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The association of Incontinence Symptom Index scores with urethral function and support

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Abstract

OBJECTIVE—The objective of the study was to establish categories of symptom severity based on Incontinence Symptom Index (ISI) scores and show how these categories are associated with urethral function and support.

STUDY DESIGN—Women with stress incontinence (n = 97) and asymptomatic controls (n = 98) completed the ISI. Asymptomatic women's scores were between 0 and 6; this range was designated as absent/mild (n = 104). The median score for symptomatic women was 16; scores from 7 to 16 (n = 50) were designated as moderate, and scores of 17 or greater (n = 40) were designated as severe.

RESULTS—Urethral function differed in women with mild, moderate, and severe scores: Valsalva leak point pressure (162.3 vs 123.5 vs 101.9 cm H_2O; $P = .001$), cough leak point pressure (202.0 vs 163.0 vs 134.3 cm H_2O; $P = .001$), and maximum urethral closure pressure (69.1 vs 44.1 vs 35.3 cm H_2O, $P = .001$). Loss of urethrovesical support (point Aa: −1.0 vs −0.6 vs −0.5 cm; $P = .004$) was found in women with moderate and severe symptoms, compared with those with mild symptoms.

CONCLUSION—Categories of symptom severity assessed by the ISI are associated with urethral function and support.

Keywords

Incontinence Symptom Index; stress urinary incontinence; symptom severity

Urinary incontinence is a common condition reported by approximately 38% of community-dwelling women.[1] Its negative impact on quality of life makes it important to evaluate the severity of symptoms caused by urinary incontinence.[2] The Incontinence Symptom Index (ISI) is a novel, newly validated urinary incontinence symptom questionnaire, developed with the intent of creating a clinically relevant, brief, and comprehensive index of urinary incontinence symptoms. [3] It assesses the type and frequency of symptoms, pad use, and bother caused by urinary incontinence.

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Developing symptom severity groupings of scores (ie, mild, moderate, and severe) is an important component of the ISI's development. Validated urinary incontinence questionnaires are available.[4–7] Items within these instruments are associated with the presence of specific symptoms, but the overall scores have not correlated with abnormalities in urethral function and support.[8–10] There remains a need for an instrument that assesses the severity of patient-reported symptoms, is readily interpreted in clinical practice, and is associated with the pathophysiology underlying urinary incontinence.

The purpose of this study was to develop clinically relevant categories of mild, moderate, and severe symptoms on the ISI and to establish their validity by associating these categories with urethral function (urethral pressure profiles and leak point pressures) and support (pelvic organ quantification findings).

Materials and Methods

This was a secondary analysis of a case-control study investigating the pathophysiology of stress urinary incontinence.[11] Questionnaire, clinical, and urodynamic data were analyzed to develop clinically useful categories of urinary incontinence severity. Symptomatic women with stress-predominant urinary incontinence symptoms were recruited from university-based urogynecology and urology clinics (n = 97). These women had to report at least 2 episodes of stress incontinence on a 3-day voiding diary and to demonstrate stress incontinence during a full bladder stress test. Asymptomatic women were recruited from the community via advertisements (n = 98) and were included if they did not report any episodes of incontinence during a 3-day voiding diary and had a negative full bladder stress test.

Participants were matched for age, race, parity, and hysterectomy status. Women were excluded if they had previous surgery for urinary incontinence or pelvic organ prolapse greater than 1 cm below the hymen.

The study was approved by the University of Michigan Institutional Review Board (#2002-0636).

Pelvic examinations were performed with women in a semirecumbent position in a urodynamics chair at a 45o angle. Assessment of vaginal and uterine support was conducted using the Pelvic Organ Prolapse Quantification System (POP-Q). Urethral axis inclination measurements were made from the horizontal with a cotton-tipped swab at rest (Q-tip rest), with Valsalva (Q-tip straining), and with Kegel contraction (Q-tip Kegel). Similarly, measurements of the genital hiatus were made at rest, with Valsalva, and with Kegel contraction.

Urethral sphincter function was assessed with urethral profilometry. The bladder was filled to a volume of 300 mL. Three serial urethral pressure profile measurements were taken using an 8 Fr Gaeltec dual-tip urodynamics catheter (Medical Measurements Inc, Hackensack, NJ) with the transducer laterally oriented and averaged. Mean maximum urethral closure pressure (MUCP) was calculated by the average difference between maximum urethral pressure and resting bladder pressure. Cough leak point pressures (CLPP) and Valsalva leak point pressures (VLPP) were determined.

