

Quality of Life of Asthmatic Children and Adolescents: Portuguese Translation,
Adaptation and Validation of the Questionnaire "Pediatric Quality of Life (PedsQL)
Asthma Module

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Keywords: Validation studies, questionnaires, quality of life, asthma, child,
adolescent

ABSTRACT

Objective: To translate, validate and verify the psychometric properties of the

Portuguese version of the instrument "Pediatric Quality of Life Asthma Module" (PedsQL Asthma) culturally adapted for the Brazilian culture.

Methods: After being translated to Portuguese and culturally adapted, the questionnaire was answered by 200 asthmatic children and adolescents (ages 2 to 18) as well as the adults responsible for them. Validation required the use of the following instruments, PedsQL Asthma Children (applied to children and adolescents), PedsQL Asthma Parents (applied to adults responsible for children and adolescents), Pediatric Asthma Quality of Life (PAQLQ), Asthma Control Test (ACT) or Childhood Asthma Control Test (C-ACT), as well as socio-economic and personal information questionnaires. A group of 45 clinically stable children repeated the questionnaires 15 to 60 days after answering the first questionnaire.

Results: Correlations between the scores of PedsQL Children and PedsQL Parents ($r=0.67$), PedsQL Children and PAQLQ ($r=0.66$) and PedsQL Parents and PAQLQ ($r=0.64$) were moderate and significant. Correlations were higher for males ($r=0.72$) when analyzing the children's and parents' answers to PedsQL according to gender. The 5- to 7-year old age group had the strongest correlations with PAQLQ ($r=0.79$). Cronbach's Alpha coefficient for PedsQL Children and Parents had values of 0.85 and 0.87, respectively. A high concordance was observed in both tests' at different times, with Kappa values of 0.89 and 0.87 for PedsQL Children and Parents, respectively.

Conclusion: The instrument used in this study was considered valid, consistent and reproducible and has acceptable psychometric proprieties for the Brazilian population.

Keywords: Validation studies, questionnaires, quality of life, asthma, child, adolescent

INTRODUCTION

Asthma is one of the most common chronic illnesses during childhood and constitutes an important public health issue. [1-3] The assessment of Quality of Life (QL) for asthmatic children has long been based on conventional measures based on the illness' severity, on lung function measurement, presence and intensity of symptoms and the need for additional medications.[4] The recent use of instruments to assess QL has shown great potential in improving asthma management.[5]

The most often used instrument to assess asthmatic children's QL globally is PAQLQ (Pediatric Asthma Quality of Life Questionnaire), a questionnaire applied to literate children and answered by the child. [6] PedsQL Asthma (Pediatric Quality of Life Asthma Module) has shown to be a possible alternative among other instruments used to assess children's QL, since it is a questionnaire validated for several languages with adequate psychometric properties, and which has been used in various studies. [7]

PedsQL Asthma has two versions, one self-applied, for children and adolescents (ages 5 to 18), with 28 multidimensional items covering the following domains: Problems with asthma (11 items), Problems with Treatment (11 items), Problems with preoccupation (3 items); and Problems with concerns (3 items); and a proxy version (answered by adults responsible for 2 to 18 year-old patients), comprising of 26 items covering the same domains. [8] Globally, PedsQL Asthma comes in second place in terms of its visibility among instruments used to assess QL in pediatric asthma. [9]

Relevant features which distinguish PedsQL Asthma from PAQLQ include: the option to be applied to a wider age range, a more concise application and the option of

applying the test directly to the child or through a proxy.[8] The latter feature is particularly interesting for pediatric questionnaires, since it allows assessment of the QL in preschool children and allows an alternative source of information for school-aged children, an age for which the acquisition of reliable data may be difficult.[7] To date, a single study has directly compared these two instruments, finding a strong correlation in their total scores ($r=0.74$).[8]

The importance of assessing QL in asthmatic children in clinical practice lies in the nature of the illness itself. The condition is characterized by its unpredictability and multiple recurrences and requires the patients' well-being to be assessed while in treatment, as well as a wider assessment of the impact of different domains of the illness on the patient.

The aims of this study were to translate and adapt to Portuguese (Brazilian culture) as well as validate the questionnaire Pediatric Quality of Life Asthma Module (PedsQL Asthma) for the Brazilian population, assessing the psychometric properties of this instrument.

