

Field-test validation of the Brazilian version of the Paediatric Asthma Quality of Life Questionnaire*, **

Versão brasileira do *Paediatric Asthma Quality of Life Questionnaire*:
validação de campo

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Abstract

Objective: To assess the psychometric properties of the official Brazilian Portuguese-language version of the Paediatric Asthma Quality of Life Questionnaire (PAQLQ) in a representative group of Brazilian children and adolescents with asthma. **Methods:** A total of 125 individuals with asthma, aged 8-17 years and being monitored at a pediatric pulmonology outpatient clinic in the city of Porto Alegre, Brazil, completed the PAQLQ. Validity was assessed by means of convergent validity (correlation between PAQLQ domains and those of the Pediatric Quality of Life Inventory (PedsQL) 4.0. Reliability was assessed by determining internal consistency (Cronbach's alpha coefficient), reproducibility (intraclass correlation coefficient), sensitivity to change (effect size), and discriminatory power (floor/ceiling effects). **Results:** The mean age was 11 years, and 75 (60%) of the participants were male. The mean PAQLQ total score was 5.1, with floor/ceiling effects < 10%. Correlations between PAQLQ domains and the PedsQL 4.0 domains were acceptable ($r = 0.37-0.40$). The Cronbach's alpha coefficient for the total score was 0.93, ranging from 0.72 to 0.88 for the domains. The overall effect size was 0.60 (range: 0.45-0.60), whereas the overall intraclass correlation coefficient was 0.80 (range: 0.66-0.79). **Conclusions:** The official Brazilian Portuguese-language version of the PAQLQ showed good psychometric performance, confirming its cultural adequacy for use in Brazil.

Keywords: Quality of life; Asthma; Validation studies.

Resumo

Objetivo: Determinar as propriedades psicométricas da versão oficial em português do Brasil de *Paediatric Asthma Quality of Life Questionnaire* (PAQLQ) em uma amostra representativa de crianças e adolescentes brasileiros com asma. **Métodos:** Um total de 125 participantes com asma, com idades de 8-17 e monitorados em um ambulatório pediátrico de pneumologia em Porto Alegre (RS), responderam o PAQLQ. A validade foi avaliada através de validade convergente (correlação entre os domínios do PAQLQ e os domínios do *Pediatric Quality of Life Inventory* 4.0 (PedsQL 4.0). A confiabilidade foi avaliada através da consistência interna (coeficiente alfa de Cronbach), reprodutibilidade (coeficiente de correlação intraclass), sensibilidade a mudança (tamanho do efeito) e discriminação (efeitos mínimo/máximo). **Resultados:** A idade média foi de 11 anos, e 75 (60%) eram meninos. A média do escore global do PAQLQ foi de 5.1, com efeitos mínimo/máximo < 10%. As correlações com os domínios do PedsQL 4.0 foram aceitáveis ($r = 0,37-0,40$). O coeficiente alfa de Cronbach do escore global foi 0,93, variando de 0,72 a 0,88 nos domínios. O tamanho do efeito global foi de 0,60 (variação: 0,45-0,60), e a correlação intraclass global foi de 0,80 (variação: 0,66-0,79). **Conclusões:** A versão oficial em português do Brasil do PAQLQ demonstrou boa performance psicométrica do instrumento, confirmando sua adequação para uso no contexto cultural brasileiro.

Descritores: Qualidade de vida; Asma; Estudos de validação.

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Introduction

The progressive use of health-related quality of life (HRQoL) measures, combined with more traditional clinical endpoints in medicine, has shown great potential for improving the health care of patients, particularly that of those with chronic conditions.^(1,2) When such measures have been developed in a country other than that in which they will be applied, the appropriateness of the validation process (translation into the local language and adaptation for use in the target cultural context) is as important as is the selection of the instrument itself.⁽³⁾

There are approximately eleven specific questionnaires designed to assess HRQoL in children with asthma.^(4,5) The most well-known and widely used of those is the Paediatric Asthma Quality of Life Questionnaire (PAQLQ).⁽⁶⁾ In 2001, the PAQLQ was supposedly validated for use in Brazil under the guidance of the MAPI Research Institute, a center specializing in the validation of HRQoL instruments. However, no study reported the results of this validation process. When queried, the MAPI staff stated that they had accredited only the linguistic component, having tested it in a small sample, consisting of 11 children (7-17 years of age).