Patients completed questionnaires regarding their medical and reproductive histories and completed a protocol of symptom questionnaires. Urinary incontinence symptoms and the bother associated with them were assessed by the ISI, a 10 item instrument scored on a Likert scale (range 0–4). Higher scores indicate worse symptom severity or bother. The ISI "severity" score is the sum of 8 items and ranges from 0 to 32. The ISI "bother" score is the

sum of 2 items and ranges from 0 to 8. Total number of medical comorbidities was summed (including hypertension, diabetes mellitus, lung disease, heart disease, arthritis, and neurologic disease). The number of depressive symptoms was determined by responses to the Center for Epidemiologic Studies Depression Scale (CES-D).[12]

Statistical analysis

Using the distribution of scores within this population, clinically relevant categories were constructed for the ISI. The range of scores observed in asymptomatic women was used to develop a grouping of women with absent or "mild" symptoms. The median score of symptomatic women was used to divide the remaining women into groups with "moderate" and "severe" symptoms.

Bivariate relationships were explored between the groups with mild, moderate, and severe and ISI bother scores, demographic data, POP-Q points, Q-tip angle measurements, maximum urethral closure pressures, cough leak point pressures, and Valsalva leak point pressures with χ^2 and analysis of variance (ANOVA) tests. Additional pair-wise comparisons with Student *t* tests were made when a significant difference was detected between the mild, moderate, and severe ISI groups with the ANOVA. An alpha of 0.05 was used for significance in all tests. All analyses were performed using STATA version 9.2. (StataCorp, College Station, TX).

Results

The distribution of ISI scores among symptomatic and asymptomatic women is presented as a histogram (Figure 1). The range of scores observed among asymptomatic controls was 0 to 6. Six individuals meeting "symptomatic" inclusion had ISI scores in this range. Thus, there were 104 individuals who had ISI scores in this range; they were considered to have absent or mild symptoms. The median ISI score of 16 for symptomatic women was used to develop groups with moderate and severe symptoms. Women with ISI scores of greater than 6 and 16 or less were considered to have symptoms of moderate severity (n = 50). Women with ISI scores of 17 or greater were considered to have symptoms that were most severe (n = 41) (Figure 2).

The demographics of the mild, moderate, and severe ISI groupings are shown in Table 1. There was a difference between the groups with respect to vaginal parity, body mass index (BMI), the count of depressive symptoms by the CES-D, and the number of medical comorbidities. Pair-wise comparisons were used to determine that parity was lower among women in the severe symptom category, compared with those in the moderate group; that BMI and the count of depressive symptoms on the CES-D were greater among the women with moderate and severe symptom severity, compared with the mild group; and that the number of comorbidities was greater among the severe group compared with the mild group.

Measures of urethral function (Table 2) were associated with the symptom severity reported on the ISI. There were significant differences in MUCP between each of the ISI severity groupings. Cough and Valsalva leak point pressures were lower among the women in the severe ISI group, compared with those with either mild or moderate symptoms. Because of a small number of individuals in the mild group who had demonstrable stress incontinence during urodynamics, there were nonsignificant differences between the mild and moderate groups in cough leak point pressure (P =0.072) and Valsalva leak point pressure (P =0.117).

Differences in urethral support (POP-Q points Aa and Ba, genital hiatus measures, and urethral axis by Q-tip test) were also observed (Table 3). There was a consistent pattern in which the group with mild symptom severity differed from the moderate and severe groups.

However, the groups with moderate and severe symptom severity did not differ from one another. The moderate and severe groups did not differ with respect to urethral axis at rest by Q-tip ($P = .103$), urethral axis with Kegel contraction by Q-tip test ($P = .123$), urethral axis with straining by Q-tip ($P = .636$), point Aa ($P = .363$), point Ba ($P = .502$), genital hiatus at rest ($P = .651$), genital hiatus with Kegel contraction ($P = .703$), or genital hiatus with straining ($P = .501$).

Other areas of vaginal support assessed by the POP-Q did not differ. The mean (± SE) apical and posterior POP-Q points of the mild, moderate, and severe groups were the following: point C (6.3 ± 0.1 cm vs −6.3 ± 0.2 cm vs −6.2 ± 0.3 cm, $P = 1.0$), point D (−8.9 ± 0.1 cm vs −8.8 ± 0.1 cm vs −8.6 ± 0.3 cm, $P = .8$), point Ap (1.5 ± 0.1 cm vs −1.36 ± 0.1 cm vs −1.5 ± 0.1 cm, $P = .8$), and Bp (−1.4 ± 0.1 cm vs −1.3 ± 0.1 cm vs −1.5 ± 0.1 cm, $P = .2$).

