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Validation of the Spanish version of the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) in a population of Hispanic children

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Abstract

Objective—The Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) is intended to measure the impact of children's asthma on their parents/caregiver's QoL. However, there are no formal validation studies of the Spanish version of PACQLQ.

Methods—In a prospective cohort validation study, asthmatic children aged between 7 and 17 years and their parents, attended both a baseline and a follow-up visit 2–6 weeks later. In these two visits, we gathered the necessary data for assessing the criterion validity, construct validity, test–retest reliability, sensitivity to change, internal consistency and usability of the PACQLQ.

Results—At baseline, PACQLQ scores were significantly different between patients with controlled, partly controlled and uncontrolled asthma (median [IQR] 78.0 [61.0–85.0], 71.0 [37.0–76.0] and 48.0 [40.7–55.0], respectively, $p < 0.001$), and also between patients for whom this visit resulted in a step-up versus no change or a step-down in therapy (50.0 [40.0–60.0] versus 78.0 [61.0–85.0]; $p < 0.001$). PACQLQ scores at baseline were significantly lower than those obtained in the follow-up visit in patients with change for the better in the global rating of change questionnaire (median [IQR] 50.0 [42.5–56.0] versus 80.0 [78.5–85.0]; $p < 0.001$). The intraclass

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Declaration of interest

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correlation coefficient of the measurements was 0.839 (95% CI: 0.735–0.902). The Cronbach α was 0.914 for the questionnaire as a whole.

Conclusions—The Spanish version of the PACQLQ has adequate construct validity, adequate sensitivity to change, good internal consistency, excellent test–retest reliability and good usability when employed in children aged between 7 and 17 years with physician-diagnosed asthma.

Keywords

Asthma; health-related quality of life; pediatrics; reliability; validation studies; validity

Introduction

Childhood asthma is recognized as being the most common chronic disease among children and a major public health problem in the US as well as in many other countries, such as Colombia [1,2]. A number of studies have found a high prevalence of inadequately controlled asthma in children despite recent advances in our understanding of the inflammatory nature of asthma and the availability of highly effective medications to control the disease [3,4]. Likewise, in recent years, there has been an increasing amount of literature that have shown that childhood asthma not only has impact on patient, but also affects the quality of life (QoL) of the family, especially the primary caregiver [5,6].

In recent years, there has been an increasing interest in the influence of chronic pediatric diseases in the QoL of parents and other caregivers. This is mainly because this affection of QoL not only has significant effects on both the physical and mental health of the parents/ caregivers, but also has adverse effects on disease outcomes in children under their care. In the context of pediatric asthma, previous research has shown that maternal depressive symptoms are associated with attitudes that may significantly influence adherence to asthma medications and illness management of their asthmatic children [7]. Likewise, a number of studies have found an association between QoL in parents and the level of asthma control in children [8–10]. In order to measure the impact of children's asthma on their parents/ caregiver's QoL, in 1996 Juniper et al. [11] published a study in which they developed and evaluated the measurement properties of the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ). The PACQLQ is a disease-specific questionnaire that includes 13 items in two domains (activity limitations and emotional function) that showed adequate construct validity, and high reliability and sensitivity to change when tested in parents/ primary caregivers of asthmatic patients aged between 7 and 17 years. A limited number of studies have subsequently shown additional data that further support the PACQLQ's validity, sensitivity to change and test–retest reliability and have also provided evidence for its internal consistency and usability [5,12–17]. However, to the best of author's knowledge, very few studies have evaluated the measurements properties of the questionnaire in Spanish-speaking populations [15–17]. Spanish is one of the most widely spoken languages in the world with nearly 500 million native speakers [18], and the official language of two of the four countries with the highest prevalence of pediatric asthma in the entire world [19]. In this context, there is a critical need for additional validation studies of the questionnaire that further examine its measurement properties in Spanish-speaking populations.

The aim of this article is to validate the Spanish version of the PACQLQ in a population of parents/primary caregivers of pediatric patients with physician-diagnosed asthma living in urban Bogota, Colombia.

