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Validation of a Quality of Life Scale for Women with Bladder Pain Syndrome/Interstitial Cystitis

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Abstract

Purpose—To validate a disease-specific scale to measure impact of symptoms of bladder pain syndrome/interstitial cystitis (BPS/IC), a condition that affects up to 6.5% of U.S. women.

Methods—Participants were drawn from the RAND Interstitial Cystitis Epidemiology Study (RICE), a telephone probability survey of 146,231 U.S. households. Women who met RICE BPS/IC symptom criteria (n=3,397) completed the 6 -item RAND Bladder Symptom Impact scale (RICE BSI-6). The RICE BSI-6 was adapted from a scale used to assess impact of diabetes on life and sexuality, and modified based on expert input on face validity and focus group work; items specific to diabetic symptoms were eliminated. Validated scales of symptom severity, mental-and physical -health-related QoL, depression, coping, and perceived control were used to assess convergent validity.

Results—The RICE BSI-6 ($\alpha=.92$) was significantly related to greater symptom severity, worse general mental and physical health-related QoL, more severe depression symptoms, and lower perceived control over life in general and over BPS/IC symptoms (p-values<.05). It was also associated with less use of distancing coping (p<.05).

Conclusion—The RICE BSI-6 shows excellent internal consistency and strong convergent validity. It can be used to examine effects of psychosocial and treatment interventions on QoL among women with BPS/IC.

Keywords

Painful Bladder Syndrome; Interstitial Cystitis; quality of life; women

Women with BPS/IC report a constellation of bladder symptoms, including bladder/pelvic pain, and urinary frequency or urgency [1]. No objective signs or tests exist to confirm a BPS/IC diagnosis and thus clinical diagnosis of BPS/IC is based on patient-reported symptoms. In our representative population survey, the RICE study, 6.5% of U.S. women reported experiencing BPS/IC symptoms, 90.7% of whom were not diagnosed [2; 3]. BPS/IC can severely affect QoL, leading to decrements in mental and physical health functioning [4–9]. Because no cure exists, management of symptoms is critical for improving QoL.

Valid measurement of bladder symptom impact on QoL is necessary for routine screening of patients and examining effects of psychosocial and clinical treatment interventions on reduced disease burden. BPS/IC research has used general non-condition-specific QoL measures to examine relationships of symptoms to QoL, or tested differences in QoL among women with BPS/IC versus other conditions [4–9]. Due to a lack of BPS/IC condition-specific QoL scales, research has not comprehensively examined effects of symptom severity on decrements in QoL domains identified as important by individuals with BPS/IC. Studies of diagnosed women may miss a substantial number of those with symptoms, because women with BPS/IC symptoms may visit multiple healthcare providers, and many are not diagnosed [3; 10; 11].

We tested the reliability and validity of a brief BPS/IC-specific symptom impact scale in women with BPS/IC symptoms. We focused on QoL domains identified in prior BPS/IC research [5; 9]: emotional functioning, social functioning, and role responsibilities. In addition to internal consistency, we examined convergent validity using measures associated with QoL in prior chronic disease research (i.e., greater symptom severity, worse mental health and coping, lower perceived control in general and over symptoms, and worse general health-related QoL).

Methods

Participants

Data were drawn from RICE, in which 146,231 U.S. households were screened, of which 131,691 (90.1%) were eligible for further screening because they reported an adult female in the household [1; 2]. Those 32,474 households reporting a female aged 18 years or older with bladder symptoms or a BPS/IC diagnosis were asked to undergo a second-stage telephone screening for study eligibility; of these, 12,752 (39.3%) agreed to further screening, and 10,474 (82.1%) were successfully screened. Among those screened, 3,397 (32.4%) contained at least one female who met the following high-sensitivity RICE symptom criteria: (1) pain, pressure, or discomfort in pelvic area; (2) urinary frequency 10+ times/day or urgency due to pain, pressure, or discomfort (not fear of wetting); (3) pain that worsens as bladder fills; (4) no resolution of bladder symptoms after antibiotic treatment; and (5) never treated with hormone injections for endometriosis.

