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Mixed Incontinence: Comparing Definitions in Non-Surgical Patients

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Abstract

Purpose—We aimed to explore operational definitions of mixed urinary incontinence (MUI) for use in incontinence outcomes research for non-surgical patient populations.

Methods—A secondary analysis of women with urge incontinence or urge predominant MUI enrolled in the Urinary Incontinence Treatment Network BE-DRI randomized clinical trial was performed. Subjects were characterized at baseline for urinary incontinence severity and incontinence subtype (stress or urge) using the Medical, Epidemiologic and Social Aspects of Aging (MESA) questionnaire, the Urogenital Distress Inventory, and a 7-day urinary diary. Various different definitions of MUI, ranging from low to high threshold, were created using a combination of these baseline incontinence measures. Prevalence of MUI based on each definition was described and compared to treatment response. Logistic regression analysis was used to estimate the association between the study outcomes and the different definitions of MUI.

Results—The 307 participants in the BE-DRI study had a mean age of 56.9 ($\pm$ 13.9) years with a mean total MESA score of 21.7 ($\pm$ 8.9) and a mean total UDI score of 120.5 ($\pm$ 49.6). The proportion of women diagnosed with MUI varied significantly by definition ranging from (63.5%) to (96.4%). Low threshold symptom-based definitions resulted in nearly universal diagnosis of MUI. No strict cut-off value for these baseline measures was identified to predict clinical outcomes.

Conclusions—Current MUI definitions do not adequately categorize clinically relevant UI subgroups. For research purposes we believe it necessary to describe the severity of each incontinence subtype separately in subjects with MUI.

Keywords

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

INTRODUCTION

The International Continence Society's standardized nomenclature defines mixed urinary incontinence (MUI) as "the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing"¹. The term "mixed urinary incontinence" reflects an incontinence specialist's understanding of the underlying pathophysiology and divergent treatment strategies for this common condition. The clinical term also proves useful in allowing clinicians to communicate their belief that an individual patient has more than one clinical subtype of urinary incontinence.

The traditional paradigm for treatment of MUI, based on expert opinion, has been to focus initial treatment on the predominant incontinence subtype. However, the incontinence subtype "predominance" may vary depending on the technique of assessment. It is not uncommon for patients to report a higher number of stress incontinence episodes, but be more bothered by less frequent urge incontinence episodes. Predominance can be determined by subjective measures, such as degree of bother and quality of life impact, or by objective measures such as the frequency of incontinence episodes and urodynamic testing. Unfortunately, current nomenclature does not provide an operational definition of MUI for research purposes.

Well-designed clinical research is essential to inform patients with MUI and their clinicians about the chance for a favorable outcome following their primary treatment. Unfortunately, MUI remains a troublesome entity for patients and incontinence specialists as there are no commonly accepted definitions used for clinical outcomes. This lack of clarity in the definition of MUI makes counseling and treatment algorithms difficult. For example, patients often perceive post-operative urge incontinence as a surgical failure²⁻⁴, even though the surgery was designed to treat the stress incontinence. Our prior work in a large surgical trial found that MUI definitions did not adequately categorize clinically relevant UI subgroups of women planning SUI surgery⁵. While that study examined the definitions of MUI in a cohort of women with stress predominant⁵ incontinence, it is unclear if these same conclusions can be generalized to a population of women with urge predominant MUI receiving medical or behavioral therapy.

This secondary analysis examined a group of women planning non-surgical treatment for urge incontinence who had urge as the pure or predominant incontinence subtype. In the BE-DRI trial participants were well-characterized for lower urinary tract symptoms by a variety of validated instruments. The objective of this analysis was to explore various definitions of MUI using validated research instruments in women with urge predominant MUI.