Methods

Study population

The study was undertaken at Clinica Infantil Colsubsidio, a tertiary care, multidisciplinary teaching hospital located in the metropolitan area of Bogota, Colombia. Parents/primary caregivers of children older than 6 years old evaluated in our pediatric respiratory service with a history of physician-diagnosed asthma were invited to participate in the study. Parents/primary caregivers of participating children were native Spanish speakers, with widely varied educational backgrounds (at least 5 years of formal education) and socioeconomic status but with an acceptable reading speed and ability. Children with respiratory conditions not consistent with asthma that might affect the cardiopulmonary status (i.e. chronic lung disease or congenital heart disease) and those with other significant chronic disorders or congenital abnormalities were excluded from the study.

PACQLQ questionnaire

The PACQLQ is a 13-item caregiver-completed disease-specific questionnaire useful in addressing the impact of children's asthma on their parents/primary caregivers lives. Parents/primary caregivers of children aged between 7 and 17 years recall the impact that their child's asthma has had during the previous week. Four items of the PACQLQ evaluate the activity limitations domain, and the nine remaining items evaluate the emotional function domain [11]. The score for the response to each item ranges from 1 to 7 points on a 7-point Likert scale, with 1 indicating severe impairment and 7 indicating no impairment (Supplemental Table S1). The scores of the individual items are added to obtain the overall unweighted PACQLQ score. The possible total score ranges from 13 to 91, with a higher score indicating a better quality of life. The PACQLQ was developed by Juniper et al. and the original version and its translations are copyrighted. To perform this study, Professor Elizabeth Juniper provided the Spanish version for Colombia of the PACQLQ and granted us permission to use and validate it. Translation and back-translation were used to develop the Spanish version of the questionnaire that was used in this study.

Study design and procedures

We conducted a prospective cohort validation study that followed a convenience sample of children who fulfilled the eligibility criteria (inclusion and exclusion criteria) and whose parents/primary caregivers agreed to participate and signed the informed consent. At baseline, we used standardized forms to collect demographic data of the children (age/gender) and their respective parents/primary caregivers (age, highest level of education), and assessed all the children with the Spanish version of the PACQLQ. In addition, at baseline, separately and blinded to the caregiver's responses to the PACQLQ, we collected the following clinical information about the respiratory condition of all included patients: the level of asthma control based on the Global Initiative for Asthma (GINA) guideline recommendations [20], and whether the baseline visit resulted in a step-up in therapy, no

change or step-down in therapy. During the follow-up visit, 2–6 weeks later, we also assessed all the children with the Spanish version of the PACQLQ, and in the same manner as in the original PACQLQ study [11], we asked caregivers whether they had experienced any change in their overall QoL, emotions or activity limitations related to their asthma since the baseline visit. Responses of this global rating of change questionnaire were scored on a 15-point scale from –7 (indicating maximum change for the worse) to +7 (indicating maximum change for the better), with 0 indicating no change at all. In order to determine the level of asthma control based on the GINA guideline recommendations, we completed five specific questions that assess daytime symptoms, limitation of activities, nocturnal symptoms/awakenings, need for reliever rescue treatment and lung function when available. Each question was scored on a 2-point Likert-type scale (1, controlled; 2, partly controlled). The scoring of these questions were used to stratify the sample into categories of controlled asthma (if a score of 1 was selected for all questions), partly controlled asthma (if a score of 2 was selected for 1 or 2 questions) or uncontrolled asthma (if a score of 2 was selected for 3 or more questions). This study was approved by the local research ethics committee.

Assessment of the psychometric characteristics of the PACQLQ

To assess the PACQLQ's construct validity (i.e. the degree to which the measurement corresponds to other variables and measures that are not identical to the construct of parental/primary caregiver QoL but to which the construct of parental/primary caregiver QoL should be related), at baseline we compared PACQLQ scores across the three categories of therapeutic decision (a step-up in therapy, no change or a step-down in therapy). In addition, at baseline and in the follow-up visit, we compared PACQLQ scores across the three categories of the GINA guidelines criteria of asthma control (controlled, partly controlled and uncontrolled).

To evaluate the PACQLQ's test–retest reliability (i.e. the consistency of the instrument results measured on two occasions with no change in parental/primary caregiver QoL in between), we compared PACQLQ scores in patients whose asthma was classified as controlled at baseline in whom no change or a step-down in therapy occurred and who were classified in the same manner in the follow-up visit 2–4 weeks later.