Exclusion criteria were based on prior research (i.e., the Interstitial Cystitis Database)[8]; specifically, participants were excluded if they were ever diagnosed with genital herpes, bladder cancer, diverticulum of the urethra, a spinal cord injury, stroke, Parkinson's disease, multiple sclerosis, spina bifida, tuberculosis affecting the bladder, or cancer of the uterus, ovaries, vagina, or urethra; ever had Cyclophosphamide (Cytosan) therapy, or radiation therapy to pelvic area; or were currently or possibly pregnant. The 3,397 eligible women completed a telephone interview.

We derived population weights from data from the first -screening to account for differences between responders and non-responders. We controlled for whether women had symptoms only, a diagnosis only, or both; and socio-demographic/household characteristics [3].

All procedures were approved by the RAND Human Subjects Protection Committee (#b4822-04-01). Participants gave informed consent.

Measures

RICE Bladder Symptom Impact Scale—To determine how to measure bladder symptom impact, we searched the medical literature for scales developed to assess impact of specific disease conditions on quality of life in different domains. We selected for adaptation

the 35-item Perceptions of Diabetes Mellitus Questionnaire(PDMQ) [12], which contains three domains (Psychosocial, Sexual-Relationship, Blood Sugar-Diet), two of which were relevant to BPS/IC (Psychosocial and Sexual-Relationship), and has high reliability, face validity, and initial support for construct validity [12]. It had previously been adapted to assess impact of other conditions, including lung disease and ostomy [13; 14]. For the RICE BSI-6, we eliminated the 8-item Blood-Sugar/Diet domain because it was not relevant to BPS/IC, and then selected 15 items based on our focus group work with women with BPS/IC, prior literature on QoL and BPS/IC [6; 7; 9], and face validity assessments of researchers and clinicians.

Participants rated each item using the stem: “Please rate the effect of your bladder symptoms on your...” from 1=*a very small negative or bad effect*, to 7=*a very large negative or bad effect*; 0 indicated *no effect*. We selected 6 items that were most highly correlated with the average of the 15-item scale (i.e., item-total correlations corrected for overlap) and that showed the greatest breadth of meaning and broad applicability to the population. We eliminated nine items: three items about employment outside of the home, intimate relationships, and childcare, which would have restricted the sample(“ability to be employed outside the home,” “ability to care for children or grandchildren,” “marriage or relationship”; four items that were endorsed at lower levels(by less than 40% of the sample; “ability to have enough money to live on,” “ability to get along with people and have friends,” “ability to care for yourself, such as bathing, dressing, and grooming,” and “need to rely on others”); and two items that were conceptually and statistically redundant ($r = .70$) with the selected items (“ability to take care of personal business such as attending school, banking, or shopping,”; “feelings about yourself as a woman”). The final items, which were averaged, included: “interest in life,” “energy level”, “moods,” “feelings of self-worth,” “social life,” and “ability to carry out your home responsibilities.” The lowest possible score was zero (all items rated as not having an effect), and the highest possible score was 42 (all items rated as having a very large negative/bad effect).

BPS/IC symptom severity—Participants completed the Interstitial Cystitis Symptom Index, which quantifies past-month urinary and pain symptoms (score range 0–20)[15]. Internal consistency exceeds .85, and test-retest reliability exceeds .90 [17].

Health-related QoL—Participants completed the SF-36, which assesses physical functioning, role functioning, bodily pain, general health, vitality, social functioning, and mental health [16]. It was scored on a standardized T-metric ($M=50$, $SD=10$) derived from the U.S. adult female population; scores were age-adjusted and ranged from 0 to 70, with higher scores indicating better functioning.

Depression—The PHQ-8 was used to assess depression symptoms [17]. PHQ-8 scores can range from 0 to 24, with higher scores indicative of greater depression symptoms. A score of 10 or greater corresponds with moderately severe depression and is indicative of probable depressive disorder. The scale has a sensitivity of 73% and a specificity of 98% for the diagnosis of major depression.

