Title

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The University of Michigan Incontinence Symptom Index (M-ISI): a Clinical Measure for Type, Severity, and Bother related to Urinary Incontinence

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Abstract

Aims—To develop a clinically relevant, easy to use, and validated instrument for assessing severity and bother related to urinary incontinence.

Methods—Survey items were piloted and refined following psychometric principles in five separate patient cohorts. Patient and expert endorsement of items, factor analyses, Spearman rank correlations and response distributions were employed for item selection. Formal reliability and validity evaluation were conducted for the final questionnaire items.

Results—Expert physicians and patient focus groups confirmed face and content validity for the measure. A 10-item measure called the Michigan Incontinence Symptom Index (M-ISI) was developed with two domains: a Total M-ISI Domain consisting of subdomains for stress urinary incontinence, urgency urinary incontinence, and pad use, and a Bother Domain. High construct validity was demonstrated with a Cronbach's alpha for the Total M-ISI Domain (items 1–8) of 0.90 and for the Bother Domain (items 9–10) of 0.82. Cronbach's alpha for the subdomains were all > 0.85. Construct validity, convergent and divergent validity, internal discriminant validity, and predictive validity were all robust. The minimally important difference for the measure was determined to be 4 points (out of 32) for the Total M-ISI Severity Domain, and 1–2 points (out of 8–12) for the individual subdomains.

Conclusions—The M-ISI is a parsimonious measure that has established reliability and validity on several levels and complements current clinical evaluative methods for patients with urinary incontinence.

Keywords

quality of life; urge urinary incontinence; stress urinary incontinence; bother; impact; pad use

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Introduction

Urinary incontinence (UI) is a highly prevalent condition that affects both men and women across the age spectrum. It is estimated that up to 13.9% of men and 51.1% of women live with this condition,(1) accounting for large direct and indirect costs.(2, 3). In addition to being costly, UI has also been shown to have a detrimental impact on quality of life, causing men and women to alter their behaviors, to experience psychological and emotional distress, and even to live in social isolation.(4–7)

Despite being a common and costly condition, there is no single good measurement tool currently available that can be used to discern type, severity and bother attributable to UI. Presently, in order to accomplish all of these goals, a patient would have to complete multiple different questionnaires in one sitting, and the physician would then have to determine how to interpret and assimilate the results of these different measures. For example, there are several measurement tools that were specifically designed to evaluate quality of life in women with UI; however, none of these tools are useful for discerning type of urinary incontinence.(8–13) Likewise, measurement tools that were developed specifically to discern type of UI, such as the Questionnaire for Urinary Incontinence Diagnosis (QUID),(14) are not equipped to evaluate quality of life issues. The International Consultation on Incontinence Questionnaire (ICIQ), on the other hand, evaluates both quality of life and type of urinary incontinence, but does not assimilate severity with type of urinary incontinence.(15) In addition to not being comprehensive, these tools tend to be long, making them difficult for patients to complete as part of the clinical encounter. A simple measure that incorporates all of these necessary components for diagnosing, treating, and following UI over time is currently lacking.

The purpose of this study was to develop a parsimonious measure that that addresses all of these concerns. We used Classical Test Theory in multiple patient populations to develop and validate a measure that can discern type, severity, and bother related to urinary incontinence. The product was an instrument called the Michigan Incontinence Symptom Index (M-ISI), that has proven reliability and validity for use in both clinical and research purposes.

Materials and Methods

Participants

There were 5 different participant groups used in the development of the incontinence symptom index: the focus, pilot, test-retest reliability, cross-sectional, and predictive validity groups. Populations were recruited on an as-needed basis to test new phases of instrument development. The focus group consisted of 3 separate groups (2 female groups and 1 male group) comprised of a total of 26 women and 9 men with UI. These participants were recruited from local newspaper advertisements and from our institution’s urology clinics. Subjects were prescreened to ensure that their UI was not due to a secondary condition such as pregnancy, chronic urinary tract infection, or bladder malignancy.