MATERIALS AND METHODS

The biostatistical coordinating center and nine clinical sites involved in the Urinary Incontinence Treatment Network had approval by the relevant Institutional Review Boards and all participants provided written consent for research participation. The methods and primary outcomes of this trial have been previously reported^{6, 7}. Briefly, participants for the BE-DRI study were community-dwelling women seeking treatment for pure urge or urge predominant incontinence as defined by baseline Medical, Epidemiologic, and Social Aspects of Aging (MESA) scores. Potential participants were required to have a MESA urge subscale index higher than their MESA stress subscale index for entry into this trial. In addition, participants had at least 7 episodes of incontinence on a 7-day bladder diary, were clinically eligible to receive both anticholinergic medication and behavioral training over 10 weeks, were able to complete all study assessments at a minimum of 5.5 months after completion of the intervention phase and drug withdrawal, and provided informed consent.

Participants were assessed at baseline, the end of Stage 1 (10 weeks), and at the end of Stage 2 (8 months).

The primary outcome was measured at the end of Stage 2 (8 months) and success was defined as not taking drug or receiving any other therapy for urge incontinence *and* a 70% or greater reduction in frequency of incontinence episodes from baseline to end of Stage 2 recorded on the bladder diary. The criterion of 70% reduction in incontinence episodes was based on data indicating that this was a critical threshold for patient satisfaction⁸. The secondary outcomes included changes in frequency of incontinence episodes on bladder diary. Symptom distress was also measured using the Urogenital Distress Inventory (UDI)⁹.

The MESA is a self-reported questionnaire that includes nine questions on stress incontinence and six questions on urge incontinence, with four response categories: “never” (0 points), “rarely” (1 point), “sometimes” (2 points) and “always” (3 points). The subscale scores are the sum of responses to the individual items with higher scores indicating more frequent symptoms of incontinence. The “Urogenital Distress Inventory” is self-reported questionnaire with three sub-scales that measures distress with: obstructive symptoms (11 questions), irritative symptoms (6 questions) and stress symptoms (2 questions) Each sub-scale has a possible range of 0 to 100 and a higher score indicates greater distress The 7-day diary was used to record incontinence episodes, type of leakage, degree of urgency sensation, voids at baseline and each endpoint. We created definitions of MUI using the MESA, the UDI, and the stress incontinence question from the patient expectation questionnaire. Using the MESA instrument we created the following definitions of MUI: 1) the “low threshold” definition was defined as: any answer 1 on both the MESA stress and urge subscale (any response of “rarely”, “sometimes” or “quite a bit”); 2) the “intermediate threshold” MESA definition was defined as: score total > 3 for stress subscale, and 3) the “high threshold” MESA definition was defined as: any answer 2 for stress subscale (sometimes, quite a bit). The fourth definition involved converting scores to a percentage of the total and of MUI using MESA compared the subscale indices and resulted in three categories: pure urge incontinence (stress index = 0), urge predominant MUI ($0 < \text{stress index} < \frac{1}{2} \text{urge index}$) and MUI ($\frac{1}{2} \text{urge index} \leq \text{stress index} < \text{urge index}$).

Similarly, we created additional definitions of MUI based on the UDI question related to stress incontinence symptoms “Do you currently experience leakage related to physical activity?”. The UDI “low threshold” definition of MUI was defined as any response of “yes” to that question. The “intermediate threshold” definition was a UDI stress symptom scale > 20. The “comparative” definition was a score converted to a percentage based on the number of items. The UDI comparative score was based on two UDI subscales: Irritative (UDI-i) and Stress (UDI-s): pure urge incontinence (UDI Stress symptom scale = 0), urge predominant MUI ($0 < \text{UDI-s} < \frac{1}{2} \text{UDI-i}$) and MUI (the rest of the cases).

STATISTICAL ANALYSIS

All analyses were carried out using the personal computer version of SAS statistical software (SAS Institute, Inc, Cary, NC. Version 9.2). Statistical significance was defined by a p-value < 0.05. Estimates of the proportion of participants diagnosed with MUI were calculated based on each of the definitions of MUI. Logistic regression analysis was used to estimate the association between the two study outcomes (success vs. failure at 10 weeks and 8 months) and different definitions of MUI. We used linear regression analyses to assess the relationship between MUI based on each of our definitions and the number of incontinence episodes per day, scores on the individual MESA subscales, and scores on the UDI subscales.

