

VALIDATION OF THE PERCEPTION OF BLADDER CONDITION MEASURE IN OVERACTIVE BLADDER

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OBJECTIVE

Overactive bladder (OAB) is characterized by bothersome symptoms of urinary frequency and urgency that occur with or without incontinence.¹ Both continent and incontinent OAB have been shown to have significant impact on health-related quality of life (HRQL), which includes subjective perceptions of social functioning, daily activities, and well-being. Therefore, the evaluation of treatment for OAB should be based upon patient perception. 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

PARTICIPANTS

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.

MEASURES

Perception of Bladder Condition Measure (PBC): Patients rated their subjective perceptions of their current urinary problems on the single-item PBC. The item is as follows:

My bladder condition (please check one):

- Does not cause me any problems at all
- Causes me some very minor problems
- Causes me some minor problems
- Causes me (some) moderate problems
- Causes me severe problems
- Causes me many severe problems

Three-day Micturition Diaries: Patients reported frequencies of three clinical variables, and change scores were calculated from baseline to 12 weeks.

- Urgency episodes
- Micturitions
- Incontinence episodes

Overactive Bladder Questionnaire (OAB-q): This instrument assesses health-related quality of life (HRQL) among patients with OAB. The OAB-q 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. Higher symptom scores are indicative of increasing symptom bother, and higher HRQL scores are indicative of better HRQL.²

Physician and Patient Assessments of Treatment Benefit: Physicians and patients reported on whether there was a treatment benefit, using a three point scale with the following response options:

- Yes, very much
- Yes, a little
- No

DATA ANALYSIS

To assess treatment effect with the PBC, two categorical change variables were derived from the single item scale. First, a 2-level improvement variable was computed: Improvement (negative difference of scores), No Improvement (difference of scores is 0 or more). Second, a 4-level magnitude of improvement variable was computed: Major Improvement (difference in scores is negative in magnitude of 2 or more), Minor Improvement (difference in scores is negative in magnitude of 1), No Change (difference in scores is 0), and Deterioration (difference in scores is positive). Change scores for the OAB-q and micturition diaries were calculated from baseline to week 12. Validity and responsiveness of the PBC were evaluated by comparing the PBC scores with the other measures of treatment efficacy using t-tests, ANOVAs with Student-Newman-Keuls post hoc pairwise comparisons, and chi-square tests.

RESULTS

A total of 865 patients completed the 12-week study. Demographic and baseline characteristics are presented in Table 1.

Table 1. Demographics and Baseline Clinical Characteristics

Characteristic	Study Completers (N=865)	P
Age (mean years)	61.0	0.77
Gender (% female)	73.5	0.80
Race (%)		
White	89.2	
Black	8.3	0.92
Other	2.1	
Not Reported	0.3	
Symptom History (%)		
< 6 Months	5.7	
6 Months – 5 Years	64.1	0.89
> 5 Years	30.3	
Mean Micturitions per 24 Hours (Mean, SD)	13.3 (5.1)	0.59
Mean Incontinence Episodes per 24 Hours (Mean, SD)	2.5 (3.5)	0.82
Mean Urgency Episodes per 24 Hours (Mean, SD)	5.0 (4.2)	0.55

Table 2. OAB-q Scores by Perception of Bladder Condition: Baseline

OAB-q Subscales Mean	Perception of Bladder Condition					Many Severe n=58
	No Problems n=4	Very Minor n=37	Minor n=123	Moderate n=410	Severe n=231	
Symptom Bother	53.1 ^a	37.3 ^a	43.1 ^{a*}	51.1 ^b	65.0 ^c	77.9 ^d
Coping	60.7 ^a	82.8 ^a	77.8 ^{a*}	62.3 ^b	45.7 ^{b*}	31.8 ^b
Concern	59.3 ^a	79.6 ^a	74.9 ^{a*}	61.9 ^b	42.5 ^{b*}	26.8 ^b
Sleep	64.0 ^a	63.4 ^a	58.9 ^{a*}	48.9 ^b	41.7 ^{b*}	25.5 ^b
Social Interaction	96.5 ^a	93.6 ^a	95.6 ^{a*}	87.2 ^b	75.0 ^{b*}	35.2 ^b
Total HRQL Score	68.1 ^a	80.3 ^a	77.3 ^{a*}	64.7 ^b	50.4 ^{b*}	24.0 ^b

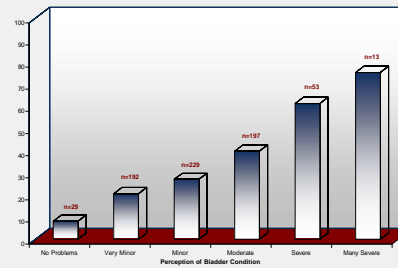
- Superscript letters within each row indicate significant differences among means at a level of at least $p < 0.05$.
- Higher severity PBC responses were significantly associated with greater symptom bother and lower HRQL as reported on the OAB-q at baseline; similar results were found at weeks 4 and 12.
- Findings for the No Problems group at baseline should not be interpreted because of the small group size (n = 4).