The pilot group consisted of male and female patients who presented to the Urology clinic with a chief complaint of UI and were recruited into the study. These subjects completed the M-ISI at their initial clinic visit. A subset of these subjects also filled out the M-ISI via a postal survey approximately 2–3 weeks later, representing the test-retest reliability group. All subjects were screened with a urinalysis and exclusionary criteria were pregnancy, urinary tract infection, diagnosis of interstitial cystitis or urinary retention, history of bladder malignancy, presence of ureteral calculi and hematuria suspicious for bladder malignancy.

The cross-sectional group consisted exclusively of women who underwent surgery for UI at our institution. These women were identified via administrative databases and invited to participate in a questionnaire survey. Women with a history of multiple sclerosis, spinal cord injury, urinary diversion, urethral diverticula, urethrovaginal/vesicovaginal fistuals, or age <18 were excluded.(16)

The predictive validity group was made up of a convenience sample of women aged 18 years or older who presented to our institution's Multidisciplinary Urology/Urogynecology Clinic with a chief complaint of UI. Similar inclusion and exclusion criteria to the pilot group were applied. Baseline evaluation included a physical exam, urodynamic studies, and the M-ISI. Based on the results of the baseline evaluation, the primary type of UI was classified by the physician as either stress, urgency or mixed. Patients were then treated per the physicians' usual clinical practice with surgery, medications, behavioral therapy, combination therapy, or no treatment and were assessed again at approximately 3 months post-treatment with a repeat administration of the M-ISI.

Measures

Several existing questionnaires were administered to the cross sectional group to establish both convergent and divergent validity. Convergent validity was established by comparing the M-ISI results with the results from Sandvik-Hunskaar incontinence severity index and the incontinence impact questionnaire (IIQ). Discriminant validity was established using the 12-item short form health survey (SF-12) and the pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ).

Sandvik-Hunskaar/incontinence severity index—The Sandvik-Hunskaar severity index is a 2-item questionnaire that classifies urinary incontinence based on frequency and amount of urinary leakage into 4 categories (slight, moderate, severe, and very severe). Scores range from 1 (slight) to 12 (very severe).(8) This index was validated against a 48 hour pad weight test for amount of leakage(17) and a postal questionnaire survey for severity of leakage.(18)

Incontinence Impact Questionnaire (IIQ)—The IIQ is a 30-item measure that assesses the impact of urinary incontinence on various activities, roles, and emotional states. The IIQ has 4 subscales (physical activity, travel, social relationships, and emotional health), including items that address shopping, recreation, entertainment, and various feelings such as fear, frustration, and anger. The patient responds to each item based on the degree to which their urinary incontinence affects each activity or feeling from 'not at all' to 'greatly'. (9)

Short-Form (SF-12) Health Survey—The SF-12 is a 12-item survey that was reduced from the original 36-item health survey with the use of regression methods. This measure asks questions pertaining to general health related quality of life and consists of 2 components, the Physical Components Summary (PCS) and the Mental Components Summary (MCS). Each component is scored on a scale with a mean of 50 and a standard deviation of 10.(19)

Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ)—The PISQ is a 31 question measurement tool that evaluates sexual function in women with pelvic organ prolapse and urinary incontinence. This measure includes 3 domains (behavioral/emotive, physical, and partner-related) and uses 5-value Likert-based scales (always to never) with the exception of one question pertaining to masturbation.(20)

Procedures for scale development

Item selection for the M-ISI began with a thorough review of the literature and of existing measures related to UI. An initial list of 34 items was created with the specific aim of being able to discern type [stress urinary incontinence (SUI), urgency urinary incontinence (UUI), or both], severity and bother related to UI. In summary, this list of items consisted of the following distribution of topics: stress urinary incontinence, urgency urinary incontinence, symptom severity/pad usage, other urinary symptoms, and bother. These items were then reviewed by content experts and focus groups for content and face validity. Content experts consisted of urologists and urogynecologists from across the United States who had expertise in urinary incontinence (Appendix 1).