Field testing is fundamental in the process of validating a questionnaire. It allows researchers to determine the psychometric properties and acceptability of the instrument, as well as its general applicability to cultural groups or subgroups.⁽⁷⁾ In order to meet the need for a full validation of this important questionnaire in the Brazilian cultural context, the aim of this study was to assess the psychometric properties of the PAQLQ in a representative group of Brazilian children and adolescents with asthma.

Methods

Between January and September of 2007, we enrolled a convenience sample of 125 children and adolescents with asthma, ranging from 8 to 17 years of age. Subjects were being monitored, via the Porto Alegre Asthma Program, at the pediatric pulmonology outpatient clinic of the *Hospital da Criança Santo Antônio*, in the city of Porto Alegre, Brazil. The participants had been diagnosed with asthma based on signs, symptoms, clinical course, and response to treatment. The classification of severity used

was that published in 2002 by the National Asthma Council Australia, which includes the following categories of asthma: infrequent episodic asthma, frequent episodic asthma, and chronic asthma.⁽⁸⁾ For the purpose of our study, we included only individuals classified as having frequent episodic asthma, who, accordingly, used inhaled corticosteroids on a regular basis. Those experiencing an exacerbation at the time of enrollment were not selected for inclusion.

We collected data related to the following variables: socioeconomic status; Fischer asthma control scale score⁽⁹⁾; FEV₁, expressed as the percentage of predicted, according to the reference values established by Knudson et al.⁽¹⁰⁾; and family functioning, as per the Family Adaptability and Cohesion Evaluation Scale III (FACES III).⁽¹¹⁾

In order to assess socioeconomic status, we used the Brazilian criteria, based on the 1997 Brazilian Association of Survey Firms scale.⁽¹²⁾ Using the scores obtained by combining educational and economic information, this scale identifies five socioeconomic categories, ordered from highest to lowest. The Fischer asthma control scale assesses disease control between follow-up visits.⁽⁹⁾ We used a modified version of that scale, applied during the retest visit. Scores range from 1 (in use of regular inhaled corticosteroids, with no exacerbations) to 4 (hospitalization due to exacerbation). Spirometric tests were conducted using a SpiroDoc® spirometer (Medical International Research, Rome, Italy), in accordance with the American Thoracic Society/European Respiratory Society recommendations.⁽¹³⁾ Pulmonary function was classified according to FEV₁ (% of predicted) as follows: normal (80-100%); mild obstruction (60-79%); or moderate obstruction (41-59%). The FACES III scale is a twenty-item scale that evaluates family functioning by combining two domains, cohesion and adaptability, which allow families to be classified as being at low, medium or high risk for psychological disorders. We used the Brazilian Portuguese-language version of FACES III, which has been validated for use in Brazil.⁽¹⁴⁾

The psychometric properties we studied were validity and reliability. Validity was assessed on the basis of convergent validity, evaluating whether the domains measured in the PAQLQ correlated well with equivalent domains in a

generic instrument, the Pediatric Quality of Life Inventory (PedsQL) 4.0.⁽¹⁵⁾ Both instruments were applied twice (test-retest) by means of standardized interviews, with 4-5 weeks between the two tests, in order to avoid recall bias.

The reliability of the PAQLQ was assessed by determining the following: internal consistency (specific correlations between items, total and by domain); sensitivity to change (whether the instrument is capable of identifying differences in HRQoL between interviews); and reproducibility (whether the instrument produces similar results at different time points, assuming that the conditions are the same).⁽¹⁶⁾ We also estimated the proportion of participants with the lowest and highest scores (floor/ceiling effect), in order to assess the discriminatory power of the instrument.⁽⁷⁾ This last parameter, which should be < 15%, contributes to assessing aspects of validity and reliability.

The PAQLQ is a specific instrument to assess HRQoL in individuals with asthma who are between 7 and 17 years of age.⁽⁶⁾ It can be self-administered or completed during an interview. For the purposes of the present study, we chose the latter option. Originally developed in Canadian English, the PAQLQ has been translated into over twenty languages and has been either partially or fully validated for use in the corresponding cultures.⁽¹⁷⁾ It has 23 items distributed in three domains: activity limitations (5 items), symptoms (10 items) and emotional function (8 items). Three items in the activity limitations domain are individualized for each patient, who chooses from a list of common activities/sports. All PAQLQ items are similarly answered by means of a 7-point Likert scale, ranging from 1 (severely affected) to 7 (unaffected). Items are then added, and their average represents the scores (total and by domain). The minimal important difference (MID) established for this instrument is 0.5 points.⁽¹⁸⁾

The PedsQL 4.0 is a generic questionnaire that was originally developed in American English.⁽¹⁵⁾ The version for the age group we studied has 23 items, divided into four domains: physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and school functioning (5 items). A fifth domain, psychosocial functioning, encompasses the scores for last three of the four primary domains. Each item has five possible answers on a Likert

scale, ranging from 0 (never) to 4 (always), values that are later transformed into an inverse linear scale from 0-100, a higher value indicating a better state. We used the Brazilian Portuguese-language version adapted and supplied by MAPI upon our request.