Coping—Using 3 items from the HIV Cost and Services Utilization Study [18], participants were asked, “In response to having BPS/IC, how often during the past four weeks have you done each of the following (e.g., “Tried to keep yourself from worrying about BPS/IC”)? A distancing coping scale was created by averaging responses ($\alpha=.72$; 1=*All of the time*, 2=*Most of the time*, 3= *A good bit of the time*, 4=*Some of the time*, 5=*A little of the time*, 6=*None of the time*); scores ranged from 0 to 6, with higher scores indicating greater use of distancing coping.

Perceived Control—We used the 7-item Personal Mastery for general perceived control (e.g., “I have little control over the things that happen to me”; *true/false*; $\alpha=.71$), which measures whether individuals feel that they can influence outcomes in life [19]; scores ranged from 0 to 1, with higher scores indicated greater perceived control. Perceived control over bladder symptoms was measured with 3 items adapted from prior research [20] (e.g., “To what extent do you believe you can exert control over your day-to-day symptoms”; *none, a little bit, somewhat, a lot*; $\alpha=.76$); scores ranged from 0 to 3, with higher scores indicating more perceived control.

Socio-demographic characteristics—We assessed age, race/ethnicity, income, education, and marital status. For missing income data, we used responses from the first screening. When that response was also missing ($n=372$), we imputed the mean. Indicators flagging observations of imputed variables were included with imputed income variables in analyses. Cases missing >1 non-income variable (1%) were excluded.

Statistical Analysis

We followed standard steps for scale development and validation [21]: We started by examining item-level characteristics (extent of missing data, frequency distribution, mean, standard deviation); evaluated the correlation of each item to the other items in the scale; computed item-scale correlations, correcting for overlap (i.e., using a the total scale score without the item in question); and finally after eliminating items based on the first two steps, examined scale distribution characteristics (mean, standard deviation, minimum and maximum values, range) and the reliability of the scale. To evaluate convergent validity, we examined bivariate and multivariate relationships of the RICE BSI-6 with measures associated with BPS/IC disease impact in prior research [6; 7; 9; 22; 23]: symptom severity; general health-related QoL; depression; coping. Across a variety of conditions [24], research suggests that individuals who experience greater disease impact have worse mental health outcomes; in addition, greater disease impact may also result from use of more maladaptive, passive “avoidance” coping strategies, in which individuals distance themselves from reminders of the disease, rather than problem solving about how to improve the situation [25]. Thus, we hypothesized that greater RICE BSI-6 scores would be associated with worse symptom severity, lower general health-related QoL, more depression symptoms, and greater use of distancing coping.

Prior BPS/IC research has not quantitatively assessed perceived control. However, our focus group work suggested that perceived control over BPS/IC symptoms is an important predictor of perceived symptom impact, and prior work indicates that health-related perceived control is associated with lower illness severity and better adjustment [20; 26–28], possibly because those with lower perceived control feel a greater sense of uncertainty about the course of their illness and feel less able to take steps to improve their condition. Thus, we also assessed perceived control over health in general, and specific to symptoms. We hypothesized that higher RICE BSI-6 scores would be related to greater health-related perceived control.

Multivariate models controlled for age, race/ethnicity, income, education, marital status. Scales and coefficients were standardized. Analyses accounted for design effects of weights using the linearization method in SAS v9.1 [29]. We assessed the underlying assumptions of our regression model. All residuals were approximately normally distributed and were not associated with predicted values; no serious departures from the model were apparent. While the RICE BSI-6 scores had a skewness of 1.01, regression is very robust to skewness for inferences about means (including regression coefficients) with sufficient sample sizes (here, 3,397), so there should be no appreciable effects on tests of regression coefficients [30].