RESULTS

The demographic characteristics of the study sample are shown in Table 1. The proportion of women diagnosed with mixed urinary incontinence varied significantly with definition from a low of 63.5% to a high of 96.4% (Table 2 and 3). None of the definitions of MUI yielded a variable that was associated with primary or secondary clinical outcomes at 10 weeks or 6 months after discontinuation of drug and behavioral therapy (Tables 4 and 5).

In regression analysis (Table 6), none of the categorical definitions of MUI except UDI low was significantly associated with incontinence episode frequency and the multiple R^2 values ranged from 0.005 to 0.02. The MESA urge index was statistically significantly associated with incontinence episode frequency while the stress index was not. Similarly, the UDI Irritative score was significantly associated with incontinence episode frequency while the UDI stress subscale score was not. As expected, continuous measures explained substantially more variability in incontinence episode frequency as measured by the multiple R^2 value.

DISCUSSION

In 2002 the International Continence Society recommended the classification of mixed urinary incontinence (MUI) as “the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing”.¹ Although the sentiment to recognize this condition was appropriate, this is not a sufficient operational definition for research purposes. Specifically, the definition does not capture the relative contribution of stress and urge incontinence or the balance between the two in impact on the patient. Standardization of the definition has not been established and many studies addressing this issue use varying instruments to ascertain the presence of MUI.

The results of this study in women with urge predominant incontinence demonstrate a broad range of symptom prevalence of MUI depending on the definition used in the diagnosis. Using the MESA questionnaire definitions, the prevalence of MUI was as low as 72% and as high as 96%. Using the UDI questionnaire, the prevalence of MUI varied from 64% to 78%. None of the tested definitions yielded a variable that accurately predicted outcomes after treatment at either time point, and only the low threshold UDI definition predicted number of incontinence episodes per day on 7-day diary. Only the MESA urge index and UDI irritative index predicted episodes per day, reinforcing the importance of separating components of MUI in the evaluation of treatment.

Similar variation in rates of MUI have been described for women seeking surgical intervention for stress incontinence.¹⁰ These rates of MUI varied from 50.4% to 93.3% using similar MESA and UDI based definitions. Additionally, no definition accurately predicted outcomes after surgical intervention for stress incontinence. Interestingly, the women in the prior study all had stress predominant symptoms, however in the current analysis of urge predominant symptoms we see similarly high rates of MUI. This high prevalence of MUI (regardless of definition) in women with urge incontinence may be explained by recent theories postulated by Minassian et al.¹¹ The “liability model” purports that the presence of one type of incontinence predisposes to the other, and the “severity model” poses that with increasing severity of one type of incontinence there is an increased likelihood of having symptoms of the other type. Alternately, although the instruments used to assess stress and urge symptoms have been validated and widely used, they may be limited by an inability to discriminate MUI as a separate entity. Thus, we propose that for research purposes, evaluation of continence status be based on distinct descriptions of both

urge and stress subcomponents to provide details that are lost when simply using the unidimensional term “mixed incontinence.”

Researchers and clinicians agree that MUI is an important disease state that needs to be addressed as not only is it common, but also significantly impairs the quality of life in women who suffer from it. In order to better understand the impact of therapy for urinary incontinence in general, an operational definition for MUI research is necessary. The urge component of incontinence has been identified as the most bothersome form of UI with greater impact on quality of life and a major reason for dissatisfaction after surgery^{4, 12}. There is still debate over the best approach to treating MUI with some proposing medical therapy prior to surgical intervention¹³ and others reporting that surgical correction may alleviate urge symptoms in 23 – 79% of women with MUI undergoing midurethral sling procedures.^{13–16} In order to test the optimal approach to treatment the challenge will be to accurately categorize subjects with MUI symptoms. Dmochowski et al¹⁴ have proposed an algorithm for the initial stratification of MUI, which sorts subjects by symptoms and cough stress testing. Based on our findings, it would not appear that neither the MESA or UDI are ideal instruments for the assessment of MUI.

