407 Pleil A¹, Coyne K² 1. Pfizer Inc, 2. MEDTAP International

VALIDATION OF THE UK VERSION OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q) IN CONTINENT AND INCONTINENT PATIENTS WITH OVERACTIVE BLADDER (OAB)

Hypothesis / aims of study

The Overactive Bladder Questionnaire (OAB-q) has been well validated in English-speaking patients with overactive bladder (OAB) in the United States [1]; however, the reliability and validity of the OAB-q in English-speaking patients who reside in the United Kingdom is not known. The aim of this study was to evaluate the reliability and validity of the OAB-q in a cohort of English-speaking UK residents with OAB.

Study design, materials and methods

The OAB-q is a 33-item, disease-specific, symptom bother and health-related quality of life (HRQL) measure for patients with OAB. It consists of an 8-item Symptom Bother scale, 4 HRQL subscales (ie, coping, concern, sleep, social interaction), and a composite score. Higher scores on the Symptom Bother scale indicate increasing symptom bother; higher scores on the HRQL scales indicate better HRQL. Validity of the measure was evaluated using data from a 12-week, randomized, international, multicenter, placebo-controlled study of tolterodine tartrate extended release (ER) capsules (4 mg once daily) in 190 patients with OAB. Patients were recruited from the United Kingdom and the United States. To examine internal consistency reliability, Cronbach's alphas were calculated and Feldt's statistic was used to compare the US and UK alphas. Pearson's correlations of the OAB-q with micturition diaries and 2 global measures (perception of bladder condition and urgency perception scale) were calculated using baseline data without respect to group. Comparisons of UK and US responses were performed using *t*-tests.

Results

There were 190 UK and 400 US patients enrolled. Patient characteristics were similar for each country: mean age=60 years, 73% female for UK patients, and mean age=58 years, 76% female for US patients. Cronbach's alpha for the OAB-q symptom bother and 4 HRQL subscales ranged from 0.82 to 0.91 for the United Kingdom and 0.85 to 0.92 for the United States; no differences were present in internal consistency by country. Correlations were significant between the OAB-q subscales and patients' perception of bladder condition (0.28 to 0.57, P<0.0001). Similar results were seen for the correlations between the subscales and perception of urgency (0.22 to 0.37; P values <0.05), with the exception of the OAB-g sleep domain (0.12, P=0.11). All components of the OAB-q were significantly correlated with the number of micturitions/24 h, the number of urgency episodes/24 h, and the number of incontinence episodes/wk (0.16 to 0.40; P values <0.05), with the exception of the correlation of the sleep subscale and incontinence episodes (0.055, P=0.45). US patients reported significantly greater symptom bother (51.7 vs 44.1, P<0.0001) and concern (55.6 vs 62.9, P<0.001) than did UK patients. For UK patients, the OAB-q discriminated between continent and incontinent patients in all subscales except sleep in which the HRQL impact was similar for both continent and incontinent patients (P values ≥ 0.05). For US patients, there were no differences in the social interaction subscale by continent and incontinent patients. In terms of response to treatment, the effect sizes were similar for both UK and US patients ranging from 0.43 (social interaction) to -1.10 (symptom bother).

Interpretation of results

In general, the results support the reliability and validity of the OAB-q in UK residents with OAB. Internal consistency estimates exceeded the threshold criterion of 0.70 across all components of the measure. Correlations with clinical symptoms supported the criterion validity of the measure. The OAB-q showed strong discriminatory power between continent and incontinent OAB, and was highly responsive to treatment.

<u>Concluding message</u> The OAB-q was shown to be a reliable and valid tool to assess HRQL in UK patients with OAB symptoms. The measure has demonstrated validity for use in both the continent and incontinent OAB populations. These results confirm the linguistic and cultural validity of the UK-English language version of the measure.

Reference

1. Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: the OAB-q. Qual Life Res. Sep 2002;11:563-574.

FUNDING: Pfizer Inc