Using principles related to Classical Test Theory, the refined list of items was administered to the pilot group. Exploratory factor analysis was performed to identify and establish discrete domains and subdomains within M-ISI. Next, in order to determine which items discriminated well between domains/subdomains, factor loading was examined. Items that exhibited major floor and ceiling effects were either reworded and retested or removed. The final 10-item survey was then re-administered to the pilot group and confirmatory factor analysis was performed on the new data.

Statistical Analysis for Validation

Once the finalized measure was established, various aspects of formal scale validation were performed in different study populations. The cross-sectional group was used to determine reliability and validity of the M-ISI. Cronbach's alpha was used to determine internal consistency of items within subdomains and domains of the instrument. Construct validity was established in the same cohort using Spearman rank correlations to show the relationship between individual items with their scales. Convergent and discriminant validity were established through correlation with other measures, namely the Sandvik-Hunskaar/ incontinence severity index and the IIQ for convergent validity (measuring similar constructs, so desiring a high correlation) and the SF-12 and PISQ for divergent validity (measuring alternative constructs, so desiring lower correlations).

Test-retest reliability coefficients were calculated in a subset of patients from the pilot group (the test-retest reliability group). Predictive validity was established in the predictive validity group by comparing the changes in the mean scores for the two domains of the M-ISI at baseline and at 3 months after various treatments.

Next, a statistic to discern the predominant type of UI was created and validated. This statistic is represented by the following formula, which we will refer to as the Stress/Urgency/Mixed (SUM) statistic: SUI subdomain score/[SUI subdomain score + UUI subdomain score]. This statistic was then compared to the physician's (Dr. Edward J. McGuire) classification of predominant SUI, predominant UUI, or mixed UI using the predictive validity group. The physician's diagnosis was made based on clinical presentation and history, physical examination, and urodynamics testing when indicated. This statistic ranges from 0 to 1, with higher scores representing predominant SUI, lower scores representing predominant UUI, and scores near 0.5 representing mixed UI. If both SUI and UUI are equal to 0 (absence of both Stress and Urgency Incontinence), then no statistic is calculated.

The minimally important difference (MID) was determined for the total ISI and bother domains and for the SUI and UUI subdomains using both distribution- and anchor-based methods(21, 22) based on data from the cross-sectional cohort. Selected anchor measures included the Sandvik-Hunskaar/incontinence severity index and the M-ISI Bother domain. Distribution methods of MID (1/2 standard deviation and 1/3 standard deviation) were calculated by simple functions of the standard deviation of the scores. Anchor-based methods of the MID were calculated by regressing each of the M-ISI domains and subdomains on the anchor item separately. The MID for each anchor was determined by multiplying the clinically relevant change in the anchor item by the parameter estimate from the regression for that item. The prospective cohort was then used to assess the validity of the selected MID thresholds.

SAS statistical software version 9.2 (Cary, NC) was used for all psychometric analyses.

Results

The demographic characteristics of each of the 5 study groups are presented in Table I.

Final Measure and Scoring

Item selection and refinement resulted in a 10-item measure that consists of a Total M-ISI Domain (sum of items 1–8) and a distinct Bother Domain (sum of items 9–10), shown in Figure 1. The Total M-ISI Domain consists of 3 subdomains (items 1–3 for SUI, items 4–6 for UUI, and items 7–8 for Pad Use [PU]). All 10 items have Likert response options (range 0–4), with higher values representing greater symptoms/bother. The Total M-ISI Domain ranges from scores of 0 to 32, the Bother Domain ranges from scores of 0 to 8, the SUI and UUI Subdomains range from scores of 0 to 12, and the PU Subdomain ranges from scores of 0–8. The overall domains and subdomains are scored simply by summing their respective values. If any item in a domain or a subdomain is missing, the domain/subdomain score is not calculated. The only exception to this rule is for the total M-ISI score when only a single

item is missing; in this case, the missing item is assigned the mean of the 7 non-missing items, and the domain score is summed as before.

Face Validity

Both participants from the focus groups and the content experts reviewed and endorsed the final selection of items as appropriate for urinary incontinence.

