Neurourology and Urodynamics 34:332–335 (2015)

A Screening Tool for Clinically Relevant Urinary Incontinence

Anne M. Suskind,[1] Rodney L. Dunn,[1] Daniel M. Morgan,[2] John O. L. DeLancey,[2] Karl T. Rew,[3] and John T. Wei[2]
[1]Department of Urology, The University of Michigan, Ann Arbor, Michigan
[2]Department of Obstetrics and Gynecology, The University of Michigan, Ann Arbor, Michigan
[3]Department of Family Medicine, The University of Michigan, Ann Arbor, Michigan

Aims: The Michigan Incontinence Symptom Index (M-ISI) is a validated measure for urinary incontinence. This study evaluates the M-ISI as a screening tool for clinically relevant urinary incontinence in a population-based sample of women. **Methods:** The Establishing the Prevalence of Incontinence (EPI) Study is a case-control, population-based study that enrolled women ages 35–64, with and without urinary incontinence. The M-ISI is a validated questionnaire with subdomains for stress and urgency urinary incontinence. Two hundred fourteen EPI subjects underwent a clinical evaluation and urodynamic testing to establish the presence and type of urinary incontinence, and also completed the M-ISI. The M-ISI scores were evaluated using receiver operating characteristic (ROC) curves to determine the optimal diagnostic threshold scores above which women were likely to have clinically relevant urinary incontinence. **Results:** The optimal M-ISI diagnostic threshold scores were determined to be $\geq$3 for the stress urinary incontinence subdomain (area under the curve of 0.79), $\geq$5 for the urgency urinary incontinence subdomain (area under the curve of 0.88), and $\geq$7 for the Total M-ISI score (area under the curve of 0.89). The sensitivity and specificity of the M-ISI questionnaire for stress, urgency, and total urinary incontinence were 77% and 73%, 86% and 76%, and 84% and 75%, respectively. **Conclusions:** The M-ISI may be used to screen for clinically relevant urinary incontinence with high sensitivity and specificity among women ages 35–64. A brief, self-administered tool such as the M-ISI can help health care providers identify and manage women with urinary incontinence. *Neurourol. Urodynam. 34:332–335, 2015.*

Key words: population; quality of life; receiver operating characteristic curve; screening; sensitivity; specificity; validation

INTRODUCTION

Urinary incontinence is a common condition that affects up to 40% of community-dwelling women in the United States.[1] Incontinence significantly impacts the social interactions, interpersonal and sexual relationships, careers, psychological well-being, and quality of life of women with this condition.[2] Despite the availability of behavioral, medical, and surgical treatment options, only a minority of women actually seek care for this condition.[3–6]

Since few women seek care for their urinary incontinence symptoms, primary care physicians can play a key role in identifying women who may benefit from treatment.[7] However, primary care providers seeking to identify patients with urinary incontinence face several challenges, including a lack of diagnostic tools, time constraints, and a need to determine whether urinary incontinence is clinically relevant.[8] For these reasons, a validated tool that can quickly identify women with clinically relevant urinary incontinence should be of value in the primary care setting.

The Michigan Incontinence Symptom Index (M-ISI) is a validated questionnaire that assesses type of urinary incontinence (stress versus urgency) and quantifies the severity and bother of the incontinence. It is a parsimonious measure that is simple for the individual to complete, and can be used both as a clinical aid to facilitate delivery of care and as a research tool to help quantify and standardize urinary outcome measurements.[9] Using a population-based sample of women from the Establishing the Prevalence of Incontinence (EPI) Study, we identified threshold scores for the M-ISI that could be used to screen for clinically relevant urinary incontinence. This tool can be used in the primary care setting to aid in the identification of women with urinary incontinence and can help to guide management and referral of these patients for optimal treatment.

MATERIALS AND METHODS

Subjects

EPI Study recruited community-dwelling women ages 35–64 residing in three southeastern Michigan communities between 2002 and 2004. Women were contacted via telephone calls made to numbers purchased from a commercial survey-sampling firm.[10] A total of 2,814 women completed the telephone interview, and a subset of these women underwent urodynamic and clinical evaluation. These cohorts were selected to include women both with and without urinary incontinence.

