Assessing the Content Validity of the Overactive Bladder Questionnaire (OAB-q) in Vulnerable Elderly Adults With OAB

1 Introduction

• The Overactive Bladder Questionnaire (OAB-q) is a 25-item patient-reported outcome (PRO) instrument that assesses symptom bother (8 items) and health-related quality of life (HRQL; 17 items) of the OAB. The HRQL scale has 4 domains: Coping, Concerns, Sleep, and Social Interaction.

• The OAB-q has demonstrated psychometric validity and responsiveness in treatment with individuals with OAB, but data collection primarily involves individuals aged 40–70 years.

• Evidence from qualitative research is required to demonstrate that a PRO instrument measures the intended concept in the target population on which it will be used (i.e., content validity).

2 Objective

• To assess the content validity of the OAB-q in vulnerable elderly patients with OAB

3 Methods

Study Design

• In this qualitative research study, vulnerable elderly adults with clinically diagnosed OAB, including UUI, were recruited from a clinical site in which the investigators were blinded written informed consent and completed the OAB-q.

• After participants completed the OAB-q, they took part in one-on-one semistructured interviews, based on a standardized interview guide to provide feedback on the OAB-q. These interviews took place in the participants’ home and took approximately 60 to 90 minutes to complete. All interviews were audio-recorded and transcribed with participant approval.

• The study protocol was approved by an Institutional Review Board.

Participants

• Inclusion Criteria

  • Male or female participants aged 65 years or older
  • An OAB diagnosis with evidence of urodynamic stress incontinence (UUI) or detrusor overactivity (DO)
  • Living in the U.S.

• Exclusion Criteria

  • Cancer of the lower urinary tract
  • Current urinary tract infection (UTI) or history of previous UTI
  • Significant comorbidities

• Assessments and Statistical Analyses

  • Participants completed a bladder diary on 3 consecutive days prior to the scheduled interview visit.

  • At the study visit: 1) the interviewee fully explained the study to the participant and obtained written informed consent; 2) the participant completed the OAB-q; 3) the one-on-one cognitive interview was conducted on the OAB-q; 4) the Mini Mental Status Examination (MMSE) was administered to the participant; and 5) the participant completed a brief sociodemographic questionnaire.

4 Results

Participant Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD) or n (%), N=20</th>
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<tbody>
<tr>
<td>Age, mean (y)</td>
<td>79 (10)</td>
</tr>
<tr>
<td>Gender, n (% male)</td>
<td>12 (60)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>White: 19 (95)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Living situation, n (%)</td>
<td>Alone: 8 (40)</td>
</tr>
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Table 1. Participant Demographics

OAB-q Qualitative Summary

• Overall participant feedback on the OAB-q from the cohort is interpretable and meaningful and indicated that each of these items was relevant.

• The nighttime urination item (item 5) yielded some interesting comments. Four participants (20%) interpreting this item as involuntary loss of urine while sleeping and 17 participants (85%) correctly interpreting this item as waking up at night to urinate.

• A majority of the participants (75%) articulated an overall positive perception of the OAB-q (items 1–8 and 9–33). Twenty participants (100%) reported that the length of the OAB-q was appropriate.

• All participants reported that they could accurately and easily understand the OAB-q items related to symptom bother and impact on daily life.

• In general, most participants reported that the response options for both OAB-q scales were appropriate and acceptable, although a few (4%) suggested adding a “not sure” response option for the DO scale.

5 Conclusions

• The 33 items of the OAB-q are clear, relevant, and understandable to the majority of vulnerable elderly adults.

• All participants reported that all items in the OAB Symptom Bother Scale were relevant and distinct from the items of the related OAB-q scales, including UUI.

• The majority of participants understood the items of the OAB-q scales as relevant to most participants.

• This evidence supports the content validity of the OAB-q in vulnerable elderly adults with OAB, including UUI.

Table 4. OAB-q Scale and Domain Scores

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean (SD)</th>
<th>Range</th>
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<tbody>
<tr>
<td>Symptom Bother scale</td>
<td>42.8 (15.9)</td>
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<tr>
<td>HRQL, Total score</td>
<td>64.3 (8.5)</td>
<td></td>
</tr>
<tr>
<td>Coping domain</td>
<td>64.5 (8.4)</td>
<td></td>
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<tr>
<td>Concerns domain</td>
<td>67.3 (10.6)</td>
<td></td>
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<tr>
<td>Sleep domain</td>
<td>79.9 (5.4)</td>
<td></td>
</tr>
<tr>
<td>Social interaction domain</td>
<td>85.0 (6.5)</td>
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OAB-q Scores

For each of the OAB-q items, participants generally selected across the range of response options, with the mean (SD) scores across the OAB-q items ranging from 1.1 (1.0) to 15.1 (1.9).

• Fear effects were observed for 4 items: Made you feel like there is something wrong with you, Troubled your family and friends, and Caused you to have pain with your partner or spouse.

Table 3. OAB-q Item Scores and Participant Qualitative Feedback

6 References


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