0021-7557/05/81-01/54
Jornal de Pediatria

Adaptation and validation of the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) in Brazilian asthmatic children and adolescents

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Abstract

Objectives: To translate the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) into Portuguese and adapt it to the Brazilian context, for use in children and adolescents with asthma and to validate the adapted version of the questionnaire (PAQLQ-A).

Methods: Children and adolescents (7 to 17 years old) with asthma answered the PAQLQ-A on admission and were assessed using a clinical severity score. According to this score, patients were classified as mild ($\leq$ 2) or moderate/severe (> 2). They were reassessed on at least two occasions at an interval of 2 to 4 weeks. Furthermore, patients in whom asthma was properly controlled were classified as stable, and those in whom it could not be controlled, as unstable.

Results: The reproducibility of the PAQLQ-A was evaluated in stable patients by comparing the mean domain scores: symptoms, emotions, activities, and the overall clinical severity score on two predefined occasions with an interval of 15 to 30 days in between. Responsiveness was evaluated among unstable patients. The mean domain scores and the overall score were different on both occasions, and so was the clinical severity score. The validity of the questionnaire was determined by the application of Cronbach's alpha reliability coefficient (α = 0.909).

Conclusions: The translation of the PAQLQ into Portuguese did not modify the framework of the original questionnaire; the PAQLQ-A is easy to use, with easy reproducibility, constituting a valuable instrument for the evaluation of the quality of life in children and adolescents with asthma.

J Pediatr (Rio J). 2005;81(1):54-60: Asthma, questionnaire, validity, quality of life.

Introduction

In cases of chronic diseases such as asthma, criteria that allow for a thorough and comprehensive assessment and which do not only consider treatment, but also the complex nature of individuals, the disease and the relationship between them,[1] have been increasingly used.

Until recently, the main concern with asthma was related to the treatment of asthma attacks and their different severities, as well as to the prevention of recurrent episodes with environmental measures and drug therapy. With the advent of new and long-acting inhaled drugs, the prognosis of asthma has remarkably improved. Because of that, nowadays, our concern is to allow our asthmatic patients to lead a better life and improve their quality of life (QoL) day after day.

QoL varies among people, according to their expectations about the disease and about their life, and these expectations may change with time according to the

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Manuscript received Jun 16 2004, accepted for publication Sep 29 2004.

Suggested citation: La Scala CS, Naspitz CK, Solé D. Adaptation and validation of the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) in Brazilian asthmatic children and adolescents. J Pediatr (Rio J). 2005;81:54-60.

experiences undergone throughout the years.[2] QoL is determined by the perceptions of individuals about their status in life, in the cultural context (system of values) in which they are inserted and in the relationship of ideals, expectations, standards and worries, which change in response to the disease.[2]

In children, QoL used to be based on the conventional assessment of asthma severity, on pulmonary function testing, on the presence and intensity of the symptoms, on the need for medication and for discussion with the parents.[3] However, today, ample evidence exists that clinical parameters have a weak correlation with what a child is feeling and with how his/her daily functions are.[3] Some authors have described that parents may not appropriately perceive the QoL in their asthmatic children.[3,4]

Written questionnaires (WQ) have been the major tools for the assessment of QoL, and can be either general or disease-specific.[5,6] In general, disease-specific questionnaires have been more widely used since they are more sensitive and able to detect minimum changes in the health-related QoL of these patients.[5,7-11]

The Asthma Quality of Life Questionnaire (AQLQ) was one of the first WQ to be used in the assessment of QoL of adult asthmatic patients.[12] Based on clinical experience with the AQLQ and its adaptations, Juniper et al.[13] developed the Pediatric Asthma Quality of Life Questionnaire (PAQLQ), which was validated and published originally in English in 1996 and in other 20 languages after that.[3,14-18]

The PAQLQ consists of 23 questions (items) divided into three categories (domains): activity limitations (five questions), symptoms (10 questions) and emotional function (eight questions). With regard to physical activities, patients themselves select three of the activity limitation items. The answers, similarly to what occurs in the AQLQ, are assessed by way of a seven-point scale, where 1 indicates maximum impairment and 7, no impairment.[13]

After choosing the tool, it is important to make sure it has some properties so that it can be properly applied. It should therefore be valid, able to detect changes and it has to be reproducible.