Details of the clinical evaluation conducted in the EPI Study have been published. The subset of the larger cohort that was invited to come in for urodynamic and clinical evaluation were

Eric Rovner led the peer-review process as the Associate Editor responsible for the paper.
Conflict of interest: none.
Grant sponsor: University of Michigan Department of Urology; Grant number: U010531; Grant sponsor: NIH; Grant number: R01 HD 041123; Grant sponsor: ORWH SCOR; Grant number: P50 HD 044406; Grant sponsor: NIH/NIDDK; Grant number: T32 DK07782
*Correspondence to: John T. Wei, M.D., M.S., 1904 Taubman Center, 1500 E. Medical Center Dr., Ann Arbor, MI 48109-5312.
E-mail: jtwei@med.umich.edu
Received 4 September 2013; Accepted 6 January 2014
Published online 25 January 2014 in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/nau.22564

selected based on a priori sample size calculations to include 50–65 black and white women in each continence category (continent, SUI, UUI).[11] When the selected women presented to the clinic, each subject was asked at the time of her entry into the study whether or not she had urinary incontinence. A physician interviewed each woman (prior to clinical testing and the physical exam) and recorded whether or not the physician thought that the patient had urinary incontinence, and if so, the type of incontinence (stress, urgency, or both). The physician then performed a clinical evaluation, including a POP-Q pelvic exam, vaginal exam with palpation of the levator muscles, Q-tip angle test, measurement of bladder post-void residual volume, urodynamics with urethral pressure profile, leak point pressure and uroflow, and a paper towel test. At the end of the clinical visit, the physician reviewed both the findings from the patient's self-report and the objective clinical data to render a final diagnosis of the presence and type of urinary incontinence, exclusive of the M-ISI.[11]

Michigan Incontinence Symptom Index (M-ISI)

The M-ISI was developed using psychometric principles and has proven reliability and validity. It is 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). The Total M-ISI score consists of three subdomains (items 1–3 for Stress Urinary Incontinence [SUI], items 4–6 for Urgency Urinary Incontinence [UUI], and items 7–8 for Pad Use [PU]). All 10 items have Likert scale response options (range 0–4), with higher values representing greater symptoms and greater 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 to 8. The overall domains and subdomains are scored by simply adding up their respective subdomains. The minimally important difference (MID) has been determined for the following domains/subdomains: Total M-ISI (4 points), SUI subdomain (2 points), UUI subdomain (2 points), and PU subdomain (1 point).[9]

Statistical Methods

Continuous variables were summarized as means with standard deviations, and categorical variables were summarized as percentages. Receiver operating characteristic (ROC) curves were constructed for the SUI subdomain score, the UUI subdomain score, and the Total M-ISI domain score. These curves were then used to identify the inflection points that would optimize the sensitivity and specificity for each subdomain and domain.

The endpoints used to model the ROC curve for SUI required the presence of all of the following criteria: (i) the patient's self-reported presence of incontinence, ensuring that the leakage of urine was noticeable to the patient, (ii) demonstrable SUI on urodynamics, and (iii) the physician's final interpretation that the patient had SUI, based on the physician's review of the entire clinical encounter. In light of recent reports that urodynamics are not a necessary component to the workup of uncomplicated SUI in women[12] and the possibility that urodynamics may fail to demonstrate SUI in a women with these symptoms,[13] we performed a sensitivity analysis using a modified definition of SUI where leakage of urine with either cough or valsalva on physical exam substituted for the presence of SUI on urodynamics.

For our definition of UUI, which is only demonstrable on urodynamics in approximately 50% of patients with this condition,[14] urodynamic testing results were not included as part of the criteria used to define UUI. Therefore, the ROC curve for the UUI subdomain included only (i) the patient's self-reported presence of incontinence, and (ii) the physician's final diagnosis of UUI. The presence of either UUI or SUI, as defined above, was then used as the definition of clinically relevant urinary incontinence for the purpose of this study. Positive and negative predictive values were calculated for each subdomain and for the total M-ISI domain score. These potential threshold scores were then evaluated by a group of urologists and urogynecologists (AMS, JTW, DMM, JOLD) for face validity. Statistical analyses were conducted using SAS version 9.2 software (SAS Institute, Cary, NC).