Construct, Convergent, and Discriminant Validity

Individual items of the M-ISI demonstrated both high correlations with the Total Severity Domain and high correlations with their respective subdomains while exhibiting lower correlations with the other subdomains, indicating construct validity (Table II). Correlations between the M-ISI and the Sandvik-Hunskaar/incontinence severity index and the IIQ were also high, indicating convergent validity, and low to moderate correlations between the M-ISI and the SF-12 and PISQ indicated divergent validity (Table III).

Predictive Validity

The relationship between the total M-ISI score and the response to each of the bother items (adaptation [item 9] and impairment [item 10]) is shown in Figure 2. As scores for each of the bother items increases (indicating a higher degree of bother), the mean scores for the total M-ISI also increases, indicating good predictive validity.

Next, predictive validity of the change in mean M-ISI scores in response to various treatments was evaluated. Subjects completed the M-ISI at baseline (prior to any treatment) and at a mean of 3.5 months after treatment. Predictive validity of the M-ISI was calculated by comparing mean changes in domain scores from before to after different types of treatment. Statistically significant changes in mean scores were found in the Total M-ISI Domain for surgery, medication, and combination treatment, and in the Bother Domain for surgery and behavioral treatment. The greatest improvements were seen in the M-ISI scores for surgery.

Internal Discriminant Validity

Subjects who had a physician diagnosis of SUI had a mean SUM statistic of 0.56, those with a physician diagnosis of UUI had a mean SUM statistic of 0.32, and those with mixed UI had a mean SUM statistic of 0.45, in between that for SUI and UUI.

Reliability/Internal Consistency

Cronbach’s alpha were high for all domains and subdomains [Total M-ISI Domain (0.90), Bother Domain (0.82), SUI Subdomain (0.87), UUI Subdomain (0.85), and PU Subdomain (0.87)] indicating sufficient consistency of the scores.

Test-retest Reliability

Subjects in the test-retest reliability group completed the M-ISI for a second time at a mean of 18 days after taking the initial survey. Test-retest reliability coefficients were calculated for each domain and subdomain: Total M-ISI Domain (0.86), Bother Domain (0.85), SUI

Subdomain ((0.78), UUI Subdomain (0.78), and PU Subdomain (0.84), indicating sufficient reliability of the scores.

Minimally Important Difference

Minimally important difference using distribution- and anchor-based methods are shown in Appendix 2. These analyses indicated narrow MID's (i.e., fairly small changes in scores for each subdomain/domain corresponded with a clinically significant MID): 4 points for the total M-ISI domain (out of 32 possible points); 2 points for the SUI subdomain (out of 12 possible points); 2 points for the UUI subdomain (out of 12 possible points); and 1 point for the PU subdomain (out of 8 possible points).

Discussion

The M-ISI is a new 10-item questionnaire that was created to be able to discern type (SUI, UUI, or both), severity and bother attributable to UI. It is psychometrically robust and has proven validity and reliability. It can be easily used in the clinical setting to aid in the patient-physician encounter, establishing the severity and nature of type of UI, and possesses the robust psychometric criteria necessary for a research tool.

Unlike other UI questionnaires, the M-ISI covers different aspects of UI that are essential for patient care and for research. For example, there are many questionnaires for UI that focus on quality of life issues (including severity and impact), but that neglect type of urinary incontinence. Some examples include the King's Health Questionnaire,(12) the Symptom Severity Index and the Symptom Impact Index,(11) the Incontinence Quality of Life (I-QOL) instrument,(13) the Bristol Female Lower Urinary Tract Symptoms questionnaire,(10) the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI), (9) and the Sandvik-Hunskaar/Incontinence Severity Index.(18) Questionnaires that do discern type of UI like the QUID;(14) however, do not include items on quality of life. The International Consultation on Incontinence Questionnaire (ICIQ), developed by the International Consultation on Incontinence (ICI), assesses the prevalence, frequency, perceived cause of urinary incontinence, and impact on everyday life, but is not proven to reliability discriminate type and severity attributable to stress versus urgency urinary incontinence and does not address pad usage.(15) Another measure, the Female Urinary Symptom Score (FUSS),(23) was adapted from the International Prostate Symptom Score to apply to female urinary incontinence, is only meant to be used in women and does not address pad usage. The M-ISI is unique in that it accomplishes all of these goals, making it complete yet concise; a combination that is ideal for both clinical and research purposes.