Severity scores were associated with a greater impact on quality of life by the ISI bother score ($r = 0.80$, $P < .001$). The mean bother scores of the mild, moderate, and severe groups were significantly different (Figure 3).

Comment

This analysis demonstrates how the ISI is associated with abnormalities of urethral function and support commonly observed during the evaluation of stress urinary incontinence. Loss of urethral support, lower intraurethral pressures, and lower leak point pressures are correlated with absent/mild, moderate, and severe categories of symptom severity. These groupings of symptom severity reflect bother or impact on quality of life and allow ISI scores to be easily interpreted.

The administration of a questionnaire is not intended to replace a thoughtful history, physical examination, and urodynamic testing. As with any clinical tool, there are individuals who do not fit the paradigm. For instance, in this analysis, a few women with stress incontinence had ISI scores that overlapped with asymptomatic continent women. This is understandable when one considers how an individual may cope with her symptoms. Women with urinary incontinence often change their activities to remain continent and their adaptations can be effective in mitigating their symptoms. Thus, even though these women may have significant anatomic and physiologic pathology, they experience fewer episodes of incontinence and use fewer pads, leading to lower symptom severity scores.

Coping with a condition such as urinary incontinence is complex, and a thorough evaluation will continue to depend on a number of different modalities including physical exam findings, voiding diaries, and urodynamics. Which modality is most likely to direct management is often based on the provider's personal experience and cost-effectiveness.[13]

In our study, categories of mild, moderate, and severe ISI symptom severity scores differentiated women with progressively lower leak point pressures and lower urethral closure pressures. Other well-known urinary incontinence questionnaires have not performed as consistently when investigators have attempted to correlate symptom severity scores with urodynamics.

Lemack and Zimmern[10] found a moderate correlation between a positive response on item 3 of the UDI-6 (urinary leakage with physical activity) and urodynamically demonstrable stress incontinence, but neither symptom severity scores nor any single question was associated with Valsalva leak point pressure.

Fitzgerald and Brubaker were also unable to find an association between specific questions on either the Urogenital Distress Inventory-6 or the Incontinence Impact Questionnaire and

urodynamics.[14] The American Urological Association Symptom Index, a validated instrument initially used to assess the severity of benign prostatic hyperplasia,[7,15] has been associated with a negative impact on quality of life because of incontinence symptoms[16] but has not correlated well with urodynamic findings.[17–20] Thus, the fact that ISI symptom severity scores are associated with urodynamic findings is valuable and clinically useful.

The relationship of certain urodynamic findings with the ISI groupings supports the concept that urethral competence is of primary importance in the urinary continence mechanism. There were significant differences among almost all of the group comparisons of mean maximum urethral closure pressures and leak point pressures. In contrast, measures of urethral support appear to be of secondary importance because they differentiated only those who had absent/mild symptoms from those with moderate or severe symptoms.

The inconsistent ability of urethral mobility to predict the severity of symptoms has been reported in other studies as well.[11,21,22] This may be due to the fact that although there is a correlation between stress incontinence and urethral hypermobility,[23–26] there are many women with stress urinary incontinence who have normal urethral support.[27–29] Loss of urethral support is commonly observed among women with incontinence, but measures of urethral competence appear to better account for symptom severity.

There are some limitations to consider when evaluating this study. More than 90% of these women were white; similar data in more diverse populations are needed. The definition we used for “symptomatic” women (at least 2 episodes of stress urinary incontinence in 3 days on a voiding diary and a positive full bladder stress test) is somewhat rigorous; it will be worthwhile to determine in the future whether the ISI is able to discriminate between women with an even narrower spectrum of symptom severity.

In conclusion, ISI severity scores can differentiate women with physiologic abnormalities associated with SUI and may be a valuable tool in clinical settings. In assessing the severity of symptoms, clinicians can use the ISI as a quick and effective inventory of patient perceptions, knowing that increasing severity scores are a reflection of the pathophysiology underlying urinary incontinence.