This challenge is not only relevant to medical or surgical treatment of MUI, but also important to the understanding of the epidemiology of the condition. There is a poor understanding of the prevalence and impact of MUI. To date, prevalence rates for MUI vary widely within the literature. As with our data this variation is likely subject to the broad definitions of the condition. Epidemiologic studies identify rates of 34% to as low as 9% in community dwelling women.^{15, 16} A recent study of the participants in the National Health and Nutrition Examination Survey evaluated the prevalence of UI based on varying severity.¹⁷ 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 to have MUI, illustrating the importance of “definition” in the identification of MUI. Our data similarly reflect a wide variation in MUI rates depending on the definition used in an urge predominant population. Other variables important in determining the prevalence of MUI include the “time frame” in which the symptoms occur and the characteristics of the populations studied. Some studies assess prevalence based on a timeframe (i.e. in the last 12 months)¹⁸ whereas others define symptoms as “currently present”¹⁶. Prevalence of MUI symptoms may also be influenced by the characteristics of the population studied. Many studies have identified a significant relationship between the prevalence of MUI or OAB and age^{15, 17, 19}. Our data were collected in a population of women with urge incontinence using “currently present” symptoms. Thus, the prevalence in our population would be expected to be high regardless of the instruments used to assess the condition.

The strengths of our study include the use of several widely used validated instruments 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 were collected in a highly select group of women willing to participate in a clinical trial of treatment of urge predominant urinary incontinence. Thus, it may not be possible to generalize these data to other cohorts of women with differing degrees and types of incontinence. Additionally, urodynamic evaluation was not performed on this group making comparisons to objective measures of MUI impossible.

It is certainly possible that the majority of incontinent women actually have multiple urinary symptoms; the utility of a mixed diagnosis using strict symptoms scores becomes vague and non-discriminatory for clinical therapy. Investigators are aware of the need to use validated measures, such as the UDI, MESA, urinary diaries or standardized urodynamic testing for research. However, the appropriate cut-off value for the diagnosis of mixed incontinence has

not been determined for either clinical or research use. Strict definitions using symptom scores do not adequately categorize into clinically relevant subgroups, with both the UDI and MESA categorizing nearly all participants (in our previous trial of women undergoing SUI surgery and the current trial) into the mixed category, despite the clear differences in their predominant symptoms and selected therapies. Until a standard operational definition is available, we recommend that researchers characterize subjects with MUI using distinct descriptions of both urge and stress subcomponents.

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Table 1

Demographics of BE-DRI population (N=307).

Characteristic	
Age (yrs) - mean $\pm$ std, range	56.9 $\pm$ 13.9 (21.39, 87.76)
* BMI - mean $\pm$ std, range	32.7 $\pm$ 8.6 (19.13, 79.56)
MESA Total Score - mean $\pm$ std, range	21.7 $\pm$ 8.9 (5, 44)
MESA Stress Score - mean $\pm$ std, range	10.6 $\pm$ 6.2 (0, 26)
MESA Urge Score - mean $\pm$ std, range	11.1 $\pm$ 3.4 (3, 18)
UDI Total Score - mean $\pm$ std, range	120.5 $\pm$ 49.6 (0, 254.55)
UDI Irritative Score - mean $\pm$ std, range	58.4 $\pm$ 21.8 (0, 100)
UDI Stress Score - mean $\pm$ std, range	47.1 $\pm$ 28.7 (0, 100)
Race/Ethnicity	
Hispanic	30 (9.8%)
White, non-Hispanic	190 (62.3%)
Black, non-Hispanic	57 (18.7%)
Other	28 (9.2%)
Missing	2
Education	
Less than High School	13 (4.2%)
HS/GED	58 (18.9%)
Some post-HS	118 (38.4%)
BA/BS	72 (23.5%)
Graduate degree	46 (15.0%)
POP-Q Stage	
Stage 0	59 (19.3%)
Stage I	134 (43.8%)
Stage II	103 (33.6%)
Stage III	3 (1.0%)
Stage IV	7 (2.3%)
Missing	1

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

Table 2

Definition of “mixed incontinence” using baseline MESA ^{*} (N=307).

