



ELSEVIER

Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/jval

Mapping EQ-5D Utility Scores from the Incontinence Quality of Life Questionnaire among Patients with Neurogenic and Idiopathic Overactive Bladder

Stephen Kay, MSc¹, Keith Tolley, BA, MPhil², Danielle Colayco, PharmD, MS³, Kristin Khalaf, PharmD, MS³, Peter Anderson, BSc^{1,*}, Denise Globe, PhD³

¹Adelphi Real World, Macclesfield, UK; ²Tolley Health Economics Ltd., Buxton, UK; ³Allergan, Inc., Irvine, CA, USA

ABSTRACT

Objectives: To provide a mapping algorithm for estimating EuroQol five-dimensional (EQ-5D) questionnaire index scores from the Incontinence-specific Quality of Life questionnaire (I-QOL) based on nationally representative samples of patients with idiopathic or neurogenic overactive bladder (OAB) using EQ-5D questionnaire preference valuations based on both the UK and US general populations. **Methods:** Analyses were conducted for 2505 patients from the Adelphi Overactive Bladder Disease Specific Programme, a cross-sectional study of patients with idiopathic or neurogenic OAB, undertaken in the United States and Europe in 2010. A range of statistical modeling techniques was used. Tenfold cross-validation techniques were used to calculate mean absolute error (MAE) and root mean squared error (RMSE) goodness-of-fit statistics. Various predictor lists, together with a method combining stepwise selection with multivariable fractional polynomial techniques to allow nonlinear relationships to feature, were pursued. **Results:** Choice of predictors was consistent for both the UK and US EQ-5D

questionnaire tariffs. For idiopathic, the best model included the I-QOL total score and age (both modeled nonlinearly.) For neurogenic, the best model was the I-QOL social embarrassment domain score modeled linearly only. Best-fit results were better in the idiopathic ($n = 2351$; MAE = 0.10; RMSE = 0.14) than in the neurogenic sample ($n = 254$; MAE = 0.17; RMSE = 0.22). **Conclusions:** This research provides algorithms for mapping EQ-5D questionnaire index scores from the I-QOL, allowing calculation of appropriate preference-based health-related quality-of-life scores for use in cost-effectiveness analyses when only I-QOL data are available. The strongest results were for idiopathic patients, but those for neurogenic are consistent with those of other published mapping studies.

Keywords: cross-walk, EQ-5D, I-QOL, mapping, real world, utility values.

Copyright © 2013, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.

Introduction

Utilities reflect the strength of an individual's preference for specific health-related outcomes and are commonly used to generate health state values for calculating quality-adjusted life-years. A single summary score is generated by applying societal preference weights to a health state classifier, completed by the patient, that ranges from 0 to 1 on an interval scale, where 9 represents a state equivalent to death and 1 reflects perfect health [1,2]. Such utility scores may be directly elicited by using preference-based techniques (e.g., standard gamble, time-trade off, or rating scales) completed by a representative sample of a regional general population. Alternatively, they can be measured indirectly through the use of algorithms applied to either generic or disease-specific questionnaires initially generated from direct elicitation by using preference-based techniques. When direct elicitation is not feasible, algorithms to estimate indirect utilities from health-related quality-of-life (HRQOL) questionnaires may also be developed by mapping an HRQOL questionnaire onto the utility algorithm of a generic instrument [3]. The ability to

translate from health status measures to preference utility scores is appealing in terms of minimizing respondent burden and analyzing data for which only health status measures are available.

The EuroQol five-dimensional (EQ-5D) questionnaire, one of the most commonly used generic questionnaires for deriving utility scores, is composed of five dimensions (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression), each with three levels (no problems, some problems, or extreme problems/unable to). A total of 243 health states can be created, with 0 representing death and 1 representing perfect health. It has been widely used owing to its reported validity and reliability [4–6]. Country-specific value sets (community preference tariffs) exist for several countries, including the United Kingdom [7] and the United States [8]. A five-level version of the EQ-5D questionnaire is available; however, the associated tariff is interim and to date this version is not being routinely used in clinical studies [9].

Overactive bladder (OAB) syndrome is a symptom-based diagnosis and is defined as urgency, with or without urgency incontinence, usually with frequency and nocturia [10]. These

* Address correspondence to: Peter Anderson, Adelphi Real World Ltd., Adelphi Mill, Bollington, Cheshire SK10 5JB, UK.

E-mail: peter.anderson@adelphigroup.com.

1098-3015/\$36.00 – see front matter Copyright © 2013, International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Published by Elsevier Inc.

<http://dx.doi.org/10.1016/j.jval.2012.12.005>

symptoms are a consequence of the bladder's inability to effectively store urine because of an underlying dysfunction in the coordinated mechanisms that provide controlled storage and voiding of urine. Patients with underlying neurologic conditions (e.g., multiple sclerosis, spinal cord injury) often experience neurological deficits or lesions within regions of the central nervous system that govern bladder function. As a result, symptoms consistent with OAB are commonly experienced in these patient subgroups and these patients are referred to as having neurogenic OAB. In the absence of a known neurological insult or pathophysiological cause, the reason for the dysfunction is unknown in the majority of cases, resulting in the condition referred to as idiopathic OAB.