METHODS

We obtained permission to translate, culturally adapt and validate the instrument PedsQL Asthma to Portuguese from Mapi Health Research e Commercialization, the company which holds its patent.[11] The authorizations for using the other instruments mentioned in this paper were also obtained. This study has been approved by the Research Ethics Committee of the institution, protocol # 430,221.

Translation

The questionnaire's translation followed the steps proposed by Mapi Research which are commonly used in the translation of questionnaires.[11] The questions were translated to Portuguese by two bilingual professionals, both English teachers whose native language is Portuguese. The concerned researcher (FPM) worked alongside a pediatric allergist, both of which have Portuguese as native language but are also fluent in English, in order to produce a "reconciled" version, consolidating both translations.

The second step was the back translation, during which the consolidated Portuguese version produced was translated back to English by a translator who had had no previous contact with the questionnaire and whose native language was English. When finished, the result of the back translation was compared to the original (English) version of PedsQL in attempt to identify misunderstandings, grammatical errors, translation errors or inaccuracies. This activity resulted in a second Portuguese version of the questionnaire, with all appropriate changes, which was later approved by Mapi Research.

Adaptation

The next step was an experimental application of the questionnaire to asthmatic patients. Individual interviews were held with six asthmatic children and their parents/responsible adults, all native Portuguese speakers, in order to verify the adequacy of the language used and the questionnaire's acceptance and understanding.

Validation of the translated version

Minimum sample size calculations were performed based on the correlation between PedsQL Asthma and PAQLQ, considering a minimum correlation of 0.5 between the final scores of both questionnaires.[8] According to this calculation, at least 46 patients from each age group would be needed for a bidirectional significance level (α) of 0.05 and a power of 95%.[12] We defined a sample size of 50 patients from each of the following age groups: 2-4 years old; 5-7 years old; 8-12 years old; and 13-18 years old, for a total of 200 patients.

The assessed patients and their respective parents/ responsible adults were selected among those regularly registered and monitored in the Allergy Clinic of EPM-UNIFESP's Allergy, Clinical Immunology and Rheumatology Department. In order to reduce possible selection biases, asthmatic patients were ultimately approached and invited until the necessary number of patients for each age group was reached.

The study included children and adolescents with intermittent or persistent asthma, regardless of their gender, without physical or mental comorbidities. Patients with other chronic illnesses which could have a negative influence on QL, such as cardiopathies, genetic disorders, kidney, degenerative or chronic pulmonary illnesses were not included.

The selected patients and their parents answered the PedsQL Asthma questionnaire (PedsQL Asthma Children and PedsQL Asthma Parents), respecting age-group-related differences: only parents/ responsible adults answered the questionnaire for children aged 2-4; both patients and parents/ responsible adults answered for ages 5 and higher. Furthermore, the PAQLQ questionnaire, the ACT (Asthma Control Test - for

patients aged 12 or older) or C-ACT (Childhood Asthma Control Test - for patients aged 4-11) and a socio-economic questionnaire were also applied, with clinical and demographic data collected from medical records.

Questionnaires were applied in separate rooms during interviews held by the same researcher (FPM) with the children/ adolescents and with the adults responsible for them.

All patients and their parents/ responsible adults were informed of the aims of this research. All adults signed a declaration of free and informed consent, as by all children aged 5 or older.

Assessment of PedsQL Asthma's properties

For the validation study, PedsQL Asthma scores were compared to the scores for the PAQLQ test, which is validated and is well-established for the Portuguese language.[6] Correlations between these instruments were calculated for total scores and for each domain. Correlations were not calculated for the 2-4 year-old age group, since PAQLQ does not cover these ages.

The reproducibility of PedsQL Asthma Children and Parents was assessed using concordance and correlation tests between two different times of application. The interval between the first and second interview varied between 15 and 60 days. For the second interview, we randomly chose 45 patients with return visits scheduled for up to 60 days after the first interview who agreed to answer the questionnaire a second time. We assessed only patients who had similar asthma control levels at both times (less than 3 points of ACT or C-ACT variation).[13]

The total score of the PedsQL Asthma Children and Parents questionnaires was stratified according to their intensity classification, varying between 1 and 5. This classification was made in accordance to the manual provided by the companies which hold the copyright of the instruments.