Although we took a comprehensive approach to creating and validating this instrument, this body of work is not without limitations. First, the M-ISI has only been validated in English thus far, but foreign language translations are anticipated. Second, although the M-ISI was validated using cohorts that included men, the number of men in these cohorts was small. Furthermore, it is important to note that the M-ISI was not formally validated for use in men. Third, we recognize that women often experience symptoms of UUI as more severe and more bothersome than symptoms of SUI,(24) yet our measure allocates an equal amount of weight to each type (i.e. 3 questions for each subdomain). This was done purposefully so

that the SUM statistic could be developed and be easily interpreted. Finally, urinary incontinence can arise from many other health conditions such as spinal cord injury or stroke; our validation, to date, has not included these subpopulations. We do intend to implement the M-ISI in these clinical subgroups in the future.

Conclusions

The M-ISI is a clinically relevant, easy to use instrument that is validated for urinary incontinence. It can be used both as a clinical aid to facilitate physician-patient interactions and delivery of care, and as a research tool to provide a level of standardization and validity to UI outcome measurements.

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Michigan Incontinence Symptom Index (M-ISI) v.1

This brief questionnaire is designed to assess the severity of your urinary incontinence (involuntary urine leakage). For each question, please mark the number associated with the response that best describes your voiding habits during the past month.

During the Past Month...	Never	Rarely	Occasionally	About Half the time	Most or all of the time
1. How often has urine leakage occurred in association with any physical activity (such as lifting, bending, sitting down, standing up, exercising, etc)?	0	1	2	3	4
2. How often has lifting light objects (such as a gallon of milk) caused you to leak urine?	0	1	2	3	4
3. How often has walking or light exercise caused you to leak urine?	0	1	2	3	4
	Never	**Seldom**	**About once a week**	**About once a day**	**More than once a day**
4. How often have you leaked urine because you could not wait to empty your bladder?	0	1	2	3	4
5. How often has a sudden urge to urinate caused you to leak urine?	0	1	2	3	4
6. How often have you leaked urine because you could not reach a bathroom in time?	0	1	2	3	4
	None	**Thin Pad or tissue**	**Medium/ regular pad**	**Large/ maxi pad**	**Absorbant, disposable, undergarments**
7. On average, what form of protection do you use to protect against wetness during the day?	0	1	2	3	4
	None	**1 per day or less, or only for security**	**1 per day and it is usually wet**	**2-3 per day**	**4 or more per day**
8. On average, how many of these (pads, tissues, disposable undergarments) would you use to protect against wetness during the day?	0	1	2	3	4
			Total Severity Score_____		
	Never	**Rarely**	**Sometimes**	**Most of the time**	**All of the time**
9. Overall, how often have you needed to change your daily activities because of your urinary incontinence?	0	1	2	3	4
	No problem	**Very small problem**	**Small problem**	**Moderate problem**	**Big Problem**
10. Overall, how big of a social problem (anxiety/ embarrassment/ avoiding social activities) has your urinary incontinence been for you during the past month?	0	1	2	3	4
			Total Bother Score _____		

Figure 1.
Michigan Incontinence Symptom Index (M-ISI)

