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The Validation of the Patient Perception of Bladder Condition (PPBC): A Single-Item Global Measure for Patients with Overactive Bladder

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Abstract

Objectives: The purpose of this study was to evaluate the validity and responsiveness of a global measure for overactive bladder (OAB), the Patient Perception of Bladder Condition (PPBC).

Methods: Post-hoc analyses were conducted on two 12-wk clinical trials for OAB (Study 1: $n = 865$; Study 2: $n = 520$). In addition to the PPBC, patients completed two condition-specific health-related quality of life (HRQL) measures, the Overactive Bladder Questionnaire (OAB-q) and King's Health Questionnaire (KHQ), and bladder diaries at baseline and 12 wk. Validity of the PPBC was evaluated through correlations with baseline diaries, OAB-q, and KHQ. The responsiveness of the PPBC was evaluated using correlations and general linear models to assess the degree of association between change in PPBC and change in the diaries, OAB-q, and KHQ.

Results: Both samples were primarily women and white with mean ages of 61.0 and 58.8 yr. The majority of patients were incontinent (75.3% and 80.4%) with the greatest proportion of patients indicating that they had "moderate problems" (47.5% and 51.2%) on the PPBC at baseline. Significant correlations were present at baseline and among change scores between the PPBC and the bladder diaries ($p < 0.001$), OAB-q ($p < 0.001$), and KHQ ($p < 0.01$). In both studies, patients with major PPBC improvement had significantly greater reductions in frequency, urgency episodes, incontinence episodes, and Symptom Bother and significantly greater improvements in HRQL than patients with only a minor PPBC improvement.

Conclusion: The PPBC, a global patient-reported measure of bladder condition, demonstrated good construct validity and responsiveness to change. These findings support the use of the PPBC as a global assessment of bladder condition among patients with OAB.

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1. Introduction

For symptom-based conditions that have no physiologic or biochemical markers, patient-reported outcome measures are important tools for evaluating the effects of disease and treatment [1]. Consequently, for symptom-based conditions such as migraine [2], erectile dysfunction [3], and overactive bladder (OAB), patient outcomes are of paramount importance. OAB is a complex of symptoms characterized by urinary urgency, with or without urge incontinence, usually with frequency and nocturia [4]. Given the range and multitude of symptoms that patients with OAB experience, the effects of OAB on health-related quality of life (HRQL) are varied and substantial [5,6]. OAB affects all facets of life from physical and social function to sexual function and sleep, work, and interpersonal relationships [7–9]. Given that the myriad of OAB symptoms have such a broad impact on HRQL, multi-item questionnaires that evaluate the impact of OAB and treatment outcomes are widely used (eg, OAB questionnaire (OAB-q; [10]), King's Health Questionnaire (KHQ; [11])). Although such multi-item questionnaires provide a rich source of information on numerous domains of the patient's life, such questionnaires may be difficult to score and interpret quickly, particularly in a clinical setting. As such, it can be useful to assess the patient's overall perceived bladder condition with a single, global question.

Single-item global questions are practical because of their brevity, ease of use, and interpretation [12]. The inherent assumption of single-item global measures is that the patient will consider all facets of a disease or treatment. Then, the patient's response will be based on consideration of all symptoms, not just one, in addition to possible treatment side effects, cost versus benefit, and other factors related to the disease or treatment. Typically, single-item, global measures are undervalued due to the lack of internal consistency reliability and carefully evaluated measurement properties; however, their simplicity in summarizing patient assessments of multifaceted concepts within a single outcome should not be underestimated.

Consequently, the Patient Perception of Bladder Condition measure (PPBC) was developed for patients with urinary problems as a global assessment of bladder condition and is recommended as a global outcome measure for urinary incontinence by the European Medicine Evaluation Association (EMA) [13]. The purpose of this study was to evaluate and validate the PPBC as a single-item global measure among two clinical trial samples of patients with OAB. Analyses were conducted to

examine the instrument's validity and responsiveness to change in clinical symptoms.

2. Methods

2.1. Data sources

Post-hoc analyses were conducted on data from two 12-wk clinical trials of tolterodine in patients with OAB, most of whom were incontinent. Study 1 ($n = 865$) was a multicenter, open-label trial of tolterodine in the United States [14]. Inclusion criteria were: age ≥ 18 yr, diagnosis of OAB with or without urgency incontinence, and the ability to complete a micturition diary. Study 2 ($n = 520$) was a 12-wk, randomized, double-blind, placebo-controlled trial of tolterodine in the United States and United Kingdom. Eligibility for Study 2 required patients to have urinary urgency and urinary frequency (defined as ≥ 8 micturitions/24 h), with or without urgency incontinence, and symptoms of OAB for at least 6 mo.

2.2. Instruments

The following measures were collected in the trials and used in this analysis.

2.2.1. PPBC

The PPBC is a single item that assesses the patients' subjective impression of their current urinary problems (Appendix A). Patients are asked to rate their perceived bladder condition on a 6-point scale ranging from 1 "no problems at all" to 6 "many severe problems" (Appendix A). To assess change in the PPBC from baseline to the end of the study, the baseline value was subtracted from the end of study value. Thus, score changes typically range from -2 to 2 , with negative values indicating patient improvement. The PPBC has demonstrated test-retest reliability among a small sample of patients with OAB [15].

2.2.2. OAB-q

The OAB-q is a 33-item, condition-specific measure designed to assess the impact of OAB symptoms on HRQL [10]. This instrument has been adopted by the International Consultation on Incontinence Questionnaire (ICIQ) committee as the questionnaire module for OAB (ICIQ-OAB). The OAB-q consists of a Symptom Bother scale and four HRQL subscales (Coping, Concern, Sleep, and Social Interaction). All scale scores are transformed to a 0- to 100-point scale with higher Symptom Bother scores indicating greater symptom severity and lower HRQL subscale scores indicating greater impact. The OAB-q has been validated in multiple clinical and community samples in over 2500 patients and has performed well among patients with a range of mild to severe OAB symptoms. Among both continent and incontinent patients with OAB, the OAB-q has demonstrated internal consistency reliability, test-retest reliability, construct validity, and responsiveness [10,15,16].

2.2.3. KHQ

The KHQ is a 21-item HRQL questionnaire that was originally developed and validated among women with urinary incontinence [17]. This instrument has been adopted by the ICIQ as

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