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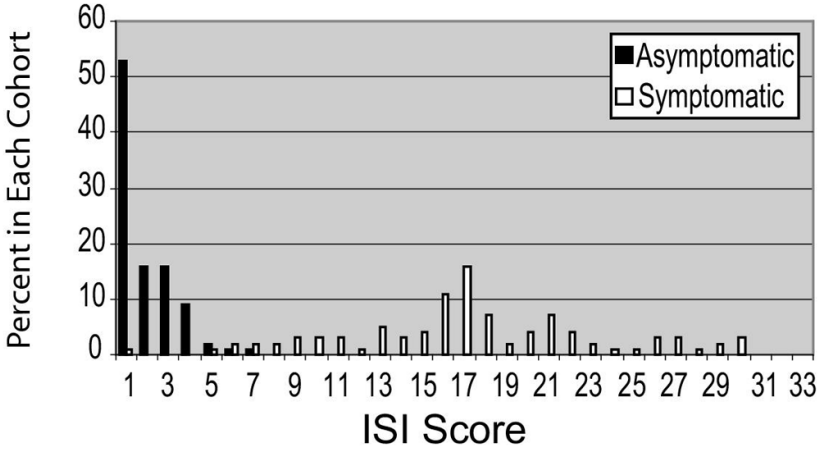

Figure 1.
Distribution of ISI severity scores among cohorts of symptomatic and asymptomatic women

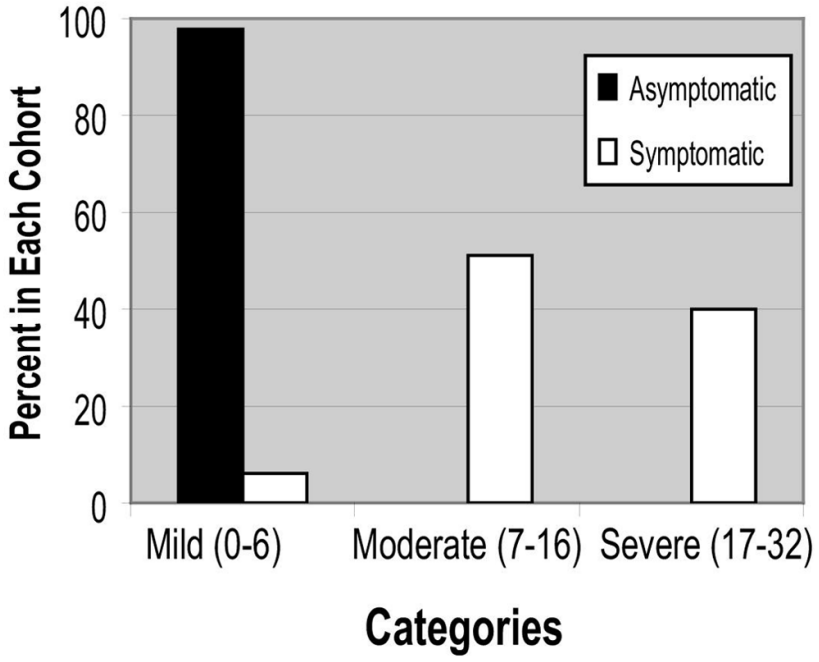

Figure 2.
Categories developed from ISI score distribution among cohorts of symptomatic and asymptomatic women

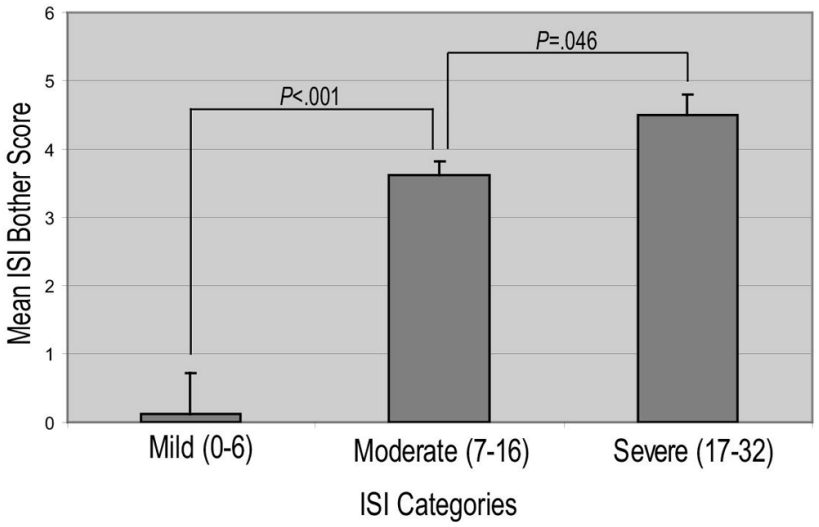

Figure 3.
Relationship between reported mean bother score and ISI score categories

