.32 - 0.82	0.006
Comparative UDI				
Pure stress vs. mixed	540	0.31	0.11 - 0.88	0.03
Stress predominant vs. mixed		0.72	0.49 - 1.05	

Table 6

Regression of incontinence episodes per day (3 day diary) on each of the MUI definitions

Definition of MUI	b	s.e	LS Means	p-value	R ²
UDI question Q3				0.40	0.001
Yes	0.21	0.25	3.26		
No			3.05		
MESA intermediate				0.34	0.001
Yes	0.29	0.30	3.26		
No			2.97		
Comparative MESA				0.02	0.01
Pure stress	-1.25	0.48	2.17		
Stress predominant	-0.32	0.24	3.11		
Mixed			3.43		
UDI intermediate				0.003	0.01
Yes	0.90	0.31	3.36		
No			2.46		
Comparative UDI				0.0008	0.02
Pure stress	-2.09	0.56	1.29		
Stress predominant	-0.33	0.26	3.04		
Mixed			3.37		
MESA Index					0.11
MESA stress index (+10)	0.55	0.08	-	<.0001	
MESA urge index (+10)	0.03	0.06	-	0.66	
UDI Score					0.06
UDI Irritative (+10)	0.21	0.05	-	<.0001	
UDI Stress (+10)	0.17	0.05	-	0.002	
UDS MUI				0.32	0.002
Yes	0.43	0.43	3.63		
No			3.20		