Results

Three-quarters were White and 28% had a college degree; 30% had annual incomes < \$35,000 (Table 1). The mean age was 51.4 years (SD=14.7). Average BPS/IC symptom severity was rated at 10.7 (SE= 0.08, range = 1–20). Mean RICE BSI-6 scores were 1.7 (SD =2.1; range = 0–7), indicating relatively low mean impact of bladder symptoms on QoL, with a wide range across participants. Among women who reported experiencing any symptom impact across the items on the RICE BSI-6 (81%), mean scores were 2.1 (SE= 0.04). Internal reliability was high; all items were highly correlated with the overall scale ($\alpha=.92$; Table 2). In bivariate and multivariate models (Table 3), the RICE BSI-6 showed high convergent validity. It was significantly related to greater BPS/IC symptom severity; worse mental-and physical -health-related QoL; more severe depression symptoms; and worse perceived general and BPS/IC-specific control. Participants who used distancing coping were significantly less likely to report that BPS/IC had an impact. All variance inflation factors were less than 1.5, indicating that multicollinearity was not a significant issue in the multivariate models (Table 3).

Discussion

In our U.S. population-based representative sample of women with BPS/IC symptoms, the RICE BSI-6 showed excellent internal reliability and good face validity, and expert clinicians and researchers agreed that it captured domains important to this population. The RICE BSI-6 also showed excellent convergent validity, demonstrating strong correlations with BPS/IC symptom severity, general health-related QoL, depression, and perceived control. Although prior research suggests distancing coping is maladaptive [25], we found that distancing was associated with lower impact. Avoidance of perseveration about symptoms may be adaptive in conditions such as BPS/IC, for which no effective treatment exists; for conditions for which there is a known cure or palliative treatment, distancing may lead to inaction and/or non-adherence.

Most prior BPS/IC prior research has assessed symptom severity rather than symptom impact, partially because of the lack of a validated instrument specific to the condition. Our findings demonstrate the potentially powerful influence of symptoms on women's relationships and psychosocial adjustment, and provide a new validated tool to examine such effects. High symptom impact among women with BPS/IC may be indicative of worse response to treatment and poor coping with the disease, and thus is an important marker for clinicians and researchers to consider. Given its brevity, the RICE BSI-6 may be easily integrated into research tools to screen patients for disease impact, and in turn, determine whether further psychosocial intervention is needed to help patients cope with their condition.

Interestingly, average perceived symptom impact was low (1.71 on a 7-point scale), indicating a generally small negative impact of bladder symptoms on quality of life. This finding may be due in part to the diverse mixture of women included in the study, some of whom had current severe symptoms, and others who had symptoms defined as consistent with BPS/IC, but that were not at a level that they perceived as causing significant impact on their everyday life.

A key limitation of the study is the use of self-reported-symptoms, and not medical examination or laboratory tests, to determine the presence of BPS/IC. However, at the time of the data collection, no validated medical examination or laboratory existed to diagnose BPS/IC, and thus we used symptom reports, the accepted method for determining a BPS/IC diagnosis. Another limitation is the brevity of the scale, which did not allow us to use more

than one item to assess different aspects of BPS/IC impact (e.g., on social life or mood). We chose to construct a short scale to increase its feasibility of use for research contexts; however, a longer scale might be able to identify more specific aspects within each domain that are causing worse disease impact. Further, our analysis to determine convergent validity was limited, because the RICE BSI-6 scale conceptually overlapped with some of the predictor variables – a limitation that applies in general to this kind of approach to scale validation. However, we used multiple types of psychosocial predictor variables to indicate that the impact scale taps into different domains in a more efficient manner (i.e., using fewer items).

In sum, the RICE BSI-6 is a short instrument and easy to use and score, and thus presents minimal patient, provider, and participant burden. It can be used to evaluate the effects of randomized controlled trials of BPS/IC treatments on QoL. It can evaluate effects of randomized controlled trials of psychosocial counseling interventions aimed to improve QoL among women with BPS/IC. We encourage further evaluation in other patient groups with BPS/IC symptoms.