The aims of the present study were to translate the PAQLQ into Brazilian Portuguese and adapt it for use in asthmatic children and adolescents; to check its validity, reproducibility and responsiveness to the adapted version of the questionnaire (PAQLQ-A).

Patients and methods

Patients

The study included children and adolescents aged between 7 and 17 years old (n = 56, 25 female individuals) regularly registered and treated at the Outpatient Clinic of Allergy, Department of Pediatrics of *Universidade Federal de São Paulo* (UNIFESP–EPM), from May 2002 to December 2003. All patients with intermittent or persistent asthma were selected, based on the definition and classification of disease severity of the Third Brazilian Consensus on the Management of Asthma.[19] Patients with history of recurrent pulmonary infection or with chronic disease that could interfere with the assessment of QoL, and those treated with systemic corticosteroids in the past two weeks or who refused to participate were excluded from the study. Based on the original study, we included at least 52 patients, since the original PAQLQ was validated with a similar number of patients.[13]

After admission, the patients were interviewed at predefined times: on admission, 15 days after inclusion, 30 days after the second and third interviews (we included an additional interview, compared with the original study, for validation of the PAQLQ).[13] Besides clinical evaluation, the patients were submitted to pulmonary function testing: forced vital capacity (FVC), forced expiratory flow between 25-75% of the FVC ($FEF_{25-75\%}$) and forced expiratory volume in first second (FEV_1) before and after bronchodilator use (Vitatrace VT – 130).

In each appointment, patients were assessed in terms of their clinical stability and proper use of medications. With these data, we established a clinical severity score (CSS): presence of nighttime symptoms, presence of daytime symptoms, use of inhaled ß-2 agonists more than twice a day, daily activity limitation, presence of expectoration, and FEV_1 below 80% of the predicted value.[13,20] The same score had been used by Juniper et al. for the validation of the PAQLQ in order to determine which patient had inadequately controlled asthma.[13] However, FEV_1 instability was less than 70% of the predicted value for these authors after bronchodilator use. Each item of the CSS was assigned one point and, according to the total sum (maximum = 6), the patients were classified as mild (≤ 2) or moderate/severe (> 2).

Besides this classification, the patients were assessed in terms of their clinical stability and were then subdivided into: stable (those remaining in the same CSS group) and unstable (those who changed groups, turning from mild into moderate/severe or vice versa).

All patients, as well as their parents and/or surrogates, were informed about the aims of the study. All those who agreed to participate signed an informed consent form. The study protocol was approved by the Ethics and Research Committee of UNIFESP – EPM.

PAQLQ - adapted (PAQLQ-A)

The PAQLQ was initially translated into Brazilian Portuguese, and then translated back into English by a language teacher who was not familiarized with the questionnaire. No discrepancy was observed between the original WQ and the translated version.

After being translated, the questionnaire was experimentally applied (pre-questionnaire) to 20 patients with (intermittent or persistent) asthma aged between 7 and 16 years old (mean 9.9±2.7 years), 13 of whom were male. After this assessment, five activities contained in the original WQ were removed for they are not part of the Brazilian culture (ball hockey, American football, skiing,

baseball and ice-skating). The other items were maintained according to the translation, but were organized in an order that facilitated its application (Figure 1). The new, translated and adapted questionnaire was called Pediatric Asthma Quality of Life Questionnaire – Adapted (PAQLQ-A) and the same scoring system (1 to 7) as that used in the original questionnaire.

Assessment of PAQLQ-A properties

The reproducibility of the questionnaire was evaluated at two different times (at an interval of 15 to 30 days), by the same observer, in stable patients. Both stable and unstable patients were used to check the validity of the questionnaire, also at two different times (at an interval of 15 to 30 days). Responsiveness was assessed by the variation of clinical parameters between two defined times and between the two groups analyzed (stable and unstable). In addition, consistency and reliability were calculated by the mean score for each of the domains and for each question separately.

Statistical analysis

After being collected, the data were exported to EXCEL 2000 and the statistical analyses were made using SPSS 11.0, INSTAT and Epi-Info 6.04. The following tests were used: chi-square test, Fisher's exact test, Wilcoxon's signed-rank test, Mann-Whitney test, Spearman's correlation test and Cronbach's alpha reliability coefficient.

