56

Kopp Z[1], Abrams P[2], Piault E[3], Evans C[3], Espindle D[3], Atkinson M[1], Brubaker L[4], Jumadilova Z[1]
1. Pfizer, Inc, 2. Southmead Hospital, Bristol Urological Institute, 3. Mapi Values, 4. Loyola University Medical Center

PATIENT SATISFACTION IN STUDIES OF OVERACTIVE BLADDER: A GENERIC QUESTIONNAIRE VERSUS A DISEASE SPECIFIC QUESTIONNAIRE

Hypothesis / aims of study
Several instruments that measure the impact of overactive bladder (OAB) on patients' quality of life are available. However, neither the overall levels nor the multidimensional aspects of satisfaction with OAB treatment have been studied in patients living with OAB symptoms. This project is aimed at identifying the difficulties involved in planning studies that involve documenting patients' satisfaction with a treatment and determining the best method for evaluating patient satisfaction with treatment in prospective evaluations. In order to determine the best measurement strategy, a comparison of the validity, reliability and responsiveness of a disease specific and a generic satisfaction questionnaire in overactive bladder (OAB) sufferers was performed in two studies.

Study design, materials and methods
Two stand-alone, four-week studies of subjects diagnosed with OAB who received pharmacologic treatment (n=201 subjects) and who were treatment naïve (n=50) were conducted. The 42-item OAB-S evaluates OAB control (10 items), impact of OAB on daily living (10 items), medication tolerability (6 items), satisfaction with OAB control (10 items), and includes 5 stand-alone items that query patients on overall expectation, satisfaction, life interruption of day-to-day life due to OAB, Life improvement due to medication and willingness to continue treatment. The 14-item generic, Treatment Satisfaction Questionnaire with Medication (TSQM) queries about medication effectiveness (3 items), side effects (4 items) and convenience (3 items) and global satisfaction with medication (3 items). A three-day patient symptom log diary and a demographic form were administered to all participants at Baseline and 2-week follow-up.

Results
Results indicated both OAB-S and TSQM questionnaires had acceptable construct validity (internal consistency reliability >0.70); however, the OAB-S had a better test-retest reliability (Intraclass Correlation Coefficient range [0.72-0.87] vs. [0.63-0.83] for the TSQM). The OAB-S also showed greater ability to discriminate among patients compared to the TSQM according to patients self-reported OAB severity (i.e., OAB-S scale score relative validity coefficient were higher than these of the TSQM scale scores [0.81-1.00] vs. [0.08-0.38]) and patient continence status (i.e., OAB-S scale effect size values moderate to high [0.69-0.81] compared to moderate effect size on the TSQM scales [o.48-0.54]). Results were confirmed in the medication-naïve population. Results showed effect sizes for change in the TSQM and OAB-S scores which were near 0 for the group of patients who reported to be "about the same" at two-week follow-up. Effect sizes for change group who reported to be "Better" were mild (0.25) only for the TSQM effectiveness score. The effect size of the OAB-S satisfaction with OAB control score was slightly higher than the effect size of the TSQM global satisfaction score (0.27 vs. 0.15, respectively). Analysis assessing the responsiveness of the questionnaires to worsening could not be performed.

Interpretation of results
In these studies, the disease specific OAB-S questionnaire performed better than the generic measure in terms of reliability, of discriminating patients by severity level and in terms of detecting change in satisfaction levels in OAB sufferers.

Concluding message
A generic satisfaction instrument has the advantage of allowing comparison between treatments for different medical conditions. However, these findings suggest that a disease-specific satisfaction measure is more appropriate than a generic measure in trials and surveys of patients' satisfaction with OAB medication where maximum sensitivity is required to detect differences between treatments.

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