RESULTS

A total of 394 women from the EPI population came to the clinic for evaluation. Of this cohort, 214 consecutive women completed both the clinical evaluation and the M-ISI (due to the late introduction of the M-ISI into the study). The demographic data and pertinent health history of these subjects are shown in Table I. Their mean age was 50.5 years, mean parity was 2.2, and mean BMI was 33.1. Of the 214 women, a total of 102 (47.7%) had a final diagnosis of urinary incontinence (of any type), 43 (20.1%) had a final diagnosis of SUI, and 90 (42.1%) had a final diagnosis of UUI. Since the presence of stress and urgency urinary incontinence were not mutually exclusive, any given subject could have a diagnosis of stress, urgency, or both stress and urgency urinary incontinence.

The ROC curves for the SUI subdomain, the UUI subdomain, and the Total M-ISI domain are shown in Figure 1, with corresponding areas under the curves of 0.79 (95% CI: 0.71, 0.86), 0.88 (95% CI: 0.83, 0.92), and 0.88 (95% CI: 0.83, 0.92), respectively. Table II presents the optimal threshold scores for each subdomain and domain, with their corresponding sensitivity, specificity, positive predictive value and negative predictive

TABLE I. Subject Demographic Characteristics and Pertinent Health History

	Estimate
Demographic factors	
Age in years (mean, SD)	50.5 (8.6)
Parity (mean, SD)	2.2 (1.7)
BMI (mean, SD)	33.1 (8.6)
Race (%)	
White	31.8
Black	68.2
Education (%)	
No high school degree	3.3
High school degree, but no college degree	18.2
4 years college degree, but no postgraduate degree	60.8
Any post graduate study	17.8
Total household income (%)	
<$20,000	14.0
$20,000–$39,000	16.8
$40,000–$59,000	7.5
$60,000–$100,000	18.7
$100,000+	43.0
Currently employed (%)	63.1
Pertinent health history	
Have not had a menstrual period in the last year (%)	57.0
On estrogen replacement (%)	14.0
Self-reported incontinence (%)	54.0
Using pads (%)	53.2
Final diagnosis of urinary incontinence (any type, %)	47.7
Final diagnosis of stress urinary incontinence (%)	20.1
Final diagnosis of urge urinary incontinence (%)	42.1

