ELSEVIER

Journal of Clinical Epidemiology 65 (2012) 643−650

Journal of Clinical Epidemiology

The standardized and mini versions of the PAQLQ are valid, reliable, and responsive measurement tools

Annie Wing[a], Jane Upton[a], Klas Svensson[b], Peter Weller[c], Monica Fletcher[a], Samantha Walker[a,*]

[a]*Education for Health, The Athenaeum, 10 Church Street, Warwick CV34 4AB, Warwickshire, UK*
[b]*HEOR Consulting, Linerov 15, S-22475 Lund, Sweden*
[c]*Birmingham Children's Hospital, Steelhouse Lane, Birmingham, B4 6NH UK*

Accepted 20 December 2011

Abstract

Objective: The Paediatric Asthma Quality of Life Questionnaire (PAQLQ) is a validated tool developed to assess the impact of symptoms on quality of life. Here we assess the validity, reliability and responsiveness of two new simpler versions of this questionnaire: the Standardised PAQLQ and the MiniPAQLQ.

Study Design and Setting: Participants included 42 children with asthma, who completed the PAQLQ, PAQLQ(S), MiniPAQLQ, Asthma Control Questionnaire, and Health Utilities Index at baseline, one, five and nine weeks. Concordance between questionnaires was examined using intraclass correlation coefficients (ICC), bias by paired Student's *t*-tests and closeness of association by Pearson correlation coefficients.

Results: Correlation coefficients for each of the corresponding domains of the PAQLQ with the PAQLQ(S) were strong ($r > 0.97$), and moderate to strong ($r = 0.50-0.94$) with the MiniPAQLQ. Reliability was strong for both the PAQLQ(S) (ICC > 0.89) and MiniPAQLQ (ICC > 0.91). The responsiveness index values for the PAQLQ(S) (0.96) and the MiniPAQLQ (1.05) were both higher than that of the original PAQLQ (0.90). Cross sectional and longitudinal correlation coefficients were similar for all three instruments.

Conclusion: The PAQLQ(S) and the MiniPAQLQ are valid, reliable and responsive to change. They can be used with confidence for long-term monitoring in clinical trials.

Keywords: Quality of life; Questionnaire; Pediatric; Validation; Reliability; Responsiveness

1. Introduction

The Pediatric Asthma Quality-of-Life Questionnaire (PAQLQ) is a validated tool, which was developed to measure the problems that children with asthma experience in their day-to-day lives [1]. It was originally developed by asking children with asthma to identify 23 items that they considered to be most troublesome to them. These were grouped into three domains: symptoms (10 items), emotional aspects (eight items), and activity limitation (five items). It has good discriminative and evaluative properties [1−5].

The PAQLQ requires children to individualize their responses by identifying three activities that they are most likely to undertake at the time they complete the questionnaire. This feature enhances content validity, accommodates cultural differences, and helps children to identify activities most relevant to them. The main disadvantage of children identifying key activities is that it is time consuming to complete. The PAQLQ also requires trained personnel to administer it, as it requires a degree of regulation for those collecting the data to ensure the same information is recorded each time. Using untrained personnel may result in the possible gains afforded by children being able to nominate their own chosen activities being lost through missing or incorrectly gathered data. Recording such specific information also requires the child to conduct that activity in between each visit, which may not occur. For some studies in which this feature is less important, generic activities may be more appropriate; for example, in long-term clinical trials and patient monitoring, patients' activities may change over time and the ease and convenience of

* Corresponding author. Tel.: +44-(0)20-7786-4918; fax: +44-(0)20-7256-6075.
E-mail address: swalker@asthma.org.uk (S. Walker).

0895-4356/$ - see front matter
doi: 10.1016/j.jclinepi.2011.12.009

What is new?

