Psychometric Performance of the Incontinence Quality-of-Life Questionnaire Among Patients With Overactive Bladder and Urinary Incontinence

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ABSTRACT

Background: The Incontinence Quality-of-Life Instrument (I-QOL) is a condition-specific questionnaire that assesses the health-related QOL impact of urinary incontinence, but it has not been validated in patients with overactive bladder (OAB) who have been inadequately managed by anticholinergic therapy.

Objective: This study assessed the reliability and validity of the I-QOL among patients with OAB with urinary incontinence.

Methods: I-QOL scores were analyzed from a Phase II study that compared the efficacy and tolerability of onabotulinumtoxinA and placebo. Conceptual framework was confirmed via confirmatory factor analysis. Reliability was assessed using Cronbach's alpha and intraclass correlation coefficients (ICCs). Validity was tested by comparing I-QOL scores to tertiles of urinary symptom severity. Effect size statistics estimated the ability of the I-QOL to detect change. Responder analysis with cumulative distribution function was plotted to show differentiation between treatment groups with respect to I-QOL scores.

Results: Comparative fit indices ranged from 0.87 to 0.99 on the confirmatory factor analysis. I-QOL scores showed high internal consistency ($0.86 \leq$ Cronbach's $\alpha \leq 0.93$), good test–retest reliability ($0.68 \leq ICC \leq 0.84$), and good differentiation between tertiles of increasing urinary symptom severity (all, $P \leq 0.002$). Significant differences in I-QOL change scores were noted between responders and nonresponders across all responder definitions (all, $P < 0.001$) and corresponded with large effect sizes among responders to treatment ($1.34 \leq$ effect size ≤ 2.82).

Conclusion: This study demonstrated that OAB with urinary incontinence affects health-related QOL and that the I-QOL reliably and validly measures these impacts. (*Clin Ther*. 2013;35:836–845)

Key words: I-QOL, onabotulinumtoxinA, overactive bladder, psychometrics, quality of life, urinary incontinence.

INTRODUCTION

Overactive bladder (OAB) is a syndrome characterized by the presence of symptoms that include urgency, with or without incontinence, which is often accompanied by frequency and nocturia.[1] A large body of evidence has shown that OAB has a tremendous personal and societal impact.[2] However, this impact is not well captured by more proximal measures of bladder function such as laboratory tests, urodynamic tests, and other clinical measures.[3–7] Increased awareness of the importance of patient-reported outcomes (PROs) including symptoms, functional status, treatment satisfaction, and health-related quality of life (HRQOL) has made way for the inclusion of such measures to monitor the course of OAB and its treatment.

Many PROs have been developed to assess symptom severity or bother and HRQOL in patients with urinary incontinence, and, more recently, many have been focused on OAB.[8] The Incontinence-Specific

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QOL Instrument (I-QOL) was initially developed as a condition-specific QOL measure to reflect the impact of urinary incontinence on a patient's activities of daily living, in the patient's language, and that could be used in epidemiologic investigations, clinical trials, and program evaluations.[9,10] Patients with stress, urge, and mixed incontinence were included in the original studies of the I-QOL, and those with OAB were included in subsequent studies. Since its inception in 1993, the I-QOL has demonstrated sound measurement properties among patients with urinary incontinence and has been modified to make it relevant to those who have symptoms consistent with OAB.[11–18] The I-QOL has been tested in the general OAB population and in populations with more heterogeneous causes and severity of incontinence; however, its measurement properties have not been fully elucidated among a more homogeneous cohort of patients with more severe symptoms, namely, those with urgency urinary incontinence who have failed initial therapies.

A PRO documents the symptoms and/or impact of a condition from a patient's perspective. In medical product development, a PRO must have demonstrated evidence of usefulness to the target population of patients (ie, persons with OAB and incontinence). An existing PRO can support a labeling claim with regulatory agencies only if it can be shown to reliably and validly measure the claimed concept in the patient population enrolled in a clinical study. Reports of an instrument's reliability and validity ensures that it is relevant to the patient and that it accurately captures the impact of the disease so that its use may be applied both in medical product development and in the clinical setting.[19] Given the wide array of instruments available for use among patients with a variety of urologic symptoms, it is important to demonstrate that the instrument in question is appropriate for use in the intended population. In doing so, clinicians will be better able to interpret the resulting scores and compare them across different groups of patients to better understand disease impact. The purpose of this research was to further assess measurement properties among a subset of patients with OAB using Phase II clinical trial data, specifically, data from patients with OAB and incontinence whose symptoms have not been adequately managed with anticholinergic therapy.

PATIENTS AND METHODS

Sample

Data were obtained from patients who participated in a 36-week, Phase II, dose-ranging, randomized, placebo-controlled, parallel-group study that evaluated the efficacy and tolerability of a single treatment of each of 5 doses of injectable onabotulinumtoxinA compared with inactive vehicle (placebo) in patients with OAB with urinary incontinence (NCT00168454). Male and female patients aged 18 to 85 years with symptoms of OAB and urinary incontinence for ≥6 months that were *not adequately managed with anticholinergic therapy* (defined as an inadequate response or intolerable adverse events after ≥1 month of anticholinergic therapy at an optimized dose) were included in the study following provision of informed consent. At baseline, patients were required to have ≥8 urgency urinary incontinence episodes per week and ≥1 per day, as reported on a 7-day bladder diary. Additional study details have been previously published.[20] The trial was conducted in full accordance with the principles of the Declaration of Helsinki.

Measures

The primary efficacy end point of the clinical trial was the change from baseline in the weekly number of urgency urinary incontinence episodes at week 12 after treatment. Several patient-completed measures were included in the study to assess the impact of treatment on patient-reported health outcomes.

The I-QOL is a questionnaire that assesses the impact of urinary incontinence on HRQOL. It consists of 22 items divided into 3 domains: an 8-item domain capturing physical impact (Avoidance and Limiting Behavior domain), a 9-item domain capturing psychological impact (Psychosocial Impacts domain), and a 5-item domain capturing social impact (Social Embarrassment domain). Scores are calculated for each domain, and a total summary score is calculated from all 22 items. Scores range from 0 to 100, with a higher score indicating a preferable health status (ie, absence of urinary incontinence impact). The symptom component of the King's Health Questionnaire (KHQ) was administered to assess the degree to which patients were bothered by their urinary symptoms. On the KHQ, symptom scores range from 0 to 100, with higher scores indicating greater symptom impact.[21] A 7-day bladder diary was used by patients to record daily urinary symptoms, including daily