To assess the PACQLQ's sensitivity to change (i.e. the ability of a score to detect a clinically important change over time), we compared PACQLQ scores at baseline and follow-up in patients with change for the better in the global rating of change questionnaire in the follow-up visit 4–6 weeks later. In addition, we calculated the proportion of patients with an increase of 0.5 or more points in PACQLQ scores between baseline and follow-up measurements as this value represents the minimal important difference for overall caregiver QoL when using the PACQLQ [11].

To examine the PACQLQ's internal consistency reliability (i.e. the degree of correlation between a scale's items), we used the responses given for all the parents/primary caregivers at baseline.

To assess the PACQLQ's usability (i.e. the speed, understandability and subjective experience when completing the questionnaire), parents/primary caregivers were asked to

qualify the ease of scoring of the PACQLQ as easy to score, moderately easy to score or difficult to score. In addition, the time to complete the questionnaire was reported.

Statistical analysis

Continuous variables are presented as standard deviation (SD) or median (interquartile range-IQR), whichever is appropriate. Categorical variables are presented as numbers (percentage). To assess the PACQLQ's construct validity, we contrasted PACQLQ scores across two previously defined categories of therapeutic decision (a step-up in therapy versus no change or a step-down in therapy) using the independent samples *t*-test or the Mann–Whitney non-parametric test, as appropriate. In addition, we compared PACQLQ scores across the three categories of the GINA guidelines criteria of asthma control (controlled, partly controlled and uncontrolled) by using the one-way ANOVA or the Kruskal–Wallis test, as appropriate. Test–retest reliability was assessed with the intraclass correlation coefficient (ICC) and Lin's concordance correlation coefficient [21], and through the construction of the Bland and Altman plot [22]. The PACQLQ's sensitivity to change was determined by comparing PACQLQ scores at baseline and follow-up with the paired Student *t*-test or the Wilcoxon signed rank test, as appropriate [23], and by calculating the proportion of patients with an increase of 0.5 or more points in PACQLQ scores between baseline and follow-up measurements. Internal consistency reliability was assessed using Cronbach's alpha coefficient [24]. The use of the method proposed by Walter et al. [25] to calculate the required number of subjects in a reliability study in which reliability is measured, yielded a sample size of 64 patients, two methods to be reported in the diagnosis, a kappa for the null hypothesis of 0.5, a kappa for the alternative hypothesis of 0.7, a statistical significance level of 0.05 and a power of 80%. In the assessment of construct validity, 64 participants provide at least 80% power (effect size, 0.4; α 0.05; two-sided test) to detect differences among the groups using one-way ANOVA [26]. Statistical analysis was done with Stata 12.0 (Stata Corp., College Station, TX).

Results

Of the total number of patients who fulfilled the eligibility criteria ($n = 121$), three were excluded because their parents refused to participate in the study, so 118 (97.5%) were finally enrolled in the study. Likewise, 2 of the total of 42 patients (4.8%) eligible for assessing sensitivity to change and 2 of the total of 66 patients (1.5%) eligible for assessing test–retest reliability did not attend the follow-up visit, so, finally, 40 and 64 patients were finally included in these two groups, respectively. The median (IQR) of the age of the 118 patients included in the study was 8.0 (7.0–11.0) years. The age group distribution was as follows: 103 (87.3%) between 7 and 12 years, and the remaining 15 (12.7%) between 13 and 17 years. Sixty-three (53.4%) patients were male and 55 (46.4%) were female. Regarding the level of asthma control at baseline based on the GINA criteria, 66 (55.9%) had controlled asthma, 10 (8.5%) partly controlled asthma and the remaining 42 (35.6%) were classified as having uncontrolled asthma. Lung function parameters were not used to assess the level of asthma control in any patient. In relation to the therapeutic decision at the baseline visit, for 66 (55.9%) patients the baseline visit resulted in no change or step-down in therapy, and for

the remaining 52 (44.1%) in a step-up in therapy. At baseline, the median (IQR) of the PACQLQ scores of the 118 patients included in the study was 60.5 (41.7–81.2) points.