This study compared the original Pediatric Asthma Quality-of-Life Questionnaire with two new, shorter, and simpler versions. The new questionnaires were shown to be valid, reliable, and responsive to change. The new questionnaires show strong evaluative and discriminative measurement properties and can be used with confidence for long-term monitoring in clinical trials or in cross-sectional surveys. This outcome means that there is an increased choice of measurement tools for researchers who want to compare burden of illness across different cross-sectional studies or compare baseline quality-of-life scores in large clinical trials and surveys. These new instruments can be used with confidence to provide a more comprehensive evaluation of patient-reported outcomes to medical interventions over time and to identify variations or trends across populations.

standardized questionnaires may outweigh the benefits of individualized questions. The standardized Pediatric Asthma Quality-of-Life Questionnaire (PAQLQ(S)) and the mini Pediatric Asthma Quality-of-Life Questionnaire (MiniPAQLQ) [6] were developed to address this need.

In this study, we compare the discriminative and evaluative measurement properties and the validity, reliability, and responsiveness of these two new questionnaires with the PAQLQ.

2. Methods

2.1. Study design

Ethical approval was granted by the West Midlands Research Ethics Committee, South Warwickshire Ethics Committee, and Birmingham Children's Hospital Ethics Committee. Signed informed consent was obtained from all the parents. The children were invited to consent or assent to participate in the study depending on their age and level of understanding.

In this 9-week observational study, all the children received standard care according to the British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) guideline on the management of asthma [7], and all the interviews were undertaken by the same qualified children's nurse researcher for the duration of the study. The researcher was trained in the administration of the disease-specific questionnaire by the developer of the questionnaire and via a training video. This was to ensure accuracy and reliability of the data and reduce bias.

The children were assessed at baseline while attending routine outpatient appointments at Birmingham Children's Hospital respiratory clinic or an asthma review at their local general practitioner's practice. Baseline data, recorded on the day of recruitment, was used to assess the internal consistency of the questionnaire. This was the first time the child had been exposed to the questionnaires; these data were therefore not subject to any bias that might occur as a result of repeated use.

After recruitment, they were followed up at 1, 5, and 9 weeks later. At each visit, the children completed the interviewer-led, structured questionnaires and lung function tests. Forced expiratory volume in one second (FEV_1) was measured using Zapletal prediction equation [8].

Administration of the questionnaires was interspersed with clinical elements of the consultation to create a break from direct questioning. When interviewing the children, the interviewer did not explain or change any of the questions within the questionnaire, but simply repeated any question the child did not understand. The child was encouraged to answer the questions themselves to ensure that they were not influenced by their parent's opinion. Parents were not explicitly told not to interrupt the interviewer, but to try and prevent them from answering questions on the child's behalf they were asked to sit behind or slightly to the side of the child during the interview.

The questionnaires were administered in the same order at each visit. The MiniPAQLQ was completed first followed by the Health Utilities Index (HUI), and then the Asthma Control Questionnaire (ACQ). The original PAQLQ and the PAQLQ(S), which are very similar, were administered last to leave as large a gap as possible between the two new questionnaires. Baseline data was recorded for each participant on the day of recruitment. The first visit took approximately 30 minutes to complete and subsequent visits lasted approximately 20 minutes. For 1 week before each follow-up clinic visit, children completed a daily diary, which recorded peak expiratory flow rate (PEFR), symptoms, and bronchodilator use.

2.2. Outcome measures

The PAQLQ, PAQLQ(S), and MiniPAQLQ each consist of three domains (symptoms, activity, and emotional function), which measure the impact of asthma on quality of life during the past week. Questions for each domain are scored on a scale of 1–7 (where 1 indicates maximum impairment and 7 indicates no impairment). The questions are equally weighted and their responses combined to create mean scores for each domain and a mean score for overall quality of life.

The PAQLQ and PAQLQ(S) both contain 23 questions (the symptom domain has 10 questions, activity domain has 5 questions, and emotional function domain 8 questions). The difference between the two tools is that in the activity domain of the PAQLQ, the child selects three activities themself and two activities are generic. In the PAQLQ(S), the three individualized items have been replaced by generic questions