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Assessing urgency in interstitial cystitis/painful bladder syndrome

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Abstract

Objective—Interstitial cystitis/painful bladder syndrome (IC/PBS) at present is a symptom-based diagnosis. The Interstitial Cystitis Symptom Index (ICSI), also known as the O’Leary-Sant Symptom Index, is a widely used scale that assesses the 4 cardinal symptoms of IC/PBS, i.e. bladder pain, urgency, frequency, and nocturia, by asking *how often* each is experienced. In an ongoing case control study of recent onset IC/PBS, we compared the ICSI to questions that addressed *severity* of these symptoms.

Methods—Recruiting nationally, we enrolled women with IC/PBS symptoms of ≤ 12 months. We assessed severity of pain, frequency, and urgency by Likert and categorical scales, and how often these symptoms were experienced by the ICSI. We compared these scales by frequency distributions and inter-scale correlations.

Results—In 138 women with recent onset IC/PBS, scores for frequency were correlated and for pain appeared to be complementary. However for urgency, the ICSI question of “the strong need to urinate with little or no warning” consistently yielded lower scores than the severity question of “the compelling urge to urinate which is difficult to postpone”. Indeed, some patients denied urgency to the ICSI question yet reported intense urgency to the severity question.

Conclusions—Compared to the severity question, the ICSI underestimated the prevalence and degree of urgency. This observation is consistent with the views of others that *sudden* urgency does not define the sensation experienced by many IC/PBS patients. Clarifying this symptom description may assist in developing a usable case definition for IC/PBS.

Keywords

Interstitial cystitis; painful bladder syndrome; symptoms; urgency

Introduction

Interstitial cystitis/painful bladder syndrome (IC/PBS) is a chronic disease manifested by bladder pain, frequency, nocturia, and urgency¹. Although observation of glomerulations after bladder hydrodistention was promulgated as an objective criterion for IC/PBS², subsequent work has questioned the sensitivity and specificity of this finding^{3,4}. Moreover, physical signs,

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urodynamics, histopathology, and available laboratory tests also lack sensitivity and/or specificity for IC/PBS^{1,5–8} and, at present IC/PBS is a symptom-based diagnosis^{6,9}. Consequently, investigators are clarifying symptoms expressed by IC/PBS patients^{10,11}.

Thus, the sensation experienced by IC/PBS patients that is often described as urgency is receiving scrutiny. The Standardisation Subcommittee of the International Continence Society (ICS) in 2002 defined urgency as “a sudden compelling desire to pass urine, which is difficult to defer”¹². However in 2005, two of these authors, with Philip Hanno, published an opinion piece stating that this definition applied more to patients with overactive bladder (OAB) than with IC/PBS¹³. Indeed, these authors implied that the urgency of OAB is based on the fear of incontinence while that of IC/PBS is relief of pain.

An ongoing case control study to identify risk factors for IC/PBS serendipitously has provided data supporting the contention that many IC/PBS patients are experiencing a sensation of needing to void without the sudden onset described by the ICS. Clarifying this issue may assist in developing a usable case definition for IC/PBS.

Materials and methods

We are performing a national case control study called Events Preceding Interstitial Cystitis to identify risk factors for IC/PBS in women¹⁴. To evaluate eligibility, we had to identify a time interval in which to query symptoms. Onset of disease appeared to be inappropriate as two studies reported that not all characteristic IC/PBS symptoms were experienced at onset^{15,16}. In that we were not performing a prevalence study, assessing symptoms at interview was unnecessary and we did not want to exclude patients whose symptoms had ebbed. Therefore, we elected to ask cases to tell us about their symptoms when they were at their worst.

Students of symptom measurement make a persuasive case that robust assessment of a symptom requires measures of both its severity and how often it is experienced¹⁷. We thus sought to develop both types of questions, asking about each symptom with a pair of questions, the severity question placed first. As a measure of how often each symptom is experienced, The Interstitial Cystitis Symptom Index (ICSI), also known as the O’Leary-Sant Symptom Index¹⁸, has emerged as a popular instrument not only for its original intent to longitudinally assess patients in clinical trials but also as a tool to diagnose IC/PBS. Its definition of urgency is “the strong need to urinate with little or no warning”.

To develop questions eliciting severity of symptoms, we reviewed the literature and conducted focus groups and pilot studies of IC/PBS patients. For pain, we used Likert scales of 0 – 10, 10 “being as bad as you can imagine”, to describe “any bladder pain, pressure or discomfort” and for frequency “the number of times you urinated in a 24 hour period” (≤7 times, 8 – 10 times, 11 – 14 times, or ≥15 times). For nocturia, we did not use a separate severity question but used only the ICSI question: “how often did you most typically get up at night to urinate?” (0 to ≥5 times).

For urgency, selection of a severity question proved problematic. A literature review did not yield a definition that was embraced uniformly by members of our focus groups (Table 1). Specifically, many noted that their urgency did not appear “suddenly” or “with little or no warning”. Consequently, we developed a new question which we felt would include those with urgency based upon fear of incontinence, relief of pain, or other motivations: “the compelling urge to urinate which is difficult to postpone” and measured this on a Likert scale of 0 – 10.