After the participants had completed the HRQoL questionnaires during the retest visit, we also applied a modified version of the Global Index of Change (GIC) questionnaire in order to assess overall change between the two interviews.⁽⁶⁾ The GIC questionnaire consisted of a single question regarding the state of the asthma in comparison with that at the time of the test visit, and there were seven possible answers on a Likert scale, ranging from 1 ("a lot better") to 4 ("about the same") to 7 ("a lot worse"). For the analysis, subjects were divided into two subgroups: "change", those who indicated either improvement or worsening between interviews; and "no change", those who did not perceive a change. This allowed us to test the sensitivity to change and reproducibility of the PAQLQ.

Data processing was carried out with the Statistical Package for the Social Sciences, version 13 (SPSS Inc., Chicago, IL, USA). To find an MID of 0.5 points in the PAQLQ total scores between the two interviews, the estimated sample size

Table 1 - Characteristics of the 125 patients included in the study.

Characteristic	n	%
Gender		
Male	75	60.0
Female	50	40.0
Pulmonary function		
Normal	102	81.8
Mild obstruction	23	19.1
Change between interviews ^a		
Change	106	84.8
No change	19	15.0
Family psychological risk		
Low	36	32.1
Medium	61	54.5
High	15	13.4
Socioeconomic status		
Very low	8	7.2
Low	37	33.0
Medium	56	50.0
Medium high	11	9.8
High	0	0.0

^aGlobal Index of Change.

Table 2 – Correlations of the Paediatric Asthma Quality of Life Questionnaire scores (Brazilian Portuguese-language version) with the Pediatric Quality of Life Inventory 4.0 scores (Brazilian Portuguese-language version) and demographic variables in the 125 participants.

Variable	PAQLQ scores, r (p)			
	Total	Domain		
		Activity limitations	Emotional function	Symptoms
PedsQL 4.0 domains				
Total	0.37 (< 0.001)			
Physical functioning		0.34 (< 0.001)		
Emotional functioning			0.40 (< 0.001)	
Pulmonary function				
FEV ₁	0.37 (< 0.001)	0.36 (< 0.001)	0.34 (0.001)	0.33 (0.001)
Age	0.47 (< 0.001)	0.40 (< 0.001)	0.45 (< 0.001)	0.42 (< 0.001)
Fischer asthma control scale	-0.22 (0.080)	-0.21 (0.097)	-0.14 (0.245)	-0.24 (0.051)
Global Index of Change	0.95 (0.323)	0.68 (0.481)	0.98 (0.308)	0.09 (0.346)
Adherence index	0.11 (0.240)	0.08 (0.401)	0.13 (0.179)	0.09 (0.329)
Socioeconomic status	0.18 (0.590)	0.24 (0.013)	0.18 (0.068)	0.08 (0.425)
Family cohesion ^a	0.11(0.270)	0.10 (0.277)	0.08 (0.361)	-0.10 (0.308)
Family adaptability ^a	-0.08 (0.425)	-0.07 (0.459)	-0.085(0.374)	-0.06 (0.562)

PAQLQ: Paediatric Asthma Quality of Life Questionnaire; and PedsQL: Pediatric Quality of Life Inventory. ^aAccording to the Family Adaptability and Cohesion Evaluation Scale III.

was 36 subjects, with alpha and beta errors set at 5% and 20%, respectively.

For each questionnaire, the two interviews were compared by means of paired t-tests. We used Pearson’s correlation coefficient (r) to determine the strength of the association between the instruments (total scores and similar domains). Values of r > 0.3 were considered acceptable. Correlations between the PAQLQ

scores and the various demographic variables were also assessed.

