Psychometric Properties of a QOL Measure for Painful-Irritable Bladder Syndromes

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Background:

The Painful-Irritable Bladder Syndromes Quality of Life (PIBSQOL) questionnaire was developed to measure additional syndromes of urinary incontinence (UI) involving pain. Existing under terms like "interstitial cystitis", "painful bladder syndrome", "female urethral syndrome", and "sensory urgency", these syndromes (which we are calling PIBS) involve more than just the involuntary loss of urine through either activity or with a strong urge to void. Conceptually, people suffering from PIBS can be distinguished from people suffering from UI; consequently, we set out to evaluate a measure constructed to assess impacts of quality of life for this specific population.

Objectives:

To develop an instrument to measure quality of life of people with Painful-Irritable Bladder Syndromes.

To test the psychometric properties of the PIBSQOL in a small field test of 60 patients with PIBS.

Methods:

The PIBSQOL was developed using the currently validated urinary incontinence-related quality of life measure (I-QOL) as a basis. The PIBSQOL measure consists of 25 items of which 17 overlap with the I-QOL and the remaining 8 items specifically relevant to PIBS symptoms. The qualitative development process for this measure ensured completeness, relevance, and understandability.

After encountering difficulties in recruitment, probably due to the fact that this condition is not yet widely recognized by the medical field, we enrolled 60 participants, from:
- 13 clinic referrals (from earlier focus group sessions)
- 12 responses from advertisements (newspaper & cards in clinics)
- 15 from local clinician referrals
- 20 from a urology clinic in Philadelphia

Participants needed to be over 18 years old and exhibit chronic bladder problems that never go away (frequency/urgency, suprapubic pain, strangury). They were not excluded if they had, in addition to PIBS symptoms, some level of incontinence. They were excluded if their condition was related to treatment for a terminal illness, spinal cord injury, or major neurological conditions.

At the baseline appointment, participants were given the PIBSQOL, the Medical Outcomes Trust Short Form 36-Item Health Status Survey (SF-36), and demographic questions including disease severity characteristics. All measures were self-administered. About a month after their baseline, participants were mailed a follow-up assessment including instructions and a self-addressed stamped envelope to return the completed PIBSQOL.

PIBSQOL Instrument:

1. I feel tired and fatigued because of my urinary problems.
2. I feel stressed because of my urinary problems.
3. I feel frustrated because people don't understand what I am going through.
4. I'm afraid of the pain returning or getting worse.
5. I worry about not being able to get to the toilet on time. (I)
6. I feel anxious and near panic because of my urinary problems.
7. I feel irritable or angry because of my urinary problems.
8. I feel I am a burden on others because of my urinary problems.
9. I worry my close or intimate relationships are affected by my urinary problems.
10. I worry about where toilets are in new places. (I)
11. I feel depressed because of my urinary problems. (I)
12. Because of my urinary problems, I don't feel free to leave my home for long periods of time. (I)
13. *I feel frustrated because my urinary problems prevent me from doing what I want. (I)*
14. My urinary problems are always on my mind. (I)
15. It's important for me to make frequent trips to the toilet. (I)
16. Because of my urinary problems, it's important to plan every detail in advance. (I)
17. I worry about my urinary problems getting worse as I grow older. (I)
18. I have a hard time getting a good night of sleep because of my urinary problems. (I)
19. I worry about being embarrassed or humiliated because of my urinary problems. (I)
20. My urinary problems make me feel like I'm not a healthy person. (I)
21. I get less enjoyment out of life because of my urinary problems. (I)
22. *I worry about wetting myself. (I)*
23. I feel like I have no control over my bladder. (I)
24. I have to watch what or how much I drink because of my urinary problems. (I)
25. *I worry about having sex because of urinary problems. (I)*

Response Options:
1 Extremely
2 Quite a bit
3 Moderately
4 A little
5 Not at all

Italicized items indicated those dropped from item reduction criteria.

Results:

Performance of PIBSQOL Items Against Item Reduction Criteria

The response distribution showed no missing data, no evidence of ceiling effect, and only one item (#22) had an item-to-total correlation lower than 0.40. Eight item-to-item correlations were higher than 70 percent.

Item 13: Redundancy with "I get less enjoyment out of life" (0.77). The qualitative data suggested a great deal of conceptual overlap in these two items.

Item 22: While this item is more representative of a UI symptom, it was originally included because many PIBS patients are in fact, also incontinent. It was dropped of the low item-to-total correlation (0.27), indicating insignificant association to the rest of the scale.

Item 25: Originally, it was thought that while these two items had some overlap, there was enough difference to justify including both. However, the qualitative data suggested that the concept of "having sex" was included under the umbrella of "intimate relationships". Additionally, this item demonstrated a high ceiling effect (25%).

Despite high correlations between the items "I feel stressed", "I feel irritable/angry", and "I feel depressed", we decided to retain all 3 items because they measure different inter-related concepts. In the cognitive debriefing report, participants stated these aspects were related (hence the high correlations) but were not the same.