Definition	Urge (N, %)	MUI (N, %)
Low Threshold MUI definition: any answer 1 on stress subscale (rarely, sometimes, quite a bit)	Pure Urge: 11 (3.6%)	296 (96.4%)
Intermediate Threshold MUI definition: Total stress score>3 (Stress index > 11%):	Urge predominant: 40 (13.0%)	267 (87.0%)
High Threshold MUI definition: any answer 2 on stress subscale (Sometimes, quite a bit)	Urge predominant: 40 (13.0%)	267 (87.0%)
Percentage definition (score converted to a percentage based on the number of items)	Pure urge: 11 (3.6%) Urge predominant: 76 (24.7%) (0<Stress index<1/2 urge index)	Mixed: 220 (71.7%)

^{*} Medical, Epidemiologic, and Social Aspects of Aging

Table 3

UDI ^{*} based definitions of “mixed incontinence” based on women who reported baseline urge incontinence in BE-DRI population (N=307).

Definition	Urge (N, %)	MUI (N, %)
Low threshold MUI definition: “Yes” response to “currently experience leakage related to physical activity?”	Pure Urge: 112(36.5%)	195(63.5%)
Intermediate Threshold MUI definition: UDI Stress Symptom Scale>20	Urge predominant: 68 (22.1%)	239 (77.9%)
Comparative definition (score converted to a percentage based on the number of items)	Pure urge: 24 (7.9%) Urge predominant: 57 (18.7%)	Mixed: 224 (73.4%)

^{*} Urogenital Distress Inventory

Table 4

Association of MUI definitions and BE-DRI overall failure at 10 weeks

MUI Definition	n	Odds Ratio	95% C.I.	p-value
MESA mid:				
No vs. Yes	269	0.74	0.32–1.67	0.46
MESA Ratio				
Pure urge vs. Mixed	269	0.59	0.12–2.99	0.71
Predominant vs. mixed		0.84	0.46–1.54	
UDI low				
No vs. Yes	269	1.24	0.74–2.09	0.41
UDI ratio				
Pure urge vs. mixed	267	1.40	0.56–3.49	0.73
Urge predominant vs. mixed		0.93	0.49–1.79	

Table 5

Association of MUI definitions and BE-DRI failure at 6 months after discontinuation of drug therapy.

MUI Definition	n	Odds Ratio	95% C.I.	p-value
MESA mid:				
No vs. Yes	237	1.11	0.48 – 2.6	0.81
MESA Ratio				
Pure urge vs. Mixed	237	0.59	0.12 – 3.01	0.39
Urge predominant vs. mixed		1.48	0.77 – 2.85	
UDI Low				
No vs. Yes	237	1.22	0.69 – 2.14	0.49
UDI ratio				
Pure urge vs. mixed	235	1.21	0.43 – 3.39	0.25
Urge predominant vs. mixed		1.88	0.89 – 3.96	

Table 6
Regression of accidents per day on each of the MUI summary variables and on MESA and UDI scores in BE-DRI

Definition of MUI	b	s.e	LS Means	p-value	R ²
MESA mid				0.23	0.005
No	-0.50	0.41	3.27		
Yes	ref		3.76		
MESA ratio				0.11	0.015
Pure urge	-0.43	0.75	3.45		
Urge predominant	-0.68	0.32	3.20		
Mixed	ref		3.88		
MESA Index					0.08
MESA Urge index (+10)	0.21	0.10		0.04	
MESA Stress index (+10)	0.14	0.09		0.10	
UDI Ratio				0.34	0.007
Pure urge	-0.14	0.53	3.68		
Urge predominant	-0.53	0.36	3.29		
Mixed	ref		3.82		
UDI Score					0.10
UDI Irritative (+10)	0.32	0.06		<.0001	
UDI Stress (+10)	0.07	0.05		0.13	