

## **MEASURING PATIENT OUTCOMES IN OAB: THE OAB-Q, OAB-Q SF, OAB SCREENER AND ICIQ-OAB**

### **Hypothesis / aims of study**

Overactive bladder (OAB) is a symptom-based condition characterized by symptoms of urinary urgency, with or without urge incontinence, increased urinary frequency and nocturia (1). It is estimated that 10 to 20% of the population may have OAB (2). Therefore, a reliable and well-validated measure is needed to assess and track treatment outcomes. The OAB-q, which was derived from patient focus groups, is a symptom bother and health-related quality of life (HRQL) questionnaire (2). The OAB-q has been validated in over 2500 patients with good discrimination among patient subgroups and demonstrated responsiveness to treatment. However, the length of the OAB-q (33 items) may be burdensome to some patients, thus initiating a need for the development of a short form version. Additionally, many patients are not aware that OAB is a treatable condition and are not seeking care, revealing a need for a screening tool. The aim of this study is to review the development of the OAB-q and OAB-q short form (OAB-q SF) as well as the creation of the OAB screener.

### **Study design, materials and methods**

The original OAB-q was developed from patient focus groups, clinician input and a review of the literature. It has performed extremely well in both population survey research as well as clinical research. The OAB-q consists of an 8-item symptom bother scale and 25 HRQL items that form four subscales (coping, concern, sleep, social interaction).

For the development of an OAB-q SF and an OAB screener, retrospective analyses were performed on three different OAB patient samples: 1) two cross-sectional patient surveys (n=254 and 919); and 2) a 12-week clinical trial (n=865).

When developing the OAB screener, 4 draft screeners were created from the 33 OAB-q items. One screener was conceptually based (the Symptom Bother scale as a stand-alone screener), two were determined from Rasch analysis as differentiating normal from OAB, and the last was derived from recursive partitioning analysis differentiating normal from OAB patients.

For the OAB-q SF, Rasch analysis was used to identify the most discriminating items with the OAB-q so that non-discriminating or repetitive items could be recommended for deletion. Once potential screener subscales and OAB-q SF items were identified, the following analyses were performed on all newly formed item subsets: item discrimination between "normal" and "OAB", Cronbach's alphas to assess the internal consistency of each subscale, t-tests and ANOVAs. Logistic regressions were used to examine the discriminative ability of the screener in determining "normal" versus "OAB" in the patient survey datasets. Effect sizes and change scores were calculated for the OAB-q SF in the clinical trial dataset to assess responsiveness.

### **Results**

A series of iterative analyses were performed for both the screener and OAB-q SF. From the retrospective analyses, two potential screeners, the 8-item Symptom Bother scale and the 6-item recursive partitioning scale items, produced promising results and were moved forward to prospective validation. The 8-item screener performed well with little missing data (0.2%–0.6%) and high inter-item and item-to-total correlations ( $r = 0.42–0.86$ ;  $p$  values  $< 0.001$ ). The logistic regression models controlled for age and gender and the dependent variable was OAB diagnosis comparing No OAB versus Probable OAB. The c-index of this model was 0.96 with good model fit and a sensitivity and specificity of 98.0 and 82.7, respectively. For screener scores  $> 8$  (range, 0–48), the odds ratio for having Probable OAB was 95.7 (95% CI: 29.3–312.0).

For the OAB-q SF, the Symptom Bother scale was reduced to 6 items and the HRQL items were reduced to 13 items. When performing factor analysis on the 13 HRQL items, 3 subscales were formed: coping (5 items), sleep (3 items), and emotional/social (5 items). The OAB-q SF subscales were internally consistent with alphas ranging from 0.82 to 0.92 and effect sizes ranging from were 0.81 to 1.14. These ranges were comparable with the original OAB-q questionnaire version.

### **Interpretation of results**

The OAB-q SF and OAB Screener, based on the OAB-q, are both reliable, valid and pertinent tools providing patient outcome assessments and screening for OAB. Utilizing retrospective data analysis is a cost-effective and time-saving way to examine potential uses of existing patient reported outcome measures, providing that the patients in the database are consistent with the target patient population and the goal of the new measure is conceptually consistent with the initial instrument.

### **Concluding message**

For symptom-based conditions such as OAB, patient reported outcomes are the optimal treatment outcomes and relevant to disease screener development. To conserve resources and time, it is useful to adapt disease-specific questionnaires to meet current needs as long as conceptual congruency and patient consistency is present.

The modular International Consultation on Incontinence Questionnaire (ICIQ) is currently being developed to produce a comprehensive and universally-applicable questionnaire for the assessment of a variety of pelvic symptoms, including those of the lower urinary tract, lower bowel and vagina, in clinical practice and research. Under the aegis of the ICI, a new module to assess both the symptoms and impact on QoL of OAB, the ICIQ-OAB, is being developed and evaluated. The OAB-q SF will be incorporated into the ICIQ-OAB module to assess the impact of this condition on patients' lives.

### **References**

1. 2002. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Am J Obstet Gynecol 187(1):116-126.
2. 2002. Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: the OAB-q. Qual Life Res 11(6):563-574.

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