Table 2: Internal Consistency and Test-Retest Reproducibility

	Number of Items in Scale	Cronbach's Alpha	Test-Retest Reliability
PIBSQOL Summary Score	22	0.92	0.86 (p<0.001)

[1] A mean of 32 (StDev=5) days was reported between time 1 and time 2 administrations. Pearson's correlations were used to test reproducibility.

Table 3: Convergent Validity of the PIBSQOL

	SF-36 Physical Component Summary	SF-36 Mental Component Summary	SF-36 Pain Interference	Self-Reported Severity
	Correlation (Significance)	Correlation (Significance)	Correlation (Significance)	Correlation (Significance)
PIBSQOL Summary	0.60*** (0.000)	0.56*** (0.000)	0.53*** (0.000)	-0.55*** (0.000)

*** Correlation is significant at the 0.001 level (2-tailed)

We hypothesized that the effect of the dominant *pain* aspect of PIBS would result in a stronger relationship between the PIBSQOL and the more somatic-based parts of the other measures (such as the SF-36 physical dimension) than the psychological aspects. While all correlations were fairly high, the strongest associations were between the PIBSQOL and the SF-36 physical component and mental component scores (0.60 and 0.56, respectively). The lowest correlation was with the amount of pain interference (0.53).

Table 4: Discriminant Validity of the PIBSQOL

Scale and Ranges	n	PIBS-QOL Mean (sd)
Severity:		
1. Mild	11	64.2 (17.2)
2. Moderate	32	53.4 (17.1)
3. Severe	17	34.2 (13.7)
F-statistics: 12.95***		
General Health:		
1. Excellent/Very Good	17	57.8 (15.8)
2. Good	28	53.4 (20.3)
3. Fair/Poor	15	36.6 (11.1)
F-statistics: 8.26***		
Number of Appointments:		
1. 0-2 Times	22	58.9 (16.6)
2. 3-6 Times	18	50.1 (20.5)
3. 7-40 Times	20	39.9 (16.3)
F-statistics: 5.95**		
SF-36 Bodily Pain:		
1. None/Very Mild/Mild	21	59.8 (17.8)
2. Moderate	24	51.7 (17.2)
3. Severe/Very Severe	15	33.1 (12.6)
F-statistics: 11.86***		
SF-36 Pain Interference:		
1. Not At All/Slightly	31	60.4 (16.9)
2. Moderately	16	41.7 (12.9)
3. Quite a Bit/Extremely	13	35.1 (16.7)
F-statistics: 14.43***		

*** Significant at the 0.001 level
** Significant at the 0.01 level

It was hypothesized that quality of life scores would decrease as severity and bodily pain increased, and that quality of life scores would go up as the patients' general health increased. As shown in Table 7, both of these relationships were demonstrated. In addition, quality of life also decreased as the number of medical appointments per year increased.

The F-statistics for all scales were significant, indicating that the PIBSQOL was able to discriminate between different levels of self-perceived of severity, different levels of general health, number of medical appointments, and levels of bodily pain and pain-related interference.

Table 1: Sample Characteristics

	N (%)
Age (years)	
- Mean (Std.Dev)	45.6 (10.9)
- Minimum	23
- Maximum	76
Ethnicity	
% White (non-Hispanic)	47 (78%)
% Black/African American	10 (17%)
% Asian/Pacific Islander	1 (2%)
% Other	2 (3%)
Marital Status	
% Married or living as married	34 (57%)
% Widowed	3 (5%)
% Separated	1 (2%)
% Divorced	12 (20%)
% Never Married	10 (17%)
Income (annual)	
% Under $25,000	17 (28%)
% $25,000 to $49,000	18 (30%)
% $50,000 and over	22 (37%)
% Missing	3 (5%)
Education	
% High School	6 (10%)
% College	37 (62%)
% Graduate and Professional School	17 (28%)
Number of Appointments (past year)	
Never	8 (13%)
1 – 3 times	22 (37%)
4 – 7 times	11 (18%)
8 – 11 times	9 (15%)
12 or more times	10 (17%)
Length of Time with PIBS	
Less than 1 year	4 (7%)
1 – 4 years	27 (45%)
5 – 10 years	14 (23%)
11 – 25 years	12 (20%)
26 or more years	3 (5%)
Severity	
- Mild	11 (18%)
- Moderate	32 (53%)
- Severe	17 (28%)

Conclusion:

The first analysis of the psychometric properties of the PIBSQOL demonstrated a low patient burden and relative ease of self-administration. It took patients an average of 3 minutes to complete and it is written at an approximate 5th grade reading level.

Reduction criteria results lead us to drop three items prior to performing the psychometric analysis, hence, a total of 22 items were retained. The items removed were: "I feel frustrated because my urinary problems prevent me from doing what I want", "I worry about wetting myself" and "I worry about having sex because of my urinary problems".

The evaluation of the PIBSQOL psychometric properties demonstrated good internal consistency (alpha =0.92) and reproducibility (ICC=0.83). As hypothesized, the PIBSQOL scores were more strongly related to physical well-being, and were able to discriminate between levels of disease severity, bodily pain, pain interference and patient general health. Given both the strength and significance of the relationships demonstrated, PIBSQOL scores appear to be valid against other instruments that measure related domains, and able to discriminate between known groups.