Table 3. Baseline to 12 Week OAB-q Change Scores by Change in Perception of Bladder Condition: Improvement/No Improvement

OAB-q Subscales Mean	Change in PBC at Week 12		P
	Improvement n=620	No Improvement n=235	
Δ Symptom Bother	-29.4	-11.7	0.0001
Δ Coping	28.4	12.0	0.0001
Δ Concern	30.6	13.5	0.0001
Δ Sleep	31.2	12.9	0.0001
Δ Social Interaction	11.9	4.7	0.0001
Δ Total HRQL Score	26.0	11.0	0.0001

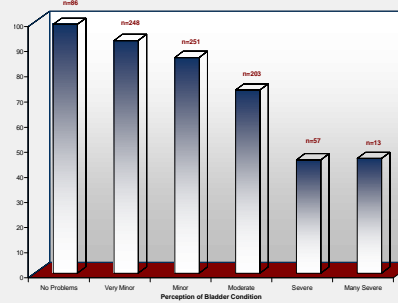
- Compared with patients who did not report improvement on the PBC, patients who improved demonstrated significantly greater improvement from baseline to week 12 on all OAB-q scales.
- Patients reporting major improvement on the PBC also demonstrated significantly greater improvement on all OAB-q scales compared to patients reporting minor improvement ($p < 0.05$; not shown in table).

Figure 1. OAB-q Symptom Bother Subscale by Perception of Bladder Condition at Week 12



- Higher Symptom Bother scores are indicative of more problematic symptoms.
- More problematic PBC ratings were consistently associated with statistically significantly greater Symptom Bother scores.

Figure 2. OAB-q Coping Subscale by Perception of Bladder Condition at Week 12



- Higher scores on this OAB-q subscale are indicative of better coping with the symptoms of OAB.
- In general, more problematic PBC ratings were associated with decreased coping scores.

Table 4. Baseline to 12 Week Change in Clinical Variables by Change in Perception of Bladder Condition

Clinical Variables Mean	Change in PBC at Week 12		p
	Improvement n=616	No Improvement n=231	
Δ Urgency Episodes per 24 Hours	-3.4	-2.6	0.005
% Change from Baseline	-67.5	-43.8	0.0003
Δ Micturitions per 24 Hours	-4.4	-2.6	0.0001
% Change from Baseline	-30.6	-16.8	0.0001
Δ Incontinence Episodes per 24 Hours	-1.6	-0.9	0.002
% Change from Baseline	-61.3	-37.7	0.01

- Compared with patients who did not report improvement on the PBC, patients who improved demonstrated significantly greater improvement and percentage improvement from baseline to week 12 on all micturition variables.
- 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 ($p < 0.05$; not shown in table).

Table 5. Physicians Perceptions of Treatment Benefit at Week 12 by Change in Perception of Bladder Condition

Physician Perceptions (n %)	Change in PBC at Week 12	
	Improvement n=616	No Improvement n=231
Yes, Very Much Treatment Benefit	411 (66.0%)	63 (26.6%)
Yes, a Little Treatment Benefit	191 (30.7%)	120 (50.6%)
No Treatment Benefit	21 (3.4%)	54 (22.8%)

- Chi-square analyses showed that physicians' perceptions of treatment benefits at 12 weeks corresponded to improvements in PBC scores from baseline to 12 weeks ($p < 0.0001$).
- Results for patients' perceptions of treatment benefits followed similar patterns.

CONCLUSIONS

- The Perception of Bladder Condition measure demonstrated construct validity and responsiveness to reductions in urgency, as well as micturition frequency and incontinence, following antimuscarinic therapy for Overactive Bladder.
- The Perception of Bladder Condition measure was also associated with patient-reported HRQL and physician-reported treatment benefits.
- The PBC appears to be a useful tool for evaluating patients' global impressions of bladder condition in clinical trials of OAB treatments.

REFERENCES

1. Abrams P, Wein AJ. The overactive bladder and incontinence. *NeuroUrol Urodyn* 1999;18:413-416.
2. Coyne KS, Revicki DA, Hunt TL, Corey R, Stewart WF, Bentkover J, Kurth H, Abrams P. Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: the OAB-q. *Quality of Life Research* 2002 (*in press*).