OAB is a prevalent disorder that is reported to affect between 12% and 17% of the general population in North America and Europe [11–14]. The negative impact of OAB and urinary incontinence has been well established. The symptoms of OAB, including urinary incontinence, have psychosocial, physical, and sexual effects that impact patients' HRQOL [15–18]. OAB symptoms and urinary incontinence can have an impact on emotions (e.g., distress, embarrassment, and self-esteem), physical activities (e.g., difficulty with daily activities due to leakage), and social activities (e.g., restriction of activities due to anxiety about not being able to reach a toilet). In addition, incontinence and frequency of urination at night have a deleterious impact on a patient's ability to sleep, leading to daytime sleepiness and decreased energy level. Thus, OAB affects the individual's ability to function physically and mentally and is associated with symptoms of depression [12,18,19].

The Incontinence Quality of Life Questionnaire (I-QOL) is a disease-specific, patient-reported instrument initially designed to measure the impact of urinary incontinence on patients' lives. It has demonstrated sound measurement properties in prior studies among patients with urinary incontinence, including those who have OAB both with and without urinary incontinence [20–23]. The I-QOL consists of 22 items divided into three domains: avoidance and limiting behavior, psychosocial impact, and social embarrassment. Scores can be calculated for each domain, and a total summary score can also be calculated from all 22 items, with 100 representing the best possible score [24]. Since its development, the I-QOL has been and continues to be used in a number of clinical trials and other research studies, and its psychometric properties have been documented in a number of validation studies, showing it to be a valid and reliable measure in patients with stress incontinence, OAB, and urinary incontinence due to an underlying neurologic condition [25–29].

This article describes the modeling techniques used to map I-QOL onto the EQ-5D questionnaire for patients with OAB due to idiopathic or neurogenic etiologies. The study was restricted to patients diagnosed with OAB with or without urinary incontinence. Methods and results are presented separately for patients with idiopathic and neurogenic etiologies to account for the inherent variability between these two populations.

Methods

Data Source

Data were drawn from the Adelphi Overactive Bladder Disease Specific Programme (OAB DSP), a multinational, cross-sectional study of real-world clinical practice conducted in the United States and four European Union countries (France, Germany, Spain, and the United Kingdom) between October 2010 and January 2011. A total of 259 primary care physicians and 445 specialists (urologists, gynecologists, and urogynecologists) participated in the program. Physicians completed a patient record

form for the next 10 consecutive consulting patients who met the eligibility criteria, and the same patients were invited to fill out a patient self-completion form, which included the I-QOL and the EQ-5D questionnaire. All patients with symptoms of OAB/incontinence, as diagnosed by their physician, were eligible for inclusion in the survey except for those younger than 18 years, those with a lower urinary tract infection, and pregnant female patients. The real-world design of the study ensured that information available to the physician/patient only at the time of the consultation was collected. Therefore, no tests or investigations were required for a patient to be included in the study, nor were they conducted as part of the study itself. This methodology has been successfully administered for other disease states including respiratory, central nervous system, cardiovascular, oncology, and autoimmune conditions and has been outlined in detail previously [30].

Analysis Plan

To address the specific objectives outlined in this article, the following patients were excluded from the sample prior to analysis:

- Patients with stress urinary incontinence only (but included mixed urinary incontinence)
- Patients who had surgery for OAB (procedures to insert indwelling catheters or inject bulking agents were not excluded)
- Patients whose primary neurogenic condition was reported as a complete spinal cord injury, stroke, Parkinson's disease, or "Other"
- Patients with concomitant cancer or benign prostatic hyperplasia.

The first two criteria were applied to minimize variability within the general OAB/incontinence population. The third criterion attempted to restrict the population to patients with either idiopathic OAB or those with a specific subset of neurologic conditions. The final criterion excluded patients whose quality-of-life decrement may be attributed to conditions other than their urinary incontinence. The final sample consisted of patients with idiopathic OAB and patients with a primary neurologic condition of either multiple sclerosis or incomplete spinal cord injury who experienced symptoms of OAB that were thought to stem from neurogenic detrusor overactivity. Given the inherent differences between these two groups, the analysis was split by disease type—neurogenic and idiopathic OAB. Results of the idiopathic OAB group are presented first, followed by the results for patients with neurogenic OAB.

Statistical Methods

A number of statistical models have historically been used to map (cross-walk) various health status measures onto EQ-5D questionnaire community preference values. Traditional mapping methods include ordinary least squares (OLS), Tobit, censored least absolute deviation (CLAD), generalized linear models (GLMs), and two-part models (2PM). Given the variety of models available, characteristics of the EQ-5D questionnaire were taken into consideration to determine which models would provide viable options to test for this mapping exercise.

An important factor to consider is the interpretation of a perfect score on the EQ-5D questionnaire (i.e., a score of 1). There is a ceiling score of 1, which means that the EQ-5D questionnaire should be considered as censored in that while the modal EQ-5D questionnaire score is typically 1, no individual observation can exceed 1. Furthermore, the modal score of 1 (perfect health) can be a direct result of the EQ-5D questionnaire being an instrument

Download English Version:

<https://daneshyari.com/en/article/989786>

Download Persian Version:

<https://daneshyari.com/article/989786>

[Daneshyari.com](https://daneshyari.com)