Results

Of the 75 initially admitted patients, 56 were assessed at least twice at different times. Nineteen patients were excluded for missing their follow-up appointment (n = 14), or because they could not understand the questions (n = 5). Patient characteristics are shown in Table 1. There was a male predominance (54.4%) and age ranged from 7 to 17 years (mean of 11.4±2.1 years). Eight-six percent of them had persistent asthma and 14% intermittent asthma, with no significant differences between male and female patients. Among asthma-related diseases, 96.4% presented allergic rhinitis (Table 1). The use of inhaled corticosteroid was reported by 32 patients (57.8%) in their first medical appointment, with no difference between male and female patients (Table 1). Thirty-four patients (60.7%) were submitted to four interviews, 11 to two (19.6%) or three (19.6%) interviews at different times (Table 1), totalizing 191 assessments. However, during follow-up, several patients changed their asthma stability and were classified as stable or unstable at some time, thus, in the final assessment, 50

Table 1 - Demographic characterisitics of patients with asthma submitted to PAQLQ-A (n = 56)

Variables	Sex		Total	Statistical test	p
	Male (%)	Female (%)			
Sex	31 (55.4)	25 (44.6)	56		
Mean age (standard deviation)	11.7 years (±1.8)	11.2 years (±2.4)	11.4 years (±2.1)		
Age < 12 years	18	16	34 (60.7%)	$\chi^2 = 0.04$	0.842
Age ≥ 12 years	13	9	22 (39.3%)		
Clinical classification					
Stable	28	22	50 (69.4%)	$\chi^2 = 0.120$	0.730
Unstable	14	8	22 (30.6%)		
Intermittent asthma	3	5	8 (14.3%)		
Mild persistent	7	1	8 (14.3%)		
Moderate persistent	21	17	38 (67.8%)		
Severe persistent	0	2	2 (3.6%)		
Associated diseases					
Allergic rhinitis	30	24	54 (96.4%)	Fisher	0.697
Allergic conjunctivitis	6	3	9 (15.8%)		
Atopic dermatitis	2	2	4 (7.0%)		
Hives	1	0	2 (3.5%)		
Contact dermatitis	0	1	1 (1.7%)		
Food allergy	0	0	0		
Previous use of corticosteroid	15	17	32 (57.8%)	$\chi^2 = 1.45$	0.113
Number of interviews					
Four	22	12	34 (60.7%)	$\chi^2 = 3.01$	0.083
Three	4	7	11 (19.6%)	Fisher	0.077
Two	5	6	11 (19.6%)	Fisher	0.342

patients (69.4%) were regarded as stable at some time during the study and 23 (30.6%) as unstable, with no difference between male and female patients (Table 1).

In terms of reproducibility, stable patients were compared as to the mean score for each of the domains (MD): symptoms (MSD), emotional function (MED), activity (MAD) and overall score, and the CSS, at two different times T_A and T_B (at intervals of 15 to 30 days). No statistically significant differences were noted between MD and CSS at the two different times (Table 2). This did not occur with unstable patients (Table 2). Among the stable patients, the symptom domain (SD) showed a stronger negative correlation with the CSS ($rs = -0.527$ at T_A and $rs = -0.574$ at T_B). Statistical significance was observed for the other domains, but at lower levels.

The assessment of responsiveness by comparing MD at two different times showed statistically significant differences in all of them, and the same occurred with the CSS (Table 2).

The evaluation of the relationship between CSS and MD of the PAQLQ-A in unstable patients is shown in Table 3, wherein only the SD revealed a stronger correlation in both time periods ($rs = -0.488$ at T_A and $rs = -0.574$ at T_B). No statistically significant values were observed for the other domains, except for the overall score at T_B.

The reliability of the PAQLQ-A and its internal consistency were assessed by Cronbach's alpha coefficient for stable and unstable patients, yielding values of 0.923 and 0.869 respectively, and of 0.909 when they were assessed together, regardless of their clinical stability (Table 4).