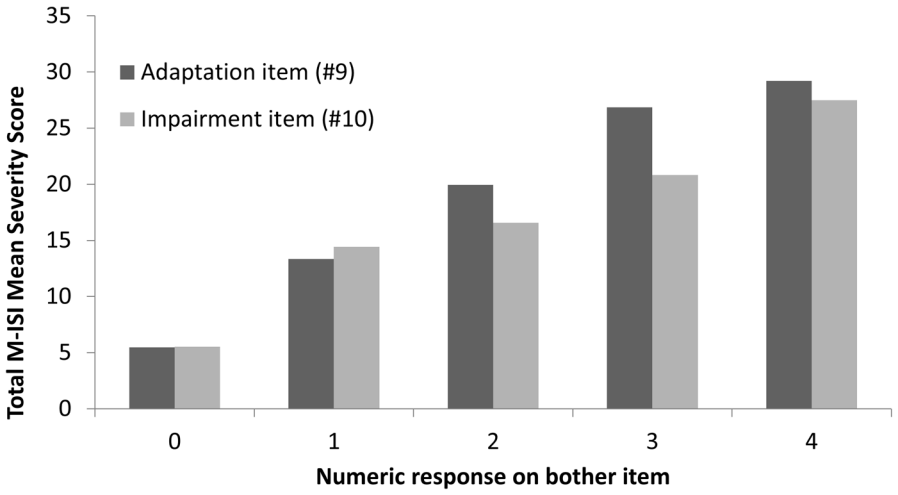

Figure 2.

Predictive validity of the Total M-ISI mean severity score to response to bother items (adaptation and impairment). Analysis was performed using the cross sectional group.

Table I

Demographic characteristics of study cohorts

	Focus group	Pilot group	Test-retest reliability group*	Cross-sectional group	Predictive validity group
Development/Validation Phase	• Face validity	• Item selection • Exploratory factor analysis • Factor loading	• Test-retest reliability	• Internal consistency • Construct validity • Convergent validity • Discriminant validity • Minimally Important Difference	• Predictive validity • SUM statistic
N	35	99	45	477	108
Female	26	64	32	477	108
Male	9	35	13	0	0
Median Age (range)	62 (32–81)	63.67 (23.56–91.27)	--	58.2 (21.3–91.7)	55.95 (27.16–87.81)
Actual therapies					
Surgery	--	--	--	477	19 (17.6%)
Medications	--	--	--	--	11 (10.2%)
Behavioral therapy	--	--	--	--	11 (10.2%)
Combination therapy	--	--	--	--	9 (8.3%)
No treatment	--	--	--	--	58 (53.7%)

* Test-retest reliability group is a subgroup of the pilot group

Table II

Spearman rank correlations within the M-ISI subdomains/domains. Analysis was performed using the cross-sectional cohort.

M-ISI	Total Severity	Severity Subdomains			Bother Subdomain
		SUI	UUI	Pad use	
Item 1	0.72	**0.88**	0.41	0.45	0.55
Item 2	0.73	**0.89**	0.48	0.39	0.57
Item 3	0.70	**0.90**	0.39	0.41	0.64
Item 4	0.82	0.49	**0.91**	0.53	0.61
Item 5	0.72	0.41	**0.87**	0.39	0.52
Item 6	0.68	0.39	**0.83**	0.41	0.59
Item 7	0.69	0.40	0.45	**0.96**	0.39
Item 8	0.73	0.48	0.47	**0.93**	0.49
Item 9	0.72	0.62	0.65	0.46	**0.91**
Item 10	0.66	0.58	0.56	0.43	**0.93**

*SUI=stress urinary incontinence, UUI=urgency urinary incontinence

Table III

Convergent and discriminant validity of the M-ISI domains and subdomains to various other measurement scales measured by correlation coefficients with corresponding p-values. Analysis was performed using the cross-sectional cohort.

	SUI	UUI	PU	Bother	M-ISI Total
Convergent Validity					
Sandvik severity measure	0.71 <.0001	0.80 <.0001	0.76 <.0001	0.73 <.0001	0.85 <.0001
IIQ Score	0.71 <.0001	0.66 <.0001	0.66 <.0001	0.85 <.0001	0.75 <.0001
Discriminant Validity					
MCS12	−0.07 0.16	−0.12 0.01	−0.08 0.11	−0.18 0.0003	−0.10 0.03
PCS12	−0.39 <.0001	−0.36 <.0001	−0.36 <.0001	−0.39 <.0001	−0.41 <.0001
PISQ	0.44 <.0001	0.37 <.0001	0.43 <.0001	0.51 <.0001	0.46 <.0001

*SUI=stress urinary incontinence, UUI=urgency urinary incontinence, PU=pad use