Internal consistency was estimated by calculating the Cronbach’s alpha coefficient for the PAQLQ during the test. The sensitivity to change was estimated by calculating the effect size of the differences between the two interviews in the GIC “change” subgroup. Reproducibility was estimated by determining the intraclass correlation coefficient (ICC) between interviews

Table 3 – Overall scores in the Paediatric Asthma Quality of Life Questionnaire (Brazilian Portuguese-language version): floor/ceiling effects and reliability results.

Variable	PAQLQ scores			
	Total	Domain		
		Activity limitations	Emotional function	Symptoms
Items, n	23	5	8	10
Theoretical score, range	1-7	1-7	1-7	1-7
Measured score, range	2.2-7	2.8-7	2.2-7	1.3-7
Mean ± SD	5.1 ± 1.1	4.9 ± 1.2	5.3 ± 1.3	5.2 ± 1.2
Floor effect, n (%)	0 (0)	0 (0)	0 (0)	0 (0)
Ceiling effect, n (%)	2 (1.6)	7 (5.6)	11 (8.8)	3 (2.4)
α-C, total	0.93	0.72	0.86	0.88
α-C, range ^a	0.93-0.93	0.65-0.71	0.83-0.85	0.86-0.87
Reproducibility ^b	0.80	0.66	0.79	0.74
Sensitivity to change ^c	0.60	0.60	0.56	0.45

PAQLQ: Paediatric Asthma Quality of Life Questionnaire; and α-C: Cronbach’s alpha coefficient. ^aRange of values by domain. ^bEffect size in the “Change” subgroup. ^cIntraclass correlation coefficient in the “No Change” subgroup.

Table 4 – The Paediatric Asthma Quality of Life Questionnaire scores: test-retest reproducibility and sensitivity to change.

PAQLQ score	Subgroup	Mean scores		Difference	p	ES	ICC
		Test	Retest				
Total	Change	5.10	5.78	0.68*	< 0.001	0.60	N/A
	No change	5.54	5.94	0.39	0.032	N/A	0.80
Activity limitations	Change	4.89	5.65	0.75*	< 0.001	0.60	N/A
	No change	5.41	5.94	0.53*	0.020	N/A	0.66
Emotional function	Change	5.27	6.01	0.74*	< 0.001	0.56	N/A
	No change	5.64	6.08	0.43	0.061	N/A	0.79
Symptoms	Change	5.13	5.67	0.54*	< 0.001	0.45	N/A
	No change	5.59	5.82	0.23	0.298	N/A	0.74

PAQLQ: Paediatric Asthma Quality of Life Questionnaire; ES: effect size; and ICC: intraclass correlation coefficient.

*≥ minimal important difference.

in the “no-change” subgroup. Cronbach’s alpha coefficient and the ICC values were considered adequate if ≥ 0.7 . To calculate the effect size, we used the method that includes the test and retest standard deviations. Conventional interpretation of effect size values is as follows: 0.2 = small; 0.5 = medium; and 0.8 = large.⁽¹⁶⁾

The study was approved by the review board of the institution, parents gave written informed consent, and the participants verbally agreed to be included in the study. Permission to use each of the questionnaires was granted by the corresponding copyright holders or their agents.

Results

A total of 125 children and adolescents participated in the study, and the mean age was 11 years. Males accounted for more than half of all subjects, and 82% of the participants had normal lung function. Most of the families (67.9%) were at medium or high risk for psychological disorders, and the socioeconomic status was low or very low in 40% of cases. Table 1 summarizes the characteristics of our study sample.

Table 2 shows how the PAQLQ scores correlated with the PedsQL scores and with the various demographic variables. The instruments correlated reasonably well with each other in terms of the total scores and the scores for equivalent domains, suggesting an acceptable convergent validity.⁽¹⁶⁾ Variables related to socioeconomic status or family risk correlated weakly with the PAQLQ scores.

The overall reliability and floor/ceiling effects of the PAQLQ are shown in Table 3. The mean PAQLQ total score was 5.18, the mean domain

scores being lowest (4.99) for the activity limitations domain and highest (5.20) for the asthma symptoms domain. Although none of the participants made the lowest possible score for the emotional function domain, some (8.8%) attained the highest possible score for that domain. The Cronbach’s alpha coefficient was 0.65 for the activity limitations domain, whereas it was ≥ 0.7 for all of the other domains, as well as for the homogeneity within each domain. For the two subgroups (“change” and “no change”), the changes over time were at acceptable levels (Table 4). In the “change” subgroup, the effect size was 0.6, and the ICC was 0.8 in the “no change” subgroup. The lowest values were for reproducibility in the activity limitations domain (0.66) and for sensitivity to change in the asthma symptoms domain (0.45). Differences between test and retest scores were greater than the MID in the “change” subgroup.