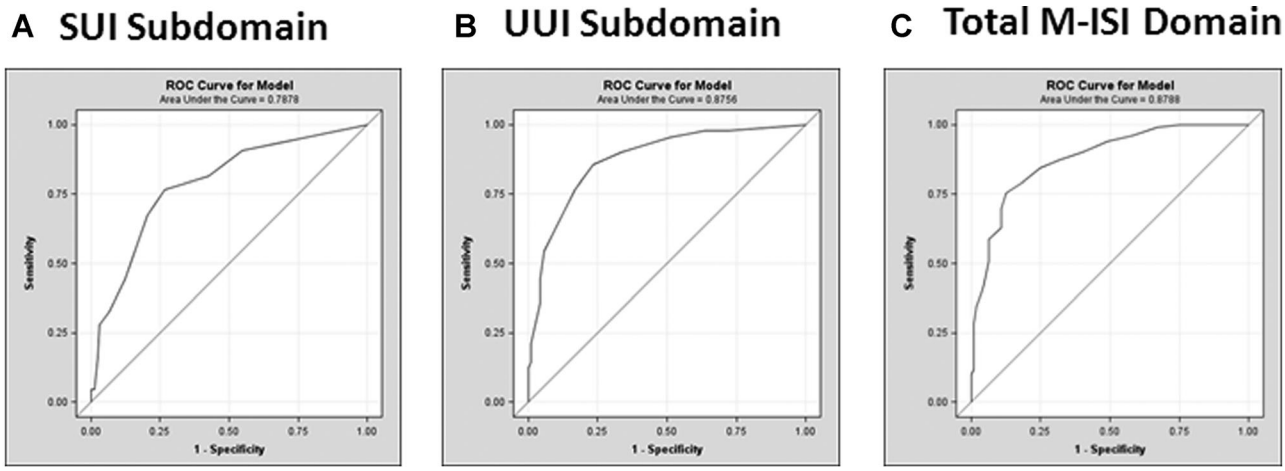

Fig. 1. Receiver operating characteristic (ROC) curves for the (**A**) stress urinary incontinence subdomain, (**B**) urgency urinary incontinence subdomain, and (**C**) total severity domain of the M-ISI questionnaire.

value. The SUI subdomain threshold score of $\geq$3 has a sensitivity of 77%, specificity of 73%, positive predictive value of 43%, and a negative predictive value of 92%. The UUI subdomain threshold score of $\geq$5 has a sensitivity of 86%, specificity of 76%, positive predictive value of 73%, and negative predictive value of 86%. The Total M-ISI domain threshold score of $\geq$7 has a sensitivity of 84%, specificity of 75%, positive predictive value of 75%, and negative predictive value of 84%.

Results from the sensitivity analysis for our SUI definition, where we substituted positive findings of leakage of urine on physical exam (with cough or valsalva) for the presence of SUI on urodynamics, yielded similar results with a screening threshold of $\geq$3, a sensitivity and specificity of 74% and 71%, and an area under the curve of 0.76 (95% CI: 0.68, 0.84).

DISCUSSION

A minority of women seek care for symptoms of urinary incontinence due to feelings of embarrassment, lack of knowledge about available treatment options, and dismissing their symptoms as being either too trivial or as a normal part of ageing.[6] A screening tool for urinary incontinence in the primary care population, such as the M-ISI, would greatly enhance the identification of women would benefit from treatment. This study identified clinically relevant threshold scores for the M-ISI to establish its use as a screening tool for urinary incontinence in the general population. Threshold scores were determined to be $\geq$3 for the SUI subdomain, $\geq$5 for the UUI subdomain, and $\geq$7 for the Total M-ISI domain. The threshold scores also exceed the minimally important difference for each subdomain and domain of the M-ISI. The minimally important difference (MID) is the smallest difference in the score that patients perceive as beneficial.[15] The MIDs for the SUI and UUI subdomains are each 2 points, and the MID for the Total M-ISI is 4 points.[9] Each of the threshold scores is higher than their corresponding MIDs, further supporting the validity of these reflex cut-offs. These values can be used to guide physicians in deciding which women might benefit from further diagnostic evaluation, treatment, and potential referral for urinary incontinence.

Our study focused on screening threshold scores for SUI and UUI, but not for mixed urinary incontinence as SUI and UUI severity are the clinically relevant concepts when it comes to practice. While the presence of both components may be qualitatively described as *mixed* urinary incontinence, referrals are likely when at least one of these components is severe enough rather than merely having *mixed* urinary incontinence. Moreover, there is no single therapy for *mixed* urinary incontinence, so we rely on clinical expertise to determine which component to address first when both are present. Such nuanced guidance on therapy is clearly beyond the primary care setting but the MISI ratio, previously published,[9] does offer an ability to determine if in incontinence is stress or urge predominant.

Other measures have been developed for use as screening tools for urinary incontinence. None of these other tools, however, combines the use of a population-based sample of women with the scope of the M-ISI to determine the type, severity, and bother of urinary incontinence. One of these other measures is the 3 Incontinence Questions (3IQ). The 3IQ has comparable sensitivities and specificities to the M-ISI, but it was developed to discern the type (urgency vs. stress), not the presence, of urinary incontinence. Additionally, the 3IQ was developed in a cohort of patients who all had clinically bothersome urinary incontinence (defined as three or more episodes of incontinence per week for at least 3 months, and symptoms that were bothersome enough for the patient to seek treatment),[16] making its use only meaningful in similar populations and not in the community at large.