Construct validity

PACQLQ scores were significantly different between patients whose baseline visit resulted in a step-up in therapy compared with patients for whom this visit resulted in no change or a step-down in therapy (50.0 [40.0–60.0] versus 78.0 [61.0–85.0]; $p < 0.001$). This difference was also statistically significant when comparing each domain separately (emotional function domain 31.5 [27.0–40.0] versus 55.0 [40.0–58.0], $p < 0.001$; activity limitations domain 16.0 [13.0–21.0] versus 26.0 [21.0–28.0], $p < 0.001$). Likewise, based on GINA criteria, PACQLQ scores were significantly different between patients with controlled asthma, partly controlled asthma and uncontrolled asthma (78.0 [61.0–85.0], 71.0 [37.0–76.0] and 48.0 [40.7–55.0], respectively, $p < 0.001$; (Supplemental Table S2). This difference was also statistically significant when comparing each domain separately (emotional function domain 55.0 [40.0–58.0], 49.0 [25.0–53.0], 32.0 [27.0–38.0], respectively, $p < 0.001$; activity limitations domain 27.0 [21.0–28.0], 22.0 [12.0–23.0], 16.0 [13.0–18.0], respectively, $p < 0.001$).

Test–retest reliability

There was no statistically significant difference between baseline and follow-up medians (IQR) of the PACQLQ scores in patients whose asthma was classified as controlled at baseline, in whom no change or a step-down in therapy occurred, and who were classified in the same manner in the follow-up visit [82.0 (80.0–85.0) versus 82.0 (80.0–85.0), $p = 0.972$]. The ICC of the measurements of the PACQLQ in these patients were 0.839 (95% CI: 0.735–0.902). Likewise the Lin's concordance correlation coefficient of the measurements of the PACQLQ scores were 0.723 (95% CI: 0.604–0.842). The Bland and Altman plot shows the agreement of PACQLQ scores between baseline and follow-up visits. Figure 1 shows that the mean difference in the PACQLQ score between the two visits was 0.06, and their corresponding 95% limit of agreement was – 4.98 to 5.11. Two outliers were found, and the points in the plot show random distribution.

Sensitivity to change

PACQLQ scores at baseline were significantly lower than those obtained in the follow-up visit in patients with change for the better in the global rating of change questionnaire in the follow-up visit 4–6 weeks later (median [IQR] 50.0 [42.5–56.0] versus 80.0 [78.5–85.0]; $p < 0.001$). This difference was also statistically significant when comparing each domain separately (emotional function domain 32.0 [27.0–38.0] versus 57.5 [42.0–60.0], $p < 0.001$; activity limitations domain 16.0 [13.0–18.0] versus 28.5 [23.0–30.5], $p < 0.001$). All the patients showed an increase of 0.5 or more points in PACQLQ score between baseline and follow-up visits.

Internal consistency

Cronbach's alpha coefficient was 0.914 for the questionnaire as a whole. For the individual items, this statistics ranged from 0.899 to 0.919 (Table 1).

Usability

All parents qualified the PACQLQ as easy to score, and the time required to complete the questionnaire ranged from 2 to 4 min.

Discussion

This study showed that the Spanish version of the PACQLQ has adequate psychometric characteristics when tested in asthmatic children aged between 6 and 17 years with physician-diagnosed asthma as demonstrated by (1) an adequate construct validity when we compared PACQLQ scores across the three categories of the GINA guidelines criteria of asthma control and across two categories of therapeutic decision, (2) an excellent internal consistency and (3) a good usability when parents and/or caregivers evaluated its ease of scoring and the time to complete the questionnaire. Likewise, the Spanish version of the PACQLQ showed an excellent test–retest reliability as well as a good sensitivity to change when we compared baseline and follow-up scores in Hispanic children with physician-diagnosed asthma.

The current study contributes to our knowledge by addressing three important issues. First, as far as we aware this is the first time that a Spanish version of the PACQLQ has a formal validation process. Second, the fact of having available a validated Spanish version of the PACQLQ will help physicians that attend Colombian patients and probably other Spanish-speaking populations to measure the impact of children's asthma on their parents/caregiver's QoL. Third, being able to measure the QoL of parents/caregivers of asthmatic children will help not only in a clinical decision-making context, but also for research purposes.