Discussion

The assessment of asthma using only clinical parameters, such as pulmonary function testing, use of medications for symptom relief, intensity and severity of symptoms and airway response to methacholine, to carbachol and to cold, allow determining its severity and defining a treatment plan.[19]

Based on epidemiological studies, on the cost analysis and on the assessment of social and psychological aspects involved in asthma, it was hypothesized that the clinical assessment of asthma was indeed just one facet of the great impact it had on patients' lives and on society. Since the 1980s, the assessment of QoL has played a key role in the treatment and follow-up of asthmatic patients, and the term QoL has become a constant characteristic in the daily life of any individual.[21]

Studies on health-related QoL (general and specific) have enabled the development of tools that are able to assess asthmatic patients in an appropriate manner. The need for a specific tool to assess QoL in asthma has arisen from some peculiarities of this disease. First, because it is an episodic disease, and when properly controlled, the patient may stay asymptomatic for some time; otherwise, the patient may have extremely severe episodes. Moreover, acute exacerbations may be triggered off according to the season of the year or due to the presence of indoor or environmental allergens. For that reason, in order to assess QoL it is necessary to conduct longitudinal studies and to add questions related to past events (past week, past month, for instance), and to try to determine the intensity

Table 2 - Mean and median for each of the domains:symptoms (MSD), emotional function (MED), activity (MAD), overall score and clinical severity score (CSS) at two different times T_A and T_B (at intervals of 15 to 30 days)

	Stable			Unstable		
	Mean	Median	p	Mean	Median	p
MSD T_A	6.60	6.23	0.889	5.85	5.64	0.012 *
MSD T_B	6.70	6.15		6.80	6.43	
MED T_A	6.63	6.22	0.250	6.25	5.82	0.003 *
MED T_B	6.88	6.41		7.00	6.68	
MAD T_A	6.40	5.59	0.067	5.70	4.86	0.005 *
MAD T_B	6.50	5.97		6.50	6.11	
Overall T_A	6.36	6.01	0.116	5.81	5.44	0.001 *
Overall T_B	6.49	6.18		6.73	6.43	
CSS T_A	1.0	1.3	0.073	3.0	3.4	0.001 *
CSS T_B	1.0	1.1		0.5	1.0	

* Wilcoxon's test.

Table 3 - Relationship between clinical severity score (CSS) and mean score for each of the domains (MD): symptoms (MSD), emotional function (MED), activity (MAD), and overall score at two different times T_A and T_B - Spearman's correlation coefficient (rs), in terms of patients' clinical stability

	Stable		Unstable	
	rs	p	rs	p
CSS T_A x MSD T_A	-0.527	< 0.001	-0.488	< 0.05
MED T_A	-0.289	< 0.05	-0.393	0.07
MAD T_A	-0.398	< 0.01	-0.158	0.483
Overall T_A	-0.458	< 0.01	-0.380	0.081
CSS T_B x MSD T_B	-0.574	< 0.01	-0.574	< 0.01
MED T_B	-0.465	< 0.01	-0.399	0.06
MAD T_B	-0.477	< 0.01	-0.414	0.05
Overall T_B	-0.571	< 0.01	-0.470	< 0.05

Table 4 - Reliability coefficient (with 95% confidence interval) in all patients (stable and unstable) and alpha values

Patients	Simple measure intraclass	Intraclass measure	Cronbach's alpha reliability coefficient
All (95%CI)	0.303 * (0.227-0.404)	0.909 * (0.871-0.939)	0.909
Stable (95%CI)	0.343 * (0.256-0.455)	0.923 * (0.888-0.951)	0.923
Unstable (95%CI)	0.224 (0.132-0.382)	0.869 * (0.776-0.934)	0.869

* $p < 0.001$.
CI = confidence interval.

and frequency of symptoms or another evaluated parameter. Furthermore, the treatment of asthma has a weaker effect on the QoL; therefore, it is necessary to have more sensitive measures to assess such impact or to analyze a larger patient population.[22]

Based on these data, questionnaires were devised to assess the QoL in asthmatic patients. According to some researchers, the assessment of QoL in affected children must be carried out with the children themselves and not with their parents or surrogates, since the latter may not appropriately perceive how their child's QoL is impaired.[3,22-24] The questionnaires applied to children work better when the perceptions of children and their parents are assessed separately.

The PAQLQ was chosen among several questionnaires for the assessment of QoL in children because, in our opinion, it contains important and crucial aspects for the proper assessment of QoL in these patients. It proved useful in assessing physical (symptom and activity domains) and psychological (emotional domain) aspects. In addition, the PAQLQ was validated in its country of origin (Canada) and in many other countries, including those of Latin origin.[3,14,16,17]

Another reason for choosing this questionnaire was that PAQLQ-A is quick and easy to use. It took from 10 to 15 minutes to be applied, depending on the child's intellectual capacity and level of education, as well as on the time of the interview (the first interview usually was longer and the last one shorter). This finding was consistent with reports on the original and adapted questionnaires.[13,14,16,17]

The application of the PAQLQ-A in children aged 7 or 8 years was not an easy task, since, contrary to what occurred in other places where it had been validated, Brazilian children this age sometimes are not literate, and when they are, they have such a poor cultural level that they cannot understand the meaning of "moderately", "frustrated" or "uncomfortable." In this case, the terms were defined according to the standard Brazilian Portuguese dictionary so as to avoid information bias during data collection. With regard to other ages, there were no problems with the application of the questionnaire.