Table 1

Demographics of women within ISI score categories

Symptom severity ISI range (n)	Mild 0–6 (n = 104)	Moderate 7–16 (n = 51)	Severe 17–29 (n = 40)	ANOVA *P* value
Age (y)	47.4 ± 1.1	46.4 ± 1.2	50.3 ± 1.6	.260
BMI (kg/m^2)	27.8 ± 0.5^{a,b}	30.1 ± 0.9^{a}	31.2 ± 1.2^{b}	**.011**
Parity	2.0 ± 0.1	1.8 ± 0.2^{c}	2.4 ± 0.2^{c}	**.048**
Weight largest infant (kg)	3.6 ± 0.05	3.8 ± 0.08	3.6 ± 0.05	.145
Caucasian race (%)	97.1	91.8	95.0	.687
Prior hysterectomy (%)	9.6	10.0	15.0	.633
Currently menstruating (%)	63.5	68.0	62.5	.825
Hormone replacement therapy use (%)	8.7	10.0	12.5	.784
Medical comorbidities (n)	0.7 ± 0.1^{b}	0.9 ± 0.1	1.2 ± 0.2^{b}	**.044**
Depressive symptoms (CES-D count)	0.7 ± 0.1^{a,b}	1.9 ± 0.3^{a}	2.2 ± 0.4^{b}	**< .001**
Tobacco ever (%)	43.3	48.0	40.0	.739
Tobacco current (%)	15.6	29.2	31.3	.277
Lifts 30 lb more than twice a day %)	15.4	14.3	7.8	.389
Employed (%)	75 .0	64.0	70.0	.364

Values reported as either percent (where indicated) or mean ± SE.

^{a}Pair-wise: mild vs moderate ($P < .01$).

^{b}Pair-wise: mild vs severe ($P < .05$).

^{c}Pair-wise: moderate vs severe ($P < .05$).

Table 2

Urethral function analyzed by mild, moderate, and severe ISI score categories

Symptom severity ISI range	**Mild 0–6**	**Moderate 7–16**	**Severe 17–29**	**ANOVA *P* value**
Urethral function				
MUCP (mm H_2O)	69.1 ± 2.2[a,b] (n = 104)	44.1 ± 2.6[a,c] (n = 51)	35.3 ± 2.4[b,c] (n = 40)	**< .001**
VLPP (mm H_2O)	162.3 ± 17.4[b] (n = 3)	123.5 ± 6.7[c] (n = 37)	101.9 ± 5.4[b,c] (n = 38)	**.001**
CLPP (mm H_2O)	202.0 ± 16.0[b] (n = 4)	163.0 ± 6.8[c] (n = 40)	134.3 ± 6.8[b,c] (n = 36)	**.001**

Values reported as means ± SE.

[a] Pair-wise: mild vs moderate ($P < .001$).

[b] Pair-wise: mild vs severe ($P < .001$).

[c] Pair-wise: moderate vs severe ($P < .01$).

Table 3

Urethral support analyzed by mild, moderate, and severe ISI score categories

Symptom severity ISI range	Mild, 0–6 (n = 104)	Moderate, 7–16 (n = 51)	Severe, 17–29 (n = 40)	ANOVA *P* value
Urethral support				
Q-tip rest (degrees)	−6.1 ± 0.1[a]	−2.4 ± 0.2	1.7 ± 0.3[a]	< **.001**
Q-tip Kegel (degrees)	−20.3 ± 0.2[a,b]	−13.9 ± 0.3[b]	−8.9 ± 0.4[a]	**.001**
Q-tip strain (degrees)	24.9 ± 1.8	29.2 ± 2.9	31.3 ± 3.3	.068
POP-Q point Aa (cm)	−1.0 ± 0.1[a,b]	−0.6 ± 0.1[b]	−0.5 ± 0.1[a]	**.004**
POP-Q point Ba (cm)	−0.9 ± 0.1[a,b]	−0.5 ± 0.1[b]	−0.4 ± 0.1[a]	**.005**
GH rest (cm)	2.8 ± 0.1[a,b]	3.3 ± 0.1[b]	3.2 ± 0.2[a]	**.007**
GH Kegel (cm)	2.4 ± 0.1[a,b]	2.8 ± 0.1[b]	2.8 ± 0.1[a]	**.012**
GH strain (cm)	3.4 ± 0.1[a,b]	4.1 ± 0.1[b]	3.9 ± 0.2[a]	**.004**

Values reported as means ± SE.

[a] Pair-wise: mild vs severe ($P < .01$).

[b] Pair-wise: mild vs moderate ($P < .01$).