Discussion

The psychometric results of our field testing demonstrate the cultural adequacy of the official Brazilian Portuguese-language version of the PAQLQ, which can therefore now be considered validated for use in Brazil.

A different and independent Brazilian version of the PAQLQ was validated in 2005.⁽¹⁹⁾ Although there were some methodological objections,⁽²⁰⁾ the authors certainly made a great investment of time and resources to develop a thorough validation process starting from zero. However, the resulting version is not available and would not be applicable, since the original author of the PAQLQ allows the use only of MAPI versions.⁽¹⁷⁾ This added to the prevailing confusion

regarding the availability of a Brazilian version of the questionnaire, since the only published validation study of the instrument did not employ the official version, and the resulting questionnaire was not made available, because it was unauthorized. In addition, field testing of the official version has not been performed since 2001, and its psychometric adequacy therefore cannot be confirmed. We hope that our findings will overcome these misunderstandings.

There are similarities between our psychometric findings and those of the original English-language version, as well as between our results and those obtained in versions in other languages. A PubMed database search (March of 2009) for PAQLQ validation studies rendered 13 articles, 8 of which were cultural validation studies.^(19,21-27) Of those, there were two different reports of the validation of the Spanish-language version and one regarding the independent Brazilian version previously mentioned. However, among those studies, diverse methodologies were used to assess the properties. Although all fall within the broad classical test theory, the logic of their use (or the lack thereof) was not always explicit or explained in the studies. In a study conducted in Singapore, for instance, only the ICC was calculated⁽²¹⁾; in one of the studies conducted in Spain,⁽²⁴⁾ the sensitivity to change was assessed using the MID, just as the original author of the PAQLQ did in the original study, not associating effect size. Another group of authors provided only the internal consistency intervals.⁽²³⁾ In two other studies, only the convergent validity of the PAQLQ was reported^(23,27); only one study evaluated floor/ceiling effects⁽²³⁾; and we were surprised to find that, in another study, no psychometric assessment was performed, the authors justifying that omission by stating that they had found scores similar to those reported in the original PAQLQ study, and that that would be sufficient to consider their validation appropriate.⁽²²⁾ In a validation study, the number of validity and reliability components included should be sufficient to provide an overview of its psychometric performance.⁽⁷⁾

Correlations between the PAQLQ scores and FEV₁ were similar to what has previously been reported,⁽²⁴⁻²⁶⁾ and the lack of strong correlations is no surprise. With a better understanding of the different spectra encompassed by type and health measures, correlations on the order

of 0.3-0.4 between total scores on HRQoL instruments and FEV₁ are now considered adequate.⁽²⁾ However, unlike what would be expected,⁽²⁸⁾ socioeconomic status correlated weakly with the PAQLQ scores. Although 40% of participants were in the two lowest socioeconomic strata, the mean score for our sample as a whole was 5.1, out of a maximum possible score of 7, which suggests the group had an acceptable HRQoL. Proper functioning of health care microsystems could account for these particular results since they can have a positive impact on patient quality of life, as suggested in different studies, including that carried out in the city of Porto Alegre, Brazil.⁽²⁹⁾

Our study has some limitations. We had a smaller number of subjects in the subgroup of patients who reported no changes in their asthma-related health status. That might have limited our assessment of reproducibility. However, the reproducibility of their PAQLQ results was in accordance with their reportedly unchanged state. Our sample size, however, was larger than the estimated sample size needed in order to perform our core analysis, as well as being larger than those evaluated in other PAQLQ validation studies. The decision not to include cases of asthma that were more severe could be considered another limitation. Severe asthma is certainly a great challenge for clinicians and asthma control programs, but we preferred to include only the most important category in terms of epidemiology, frequent episodic asthma, which is equivalent to the sum of the mild persistent asthma and moderate persistent asthma categories outlined in the Brazilian Guidelines for Asthma Management.⁽³⁰⁾

In conclusion, based on our field testing, the Brazilian Portuguese-language version of the PAQLQ, developed by the MAPI in 2001, shows good convergent validity, internal consistency, sensitivity to change, reproducibility, and discriminatory power. Consequently, we can state that the psychometric performance of this version of the PAQLQ is acceptable.

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