In our opinion, the exclusion of patients who were not able to read or who abandoned the study cannot be characterized as a selection bias (the association between exposure and outcome observed in the studied population is different from that which would be noted if all eligible

subjects had been studied),[25] since all patients were previously admitted to the study, but were excluded due to some setback. On the other hand, if we had included those patients who were not able to understand the questionnaire properly, we could have had a wrong impression about the analyzed questionnaire (information bias).[25]

Male predominance (1.24:1) was merely casual and had already been described by other authors in different studies.[26,27]

The prevalence of children with moderate persistent asthma in our sample (67.8%), comparatively to patients with mild intermittent asthma (14.3% both), reflects the situation in our setting, that is, a tertiary care hospital that only treats the most severe cases. However, only two patients with severe persistent asthma (3.6%) were included in the study, as severely ill patients are usually being treated with oral corticosteroids or immunosuppressive drugs, have some laboratory or anatomical pulmonary findings, or are still being investigated.

The reproducibility of the PAQLQ-A was assessed by applying the questionnaire to stable patients at two different times. No statistically significant difference was noted between the mean score for each of the domains in any of the time periods, that is, the score at T_A was exactly the same one found at T_B (Table 2). The CSS also was reproducible, since it did not vary over time. These findings allow us to conclude that the questionnaire is reproducible, that is, it yielded the same results after several applications to patients who showed no relevant difference.[28]

Another way to verify the reproducibility of the questionnaire was to use correlation coefficients, as the one proposed by Kirshner and Guyatt.[29] Table 3 shows the correlation between the CSS at T_A and T_B and the mean score for each of the domains at the same times.

We observed a strong negative significant correlation in the SD (rs = -0.527 at T_A; rs = -0.574 at T_B); in the other domains, the correlation was significant, but weak. Since the SD is more objective, it is probably more easily understood and more closely related to the patient's clinical status, thus showing a stronger correlation between CSS and MD.

The responsiveness was determined by studying unstable patients.[28] Table 5 compares the MD and CSS in each time period separately. The statistical analysis of both groups revealed statistically significant differences between the assessed parameters at T_A and T_B for all the items analyzed.

Spearman's correlation test was used to assess the presence of some correlation between the CSS and MD, in each time period, separately. The MSD (T_A and T_B) and MAD (T_B) had a statistically significant correlation (Table 3). This way, we showed that the PAQLQ-A assesses what it is supposed to; however, the weak correlation with clinical parameters may be a consequence of the small sample size.

General measures such as apparent validity and content validity were observed in the PAQLQ-A, which means that this questionnaire was able to assess QoL; besides, it also established a close relationship with the limitations imposed on an individual by the disease (content validity).

Another issue to be discussed is construct validity.[30,31] It consisted in comparing the PAQLQ-A with the CSS using Cronbach's alpha reliability coefficient and factor analysis.

Reichenberg & Broberg[17] applied the PAQLQ to Swedish children aged between 7 and 9 years and found a Cronbach's alpha coefficient of 0.92 for the overall mean score, 0.79 for the activity domain, 0.86 for the symptom domain and 0.84 for the emotional function domain. No difference was observed between male and female patients. Badia et al.,[16] in the Spanish version of the PAQLQ, found an alpha coefficient between 0.88 and 0.96. In our study, we obtained an alpha of 0.909 when we assessed all patients, and of 0.923 and 0.869 when stable and unstable patients were assessed separately (Table 4). These values corroborate the reliability of the PAQLQ-A.

Our conclusion is that the PAQLQ-A did not modify the original questionnaire in terms of structure; the adaptation of activities did not interfere with the application and properties of the PAQLQ. Moreover, the PAQLQ-A proved to be quick and easy to use and useful in assessing QoL. We may also say that the PAQLQ-A is valid, reproducible and responsiveness in asthmatic children and adolescents.

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