In this report, we assessed the first 138 eligible cases; their characteristics have been previously reported¹⁴. We compared individual symptoms first by distribution; for these comparisons we

collapsed the 11-point Likert scales for pain and urgency in severity responses to 6-point scales (0, 1–2, 3–4, 5–6, 7–8, 9–10) to approximate the 6-point ICSI. Secondly, we estimated correlations between the scales for each symptom. Descriptive statistics included means and standard deviations for quasi-continuous data; frequency distributions were reported for ordinal and nominal data. Spearman correlations were used to estimate inter-scale associations. Pearson and McNemar Chi-square tests were used to compare unpaired and paired proportions.

Results

Figure 1 compares the distributions of each symptom as measured by the severity scale and the ICSI. For frequency, distributions of the two scales were similar. If one uses $\geq 11/24$ hours on the severity scale (≥ 3) and its approximate analog, “about half the time” (≥ 3), on the ICSI scale as thresholds, there is no significant difference between measured prevalences of frequency: severity, 119/138 (86%), and ICSI, 125/138 (91%) ($p=0.11$).

Pain distributions (Figure 1b) revealed significant differences between the 6 point severity and the ICSI responses in means, 4.4 vs. 4.1 ($p=.0043$). Furthermore, 124/138 (90%) reported pain ≥ 4 on the severity scale while 95/138 (69%) reported pain of ≥ 4 on the ICSI ($p<.0001$). Bladder pain was an enrollment criterion so the prevalence of pain using either the severity or the ICSI scale was 100%. Distributions of urgency were quite different as assessed by the severity and the ICSI questions (Figure 1c). Mean urgency measured by the severity scale (3.9) was significantly higher than by the ICSI scale (2.8) ($p<0.001$). The distribution of ICSI responses was uniform across the scale. If one assumes that any urgency is abnormal, its prevalence by the severity scale was 135/137 (99%) and by the ICSI, 117/137 (85%) ($p=.0001$). Using urgency ≥ 2 , the prevalence measured by the severity scale was 134/137 (98%) and by the ICSI, 97/137 (71%) ($p<.0001$).

The inter-scale correlations for each symptom are revealing. Table 2 demonstrates that for frequency and pain, most cases are clustered in the lower right corner, i.e. the highest of both scales. For frequency, 85/138 (62%) cases were $\geq 11/24$ hours on the severity scale and “almost always” on the ICSI, and for pain 70/138 (51%) cases were ≥ 7 and “almost always” on the ICSI. Comparable assessments for urgency, i.e. ≥ 7 on the severity scale and “almost always” on the ICSI, revealed that only 22/136 (16%) cases reported these high scores on both scales. So, while 51 – 62% were in the high categories of both scales for frequency and pain, only 16% were in the high categories of both scales for urgency ($p<.0001$). This is because many participants reported urgency of lower intensity on the ICSI than on the severity scale.

A related feature is the left-most column in Table 1c noting that 20 cases denied any sensation of urgency on the ICSI yet 19 (95%) reported urgency on the severity scale; indeed, 10 reported severe urgency, i.e., in the 7 – 10 range.

Comment

Questions must be properly phrased to elicit accurate responses about symptoms and are critical for IC/PBS as at present symptoms are the only way to make a diagnosis. Our two sets of questions assessed frequency and pain as being similar or complementary yet yielded markedly discrepant answers for urgency. Compared to the severity question, the ICSI consistently underestimated the degree and prevalence of urgency. This observation is consistent with the hypothesis that urgency “with little or no warning” is not an accurate description of the sensation experienced by at least some IC/PBS patients.

Pain is central to the diagnosis of IC/PBS and we were not surprised to find that the majority of cases reported severe pain to both questions. Similarly, there was a strong correlation between assessments of urinary frequency. This is reasonable as the severity question measured

rate of urination while the ICSI measured *intervals* between urinations. The inverse of the rate is the interval.

However, when asked the urgency questions, most participants reported higher scores on the severity scale than on the ICSI, opposing the trends for frequency and pain. This finding lends itself to two interpretations. One is that most cases had severe urgency, but only occasionally. The second hypothesis is that the severity question and the ICSI question about urgency are asking about different sensations.

Support for the latter hypothesis lies in the observation that twenty patients flatly denied urgency to the ICSI question yet 19 of them indeed reported experiencing urgency in the severity question. These categories should have identical responses because they are absolutes: cases who report zero urgency (“not at all”) on the ICSI should report zero (“no urgency at all”) on the severity scale. That 19/20 participants appear to have contradicted themselves is thus unsettling.

These observations are consistent with the idea that these questions were actually tapping two different experiences of urinary urgency. While almost all of our participants reported a severe “compelling urge to urinate that is difficult to postpone”, their responses indicated that this urgency was not always or for all participants “with little or no warning”. Indeed, our interviewers noted that a number of IC/PBS patients offered that “I always have warning”.