Acknowledgments

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Abbreviations

BPS/IC	Bladder Pain Syndrome/Interstitial Cystitis
RICE	RAND Interstitial Cystitis Epidemiology Study
RICE BSI-6	RICE Bladder Symptom Impact Scale (6-items)
PDMQ	Perceptions of Diabetes Mellitus Questionnaire
PHQ-8	Patient Health Questionnaire-8 items
QoL	Quality of Life

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Table 1

Socio-Demographic Characteristics of the Sample of 3,397 Women with BPS/IC Symptoms

	Weighted %
Socio-Demographic Characteristics	
Race/Ethnicity	
White	75
Latino	11
African American	10
Other	5
Education	
No College	36
Some College, but no 4-Year Degree	35
Received 4-Year College Degree	28
Annual Household Income	
<\$35,000	30
\$35,000–\$59,999	24
\$60,000	46
Married	58

Table 2

RICE Bladder Symptom Impact Scale (RICE BSI-6) Item Frequencies

RICE BSI-6	M (SE), Median, and Interquartile Range	Correlation with Total Scale (95% CI)	Percent Endorsing Zero	M (SE), Median, and Interquartile Range for Non-Zero Responses
Individual Items				
Interest in Life	1.23(0.04),0,1.38	0.81(0.80,0.82)	59.6%	3.04(0.06),2.05,3.11
Feelings of Self-Worth	1.49(0.04),0,2.13	0.79(0.78,0.81)	54.3%	3.27(0.06),2.42,3.31
Social Life	2.07(0.05),0.82,3.04	0.78(0.77,0.79)	37.0%	3.29(0.05),2.35,3.40
Ability to Carry out Your Home Responsibilities	1.40(0.04),0,1.95	0.72(0.71,0.74)	52.2%	2.93(0.05),2.08,2.76
Energy Level	2.12(0.05),0.92,3.19	0.77(0.75,0.78)	36.0%	3.32(0.05),2.51,3.29
Moods	1.94(0.05),0.76,2.76	0.76(0.74,0.77)	38.3%	3.14(0.05),2.22,3.09
Total Scale ($\alpha = .92$)	1.71(0.04),1.01,2.40	-----	19.3%	2.12(0.04),1.50,2.48

Note: Instructions for participants stated: "Sometimes medical conditions can make life difficult in a variety of ways and sometimes they don't make that much difference. Using any number from 1 to 7, where 1 is *having a very small negative or bad effect* and 7 is *having a very large negative or bad effect*, please rate each of the following in terms of how negatively, if at all, your bladder symptoms affect this part of your life. If there is *no effect*, rate it as zero." The stem for each item was: "Please rate the effect of your bladder symptoms on your..."

Table 3

Convergent Validity of the RICE Bladder Symptom Impact Scale (RICE BSI-6): Bivariate and Multivariate Coefficients of the Relationships between the RICE BSI-6 and Symptom Severity, Mental and Physical Health Functioning, Depression, Perceived Control, and Coping

	Unstandardized Weighted M (SE)	Bivariate b (95% CI)	Multivariate b (95% CI)
BPS/IC Symptom Severity	10.68(0.08)	0.76 (0.69,0.82) ***	0.69 (0.63,0.76) ***
Physical Health Functioning	40.94(0.25)	-0.76 (-0.82,-0.69) ***	-0.70 (-0.76,-0.63) ***
Mental Health Functioning	45.10(0.23)	-0.64 (-0.71,-0.56) ***	-0.59 (-0.66,-0.51) ***
Depression	7.64(0.13)	0.91 (0.83,0.98) ***	0.84 (0.77,0.92) ***
Perceived Control – General	0.73(0.01)	-0.81 (-0.89,-0.74) ***	-0.72 (-0.80,-0.64) ***
Perceived Control – Specific to BPS/IC	1.79(0.02)	-0.58 (-0.65,-0.51) ***	-0.49 (-0.56,-0.42) ***
Coping - Distancing	3.63(0.03)	-0.41 (-0.48,-0.34) ***	-0.38 (-0.44,-0.31) ***

p < .001

Note: Multivariate models controlled for age, race/ethnicity, education level, income, and marital status. Coefficients have been standardized.