

VALIDATION OF THE PERCEPTION OF BLADDER CONDITION MEASURE IN OVERACTIVE BLADDER

Aims of Study

Overactive bladder (OAB) is characterized by bothersome symptoms of urinary frequency and urgency that occur with or without urge incontinence and has been shown to have significant impact on health-related quality of life (HRQL). As such, the evaluation of treatment effectiveness should be based upon patient perception. Thus, the purpose of this study was to examine the validity and responsiveness of a patient-report measure, the Perception of Bladder Condition (PBC), which assesses global perceptions of symptoms among patients with OAB.

Methods

OAB patients were treated with Tolterodine Extended Release LA 4 mg/day for 12 weeks. Patient evaluations were conducted at baseline, 4 and 12 weeks. Patients' rated their subjective perceptions of their current urinary problems on the single-item PBC, a 6-point scale ranging from "no problems at all" to "many severe problems." To assess treatment effect, two categorical change variables were derived from the single item scale: 1) a 2-level improvement variable (improvement [negative difference of scores] or no improvement [difference of scores is 0 or more]); 2) a 4-level magnitude of improvement variable (Major Improvement [difference in scores is negative by > 2 response options], Minor Improvement [difference in scores is negative 1], No Change [difference in scores is 0], and Deterioration [difference in scores is positive]).

Three day micturition diaries were collected with patients reporting their frequency of urgency episodes, micturitions, and incontinence episodes. HRQL was assessed with the Overactive Bladder Questionnaire (OAB-q) which includes an 8-item symptom bother scale as well as 25 HRQL items that form 4 subscales (coping, concern, sleep, social interaction) and a total HRQL score. Patient and physician assessments of treatment benefit were obtained at 4 and 12 weeks. Change scores for the PBC, OAB-q and micturition diaries were calculated for the 4 and 12 week visits. Validity and responsiveness of the PBC were evaluated by comparing the PBC scores with the other measures of treatment efficacy using t-tests, ANOVAs, and chi-square tests.

Results

A total of 865 patients completed the 12-week study. The mean age was 61 years, and the participants were 73% female and 89% Caucasian.

Urgency Episodes, Micturition Frequency, and Incontinence Episodes: Compared with patients who did not report improvement on the PBC, patients who improved demonstrated significantly greater improvement from baseline to week 12 among all micturition variables (Table 1). Additionally, patients reporting major improvement on the PBC consistently reported significantly greater improvements in urgency episodes, micturition frequency, and incontinence episodes compared to patients reporting minor improvement ($p < 0.05$).

Table 1. Baseline to 12 Week Clinical Variables by Change in Perception of Bladder Condition: Improvement/No Improvement

Change in Clinical Variables Mean (SD)	Change in PBC from Baseline to 12 Week				
	Improvement N=616		No Improvement n=231		p
Δ Urgency Episodes Per 24 Hours	-3.4	(3.6)	-2.6	(4.0)	
Δ Micturitions Per 24 Hours	-4.4	(4.2)	-2.6	(3.9)	0.0001
Δ Incontinence Episodes Per 24 Hours	-1.6	(3.0)	-0.9	(2.8)	0.002

HRQL: Higher severity PBC responses were significantly associated with greater symptom bother and lower HRQL as reported on the OAB-q at each assessment period ($p < 0.05$). Compared with patients who did not report improvement on the PBC, patients who improved demonstrated significantly greater improvement from baseline to week 12 on all OAB-q scales (Table 2). As with the micturition variables, patients reporting major improvement on the PBC also demonstrated significantly greater improvement on all OAB-q scales compared to patients reporting minor improvement ($p < 0.05$).

Table 2. Baseline to 12 Week OAB-q Change Scores by Change in Perception of Bladder Condition: Improvement/No Improvement

OAB-q Subscales Mean (SD)	Change in PBC at Week 12				P
	Improvement n=620		No Improvement n=235		
Δ Symptom Bother	-29.4	(19.1)	-11.7	(20.8)	0.0001
Δ Coping	28.4	(25.0)	12.0	(22.6)	0.0001
Δ Concern	30.6	(25.7)	13.5	(21.9)	0.0001
Δ Sleep	31.2	(29.0)	12.9	(26.0)	0.0001
Δ Social Interaction	11.9	(20.0)	4.7	(16.1)	0.0001
Δ Total HRQL Score	26.0	(20.5)	11.0	(17.5)	0.0001

Physician and Patient Assessment of Treatment Benefit. Chi-square analyses showed that physicians' and patients' perceived treatment benefits at 12 weeks corresponded to improvements in PBC scores from baseline to 12 weeks ($p < 0.0001$).

Conclusions

The Perception of Bladder Condition demonstrated good construct validity and responsiveness to reductions in urgency, as well as micturition frequency and incontinence, following antimuscarinic therapy for Overactive Bladder. Based on these results, the PBC appears to be a useful tool for evaluating patients' global impressions of bladder condition in clinical trials of OAB treatments.