We thus hypothesize that the ICSI urgency “with little or no warning” is not what some IC/PBS patients experience. We likewise concur with Abrams, Hanno, and Wein¹³ that the ICS definition of “sudden” urgency does not uniformly apply to IC/PBS patients. Indeed, these authors suggest that the term “urgency” should not be used for IC/PBS patients. Unfortunately, there is not readily available another one-word description. These authors suggest “a desperate desire to void because of pain and fear of worsening pain”; this phrase is difficult to use more than once in a discussion and after its introduction, how does one continue to talk about this sensation? On the other hand, the word “urgency” to describe the sensation felt by IC/PBS patients is a venerable one and is used by IC/PBS indices^{19,20} and by current IC/PBS investigators^{6, 9,11,14–16,21–24}. Indeed, our patients had no difficulty in responding to the word “urgency” to describe their sensation. A more practical approach may be to agree that “a compelling urge to urinate which is difficult to postpone”, or a similarly general description of urgency, can have several causes or motivations which probing questions can distinguish among.

Asking about urgency is of clinical importance in IC/PBS. Summing the four ICSI symptom scores has been used to define IC/PBS. For instance, Leppilahti, et al. used a threshold of 12 on the total ICSI score as a case definition of IC/PBS in a prevalence study in Finland²⁵. A perusal of Table 1c indicates that a number of our participants, as measured by the severity scale, appeared to be experiencing severe urgency yet noted zero or 1 on the ICSI. For these individuals, their summed ICSI score might be spuriously low by 4 – 5 points (of a maximum of 20). Secondly, for clinical trials, to the extent that the ICSI underestimates urgency, the investigator is deprived of the opportunity to accurately measure impact of therapies upon this symptom. Thirdly, and perhaps most importantly, a too narrow description of urgency may obscure important pathophysiologic insights: if the urgency of IC/PBS is generated by need to relieve pain, etiologic and therapeutic research might be directed more productively at pain rather than this secondary symptom.

There are several caveats. Whether these data can be extrapolated from recent onset to established IC/PBS patients is unclear. The ICSI was developed to ask about symptoms in the prior four weeks; we believe that comparing questions about the same symptoms during the same time interval should be acceptable. Finally, placing questions about each symptom in

pairs may have biased answers towards similar responses. Hence, there might have been even greater differences between the severity and the ICSI questions had they been separated.

Conclusions

The ICSI appears to consistently underreport urgency. Asking about urgency “with little or no warning” underestimates the prevalence and degree of urinary urgency in IC/PBS. What might be viewed simply as an artifact of question wording may actually be addressing an issue of pathophysiologic importance: why do IC/PBS patients have urgency?

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Figure 1.
Distributions of symptoms measured by the severity scale and the Interstitial Cystitis Symptom Index (ICSI)

Table 1

Selected published definitions of urgency

Source ^{ref}	Year	Definition	Suggested quantitation
NIDDK ²	1988	<i>Undefined</i>	None
U Wisconsin ¹⁹	1994	<i>Undefined</i>	<i>Unclear</i>
ICSI ¹⁸	1997	“strong need to urinate <i>with little or no warning</i> ”.	How often
ICDB ¹	1997	“urge to urinate such that if you do not rush to the bathroom you feel that you will not be able to <i>bear it</i> ”	How often
PUF ²⁰	2002	<i>Undefined</i>	How often, severity
ICS ¹²	2002	“ <i>Sudden</i> compelling desire to pass urine, which is difficult to defer”	Not done

Italicized words refer to items found problematic by focus groups.

Abbreviations: NIDDK – National Institute of Diabetes, Digestive and Kidney Diseases, U Wisconsin – University of Wisconsin, ICSI – Interstitial Cystitis Symptom Index, ICDB – Interstitial Cystitis Data Base, PUF – pain, urgency, and frequency, ICS – International Continence Society

Table 2

Interscale distributions

a. Frequency							
Severity	1	2	ICSI 3	4	5	Total	
1	2	0	0	0	0	2	
2	4	3	6	2	2	17	
3	1	3	9	9	19	41	
4	0	0	2	10	66	78	
Total	7	6	17	21	87	138	
b. Pain							
Severity	2	3	ICSI 4	5	Total		
3	1	0	0	0	1		
4	1	1	1	0	3		
5	0	1	0	3	4		
6	1	4	0	1	6		
7	3	5	3	8	19		
8	3	3	7	18	31		
9	2	3	3	14	22		
10	4	11	7	30	52		
Total	15	28	21	74	138		
c. Urgency							
Severity	0	1	ICSI 2	3	4	5	Total
0	1	1	0	0	0	0	2
1	1	0	0	0	0	0	1
2	3	3	0	0	0	0	6
3	0	1	0	0	0	0	1
4	0	1	0	0	0	2	3
5	3	3	2	1	0	0	9
6	2	3	2	2	5	1	15
7	1	2	3	7	5	2	20
8	3	3	5	7	11	3	32
9	3	0	0	2	3	4	12
10	3	3	3	0	13	13	35
Total	20	20	15	19	37	25	136*

* One person did not answer the severity urgency question and one did not answer the ICSI urgency question