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Transcultural and Measurement Evaluation of the Asthma Quality-of-Life Questionnaire

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ABSTRACT

OBJECTIVE: This analysis compared Asthma Quality-of-Life Questionnaire (AQLQ) data from across 16 countries (17 languages) to evaluate suitability to combine data in analyses.

STUDY DESIGN: AQLQ data from the Gaining Optimal Asthma Control study was used for the analyses; 1832 patients had an overall AQLQ score at baseline and week 12. The original North American English version, for Canadian patients only, was the reference language (RL). AQLQ scores range from 1-7, where a high score indicates no impairment. Values within 0.5 of the RL were considered comparable.

RESULTS: The number of patients varied from 27 (Canadian French) to 257 (Mandarin Chinese). Mean age ranged from 27.6 (Spain Spanish) to 52.9 years (Norway Norwegian). Mean overall AQLQ score (SD) at baseline in the RL was 4.59 (0.94). All but 3 languages reported scores within 0.5 of the RL. Mean change from baseline in the overall AQLQ score in the RL was 0.89 (1.06). Baseline overall AQLQ scores were all within 0.5 of the RL. Cronbach alpha ranged from 0.93 to 0.97 (RL 0.94). Correlation with baseline Asthma Control Questionnaire (ACQ) and the forced expiratory volume in 1 second (FEV_1) ranged from −0.76 to −0.58 (RL −0.69) and −0.02 to 0.41 (RL 0.08), respectively. Similarly, correlations with change from baseline for ACQ and FEV_1 ranged from −0.83 to −0.61 (RL −0.77) and −0.11 to 0.56 (RL 0.03). Effect sizes were all >0.50, ranging from 0.59 (Norway Norwegian) to 1.10 (New Zealand English) (RL 0.85).

CONCLUSIONS: The finding that internal consistency, construct validity, and responsiveness were demonstrated across languages and similar to the RL supports the combining of data for analyses.

KEYWORDS: Equivalence; Patient-reported outcome; Psychometric analysis

Patients with chronic disease such as asthma often experience a considerable physical, emotional, and social burden in addition to the symptoms of the disease itself. These can be measured in terms of the patients' health-related quality of life (HRQoL). HRQoL assessment is an important

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component of the evaluation of medical treatments alongside lung function to fully assess whether patients feel better and can function better.[1,2]

The Asthma Quality of Life Questionnaire (AQLQ) is a widely used instrument for evaluating HRQoL in the asthma clinical trial setting.[3] The AQLQ was developed to measure 4 domains identified as important by asthma patients: symptoms classically associated with asthma, activity limitations due to asthma, responses to environmental stimuli and the need to avoid these stimuli, and emotional dysfunction resulting from asthma. The AQLQ was developed in North American English valid for use in both the US and Canada. Currently, there are a number of translations available. Consistent with current guidelines, the translated versions of the AQLQ have undergone a complete cultural adaptation and linguistic translation, including 2 forward and 2 backward translations, followed by cognitive debriefing with patients, to ensure ease of use and accuracy of understanding.[4,5]

AQLQ data are frequently collected from patients in a number of countries in multinational clinical trials and combined in analyses. This introduces important methodological challenges to the analysis and interpretation of these trial data, with there being potential for differences in cultural and linguistic preferences in the subjective expression of outcome.[6] There are currently no established criteria concerning analytical requirements to ensure appropriateness of aggregation of data derived from multiple languages and cultures. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Patient-reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force reports that beyond ensuring linguistic and cultural equivalence as a minimum requirement, measurement equivalence should be considered for pooling of such data.[6] Measurement equivalence has a number of definitions, but it is essentially the extent to which psychometric properties of different-language versions of the same instrument are similar.[6-8] The ISPOR Patient-reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force has acknowledged the lack of consensus on the methods to be employed for this analysis.[6] The Task Force suggests that the choice of method is dependent on a number of factors, most importantly the sample size from the countries. The sample size requirements for Classical Test theory (CTT) are much smaller than those required for factor analysis, structural equation modeling, and differential item functioning. Differential item functioning was used to assess whether there were differences between 13 translations of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ)-30, representing 22 countries using a database of 27,891 respondents.[9] Given the number of patients in some countries included in this analysis, CTT is the appropriate method for this analysis.

This post hoc analysis was conducted using CTT to compare scores of the original version of the AQLQ obtained from patients across 16 countries (17 languages).[3] The analysis investigated whether the measurement properties of the AQLQ are sufficiently consistent and robust to support combining data in subsequent analyses of multinational trials.

METHODS

Patient Population

AQLQ data from the first 12 weeks of the Gaining Optimal Asthma Control (GOAL) study was used for the analyses.[10] This study randomized 3421 patients from 326 centers across 44 countries aged between 12 and <80 years with at least a 6-month history of asthma. The study used the definitions of asthma control advocated in the Global Initiative for Asthma and National Institutes of Health guidelines.[11,12] Both "total control" and "well controlled" definitions were composite measures that included the following asthma outcomes: peak expiratory flow, rescue medication use, symptoms, night-time awakenings, exacerbations, emergency visits, and adverse events. Control was assessed over an 8-week period before each clinic visit at Weeks 12, 24, 36, and 52. Control was assessed reviewing the data in diary cards and clinical record forms from the previous 8 weeks. Patients were randomized to receive 1 of 2 asthma control