Another measure, the Sandvik–Hunskaar, is a two-item questionnaire[17] that was validated in a primary health care setting to have a sensitivity and specificity of 66% and 88% for stress urinary incontinence, and 56% and 96% for urgency urinary incontinence. This questionnaire has been used in epidemiological surveys, but it is limited as a screening tool by its low sensitivities and its lack of information about the bother caused by urinary incontinence.[18]

TABLE II. Diagnostic Criteria for Threshold Scores Associated With the SUI Subdomain, the UUI Subdomain, and the Total M-ISI Domain

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Threshold score
SUI subdomain	77	73	43	92	$\geq$3 (out of 12)
UUI subdomain	86	76	73	86	$\geq$5 (out of 12)
Total M-ISI domain	84	75	75	84	$\geq$7 (out of 32)

The Incontinence Screening Questionnaire (ISQ) is an Australian measure that was developed to determine presence of incontinence in the general population; however, it was calibrated to the "gold standard" of 48-hr pad weights, rather than to patient bother or physician diagnosis.[19] While the ISQ can objectively correlate incontinence with amount of leakage measured on pads, it lacks an ability to discern incontinence that is clinically relevant or bothersome to the patient, meaning it may potentially identify incontinence that does not warrant treatment.

Finally, the Questionnaire for Urinary Incontinence (QUID) was developed to classify type of urinary incontinence (stress versus urgency) in a cohort of women who were seeking care for urinary incontinence. The QUID had a sensitivity and specificity of 85% and 71%, comparable to that of the M-ISI.[20] However, the QUID was developed in a population of women that all had urinary incontinence, so its use as a screening tool to discern whether or not women had urinary incontinence is not applicable for a more general population of women both with and without urinary incontinence. M-ISI has the advantage over these measures because it was adapted to determine the presence of urinary incontinence that is clinically relevant, and it was developed in a population-based cohort of patients who were both continent and incontinent, making it an ideal measure for use as a screening tool for urinary incontinence in the general population.

While the threshold scores for incontinence and incontinence subtypes were developed in a large, well characterized population of community-dwelling women, several limitations should be considered. First, as with all clinical studies, this work would benefit from external validation in other populations. Future work is underway to perform this validation in a population of women presenting for care to their primary care providers. Second, the M-ISI was introduced to this study cohort half way through the study period, meaning that not all of the EPI study participants had the opportunity to complete this questionnaire. However; once the questionnaire was introduced, it was completed by all participants. Third, while the sensitivity and specificity for SUI were high, 77% and 73%, respectively, the positive predictive value for the SUI was low at 43% due to the low prevalence of SUI in our cohort (per study design). This may result in referral of women who ultimately do not receive treatment; however, this is often the case in the screening setting.[21,22]

CONCLUSIONS

This study determined the clinically relevant threshold scores necessary to use the M-ISI as a screening tool for urinary incontinence in the general population ages 35–64. The use of this measure in the primary care setting can identify women with clinically relevant UI who may benefit from treatment.