The result is in the lines of earlier literature that found a significant association between PACQLQ scores in parents/caregivers and changes in asthma control/severity in their children [12,15–17], supporting the construct validity of the questionnaire. Likewise, Halterman et al. [5] found a significant correlation between PACQLQ scores in caretakers and symptom scores, symptom days and symptom nights in their children, which is in good agreement with the results of this study. In the same manner, as reported by Juniper et al. in the study in which they developed and evaluated the measurement properties of the PACQLQ, our findings provides additional support for adequate test–retest reliability and sensitivity to change of the questionnaire. Consistent with findings by Reichenberg et al. [27], we found that the Spanish version of the PACQLQ had good internal consistency and excellent usability, with a very good acceptance by the parents/caregivers of the asthmatic children included in the study. Some previous studies have compared pulmonary function tests measures with PACQLQ scores, although not all with the objective of evaluating the measurements properties of the questionnaire. While some studies have correlated PACQLQ scores with forced expiratory volume in one second (FEV1) and peak expiratory flow rate (PEFR) measures [11,12], others have correlated PACQLQ scores only with PEFR measures [27] and others have correlated PACQLQ scores only with FEV1 measures [28]. With a few exceptions, these studies have shown no significant correlations between PACQLQ scores and changes in FEV1 or PEFR measurements. Nevertheless, in agreement with our study, other studies have correlated the PACQLQ scores only with clinical parameters, without using pulmonary function tests measurements [5,15].

We aware that our research may have some limitations, comprising the relatively small number of patients included in the study, the recruitment of patients in a single center and in a unique clinical setting (outpatients) and the fact that we did not use pulmonary function tests as comparators for evaluating the measurement properties of the PACQLQ. Although our findings could not necessarily be extrapolated to the whole Spanish-speaking population of asthmatic children and their parents/caregivers, there are no reasons to believe that the measurement properties of the Spanish version of the PACQLQ would substantially change if the questionnaire is tested in other settings (inpatients, community and primary care). However, further work needs to be carried out in different settings with a larger and a more representative sample. In addition, we consider that due to the fact that most asthmatic children have FEV1 in the normal range even when they are markedly symptomatic [29], and the lack of correlation between pulmonary function measurements and asthma symptoms and other asthma severity variables [11,29], the omission of pulmonary function measurements had minimal effect on measurement properties and validity of the Spanish version of the PACQLQ. The main strength of our study is the assessment of all of the recommended psychometric characteristics in the validation process of severity scores and other outcome measures of the PACQLQ in Spanish, the native language of some countries with the highest prevalence of pediatric asthma in the world.

In summary, our work has led us to conclude that the Spanish version of the PACQLQ has adequate measurement properties for assessing the burden of pediatric asthma in their parents/caregivers. Specifically, this version of the PACQLQ showed to have adequate construct validity, adequate sensitivity to change, good internal consistency, excellent test–retest reliability and good usability when employed in children aged between 7 and 17 years with physician-diagnosed asthma. We are confident that our research will be helpful in a clinical setting, and will serve as a base for future studies for measuring the burden of children's asthma on their parents/caregiver's QoL in Colombia and probably other Spanish-speaking populations.

Conclusion/key findings

The Spanish version of the PACQLQ has adequate construct validity, adequate sensitivity to change, good internal consistency, excellent test–retest reliability and good usability when employed in children aged between 7 and 17 years with physician-diagnosed asthma.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Bland and Altman plot displaying the difference in PACQLQ scores plotted against the mean PACQLQ scores. *Horizontal lines are drawn at the mean difference and at the mean difference ± 1.96 SD of the differences.

Table 1

Values of Cronbach's α for each item and for the PACQLQ as a whole.

Item	Value of Cronbach's α
1	0.909
2	0.909
3	0.908
4	0.907
5	0.899
6	0.901
7	0.919
8	0.904
9	0.904
10	0.915
11	0.908
12	0.909
13	0.908
PACQLQ as a whole	0.914