REFERENCES

1. Anger JT, Saigal CS, Litwin MS. The prevalence of urinary incontinence among community dwelling adult women: Results from the National Health and Nutrition Examination Survey. J Urol 2006;175:601–4.
2. Kelleher CJ, Cardozo LD, Toozs-Hobson PM. Quality of life and urinary incontinence. Curr Opin Obstet Gynecol 1995;7:404–8. PubMed PMID: 8541463. Epub 1995/10/01.eng.
3. Minassian VA, Yan X, Lichtenfeld MJ, et al. Predictors of care seeking in women with urinary incontinence. Neurourol Urodyn 2012;31:470–474.
4. Norton PA, MacDonald LD, Sedgwick PM, et al. Distress and delay associated with urinary incontinence, frequency, and urgency in women. BMJ 1988; 297:1187–9. PubMed PMID: 3144344. Pubmed Central PMCID: 1835000. Epub 1988/11/05.eng.
5. Teunissen D, Lagro-Janssen T. Urinary incontinence in community dwelling elderly: Are there sex differences in help-seeking behaviour? Scand J Prim Health Care 2004;22:209–16. PubMed PMID: 15765635. Epub 2005/03/16.eng.
6. Shaw C, Tansey R, Jackson C, et al. Barriers to help seeking in people with urinary symptoms. Fam Pract 2001;18:48–52. PubMed PMID: 11145628. Epub 2001/01/06.eng.
7. Seim A, Hunskaar S. Female urinary incontinence–The role of the general practitioner. Acta Obstet Gynecol Scand 2000;79:1046–51. PubMed PMID: 11130085. Epub 2000/12/29.eng.
8. Jolleys JV, Wilson JV. Urinary incontinence. GPs lack confidence. BMJ 1993;306:1344. PubMed PMID: 8518594. Pubmed Central PMCID: 1677740. Epub 1993/05/15.eng.
9. Suskind AM, Dunn RL, Morgan DM, et al. The michigan incontinence symptom index (M-ISI): A clinical measure for type, severity, and bother related to urinary incontinence. Neurourol Urodyn 2013; doi: 10.1002/nau.22468.
10. Fenner DE, Trowbridge ER, Patel DA, et al. Establishing the prevalence of incontinence study: Racial differences in women's patterns of urinary incontinence. J Urol 2008;179:1455–60. PubMed PMID: 18295278. Pubmed Central PMCID: 2879624. Epub 2008/02/26.eng.
11. DeLancey JO, Fenner DE, Guire K, et al. Differences in continence system between community-dwelling black and white women with and without urinary incontinence in the EPI study. Am J Obstet Gynecol 2010;202:584e1–584e12. PubMed PMID: 20510959. Pubmed Central PMCID: 2897050. Epub 2010/06/01.eng.
12. Nager CW, Brubaker L, Litman HJ, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. N Engl J Med 2012;366:1987–97. PubMed PMID: 22551104. Pubmed Central PMCID: 3386296. Epub 2012/05/04.eng.
13. Swift SE, Ostergard DR. Evaluation of current urodynamic testing methods in the diagnosis of genuine stress incontinence. Obstet Gynecol 1995;86:85–91. PubMed PMID: 7784028.
14. Digesu GA, Khullar V, Cardozo L, et al. Overactive bladder symptoms: Do we need urodynamics? Neurourol Urodyn 2003;22:105–8. PubMed PMID: 12579626. Epub 2003/02/13.eng.
15. Streiner DL, Norman GR. *Health Measurement Scales; A practical guide to their development and use*. New York: Oxford University Press; 2003. 231 p.
16. Brown JS, Bradley CS, Subak LL, et al. The sensitivity and specificity of a simple test to distinguish between urge and stress urinary incontinence. Ann Intern Med 2006;144:715–23. PubMed PMID: 16702587. Pubmed Central PMCID: 1557357. Epub 2006/05/17.eng.
17. Sandvik H, Seim A, Vanvik A, et al. A severity index for epidemiological surveys of female urinary incontinence: Comparison with 48-hour pad-weighing tests. Neurourol Urodyn 2000;19:137–45. PubMed PMID: 10679830. Epub 2000/02/19.eng.
18. Sandvik H, Hunskaar S, Vanvik A, et al. Diagnostic classification of female urinary incontinence: An epidemiological survey corrected for validity. J Clin Epidemiol 1995;48:339–43. PubMed PMID: 7897455. Epub 1995/03/01.eng.
19. Gunthorpe W, Brown W, Redman S. The development and evaluation of an incontinence screening questionnaire for female primary care. Neurourol Urodyn 2000;19:595–607. PubMed PMID: 11002302. Epub 2000/09/26.eng.
20. Bradley CS, Rovner ES, Morgan MA, et al. A new questionnaire for urinary incontinence diagnosis in women: Development and testing. Am J Obstet Gynecol 2005;192:66–73. PubMed PMID: 15672005. Epub 2005/01/27.eng.
21. Schroder FH. Screening, early detection, and treatment of prostate cancer: A European view. Urology 1995;46:62–70. PubMed PMID: 7653022.
22. Carney PA, Sickles EA, Monsees BS, et al. Identifying minimally acceptable interpretive performance criteria for screening mammography. Radiology 2010;255:354–61. PubMed PMID: 20413750. Pubmed Central PMCID: 2858814.