Statistical analysis

Data was transcribed to Microsoft Excel 2013 after its collection, and statistical analyses were performed using the software SPSS v. 18.0.

Due to the nature of the variables, non-parametric tests were used for data analysis: Spearman's Rank Correlation Coefficient was used for correlations, and Mann-Whitney and Kruskal Wallis for categorical variables. Concordance was assessed using the Kappa concordance test and Cronbach's Alpha reliability coefficient (α_C) was used to assess questionnaires' internal consistency. Separate analysis was performed according to gender, age group, respondent (child or parent) and PedsQL domains.

RESULTS

The translated and adapted version of the PedsQL Asthma questionnaire to Brazilian Portuguese showed to be easily applicable and understood by respondents, with an answering time of up to 5 minutes.

The clinical and sociodemographic characteristics of the studied patients and the social and demographic characteristics of their parents/ responsible adults are shown in Table 1.

The value of α_C for PedsQL Asthma Children calculated for all 28 questions was

0.85, while the value for PedsQL Asthma Parents (26 questions) was 0.87. The internal consistency was assessed separately by domain and age group can be seen in Table 2.

We found significant and moderate correlations between the total scores of PedsQL Asthma (Children and Parents, respectively) and the scores of ACT/ C-ACT ($r=0.49$ and $r=0.56$) and PAQLQ ($r=0.66$ and $r=0.64$), as well as between PedsQL Asthma Children and Parents ($r=0.67$).

Correlations between the domains of PedsQL Asthma Children and Parents, with each domain and the total value of PAQLQ and with ACT/C-ACT, can be seen in Table 3.

When correlating the domains of PedsQL Asthma Children and Parents, we found higher coefficients for the Asthma domain ($r=0.77$) than for Treatment ($r=0.59$), Concerns ($r=0.62$) and Communication ($r=0.46$).

In the assessment by gender, correlation coefficients between answers of children and parents were stronger for boys in the Communication domain ($r=0.53$ and $r=0.38$ for boys and girls, respectively) and in total scores ($r=0.72$ and 0.56 for boys and girls, respectively), while the opposite was seen in the Treatment domain ($r=0.53$ and $r=0.67$ for boys and girls, respectively). Strong correlations with parents' answers have been found for both genders in the Asthma domain ($r=0.74$ for boys and $r=0.77$ for girls).

Table 4 shows the correlation coefficients between children's and parents' questionnaires divided by age groups.

In the analysis by gender, we found significantly higher PedsQL Asthma scores

for boys in the Asthma (Children: 68 vs. 59; $p < 0.001$) and Concern domains (Parents: 100 vs. 83; $p < 0.001$), as well as for total scores (Parents: 76 vs. 73, $p < 0.001$).

When analyzing different PedsQL Asthma domains separately by age group, we found significant differences between parent and children scores only in the Treatment domain in the 5-7 years old (median: parents 86 vs. children 73; $p = 0.02$) and 13-18 years old age groups (median: parents 92 vs. children 86; $p = 0.03$).

When stratifying data by total scores, we observed agreement of 46% between the classification of PedsQL Asthma Children and PAQLQ, with a Kappa value of 0.24 ($p < 0.001$).

We observed a strong correlation in the reproducibility analysis of PedsQL Asthma Children and Parents when comparing questionnaires' answers at two distinct times, with correlations over 0.9 for all domains and for total scores.

When comparing PedsQL answers between both times, we noticed that 42 respondents of the PedsQL Asthma Children test maintained the same classification (93%), with a Kappa value of 0.89 ($p < 0.001$). In the answers of PedsQL Parents, 41 respondents had the same classification as in the first application of the questionnaire (91%), with a Kappa value of 0.87 ($p < 0.001$).

DISCUSSION

The translated and adapted version of the PedsQL Asthma questionnaire to Brazilian Portuguese showed to be easily applicable and understood by respondents.

We noticed a greater difficulty to understand the questionnaire in children in the 5-7 years old age group. Explanations of respondents' doubts and the faces scale included in the questionnaire were very helpful for this age group.[14] No differences in the comprehension of PedsQL related to respondents' socio-economic level have been identified in this study.

We observed some difficulties in applying the questionnaire's version for toddlers (ages 2-4) to adults responsible for them with regard to the Concerns and Communication domains, since parents and adults have trouble understanding these aspects in younger children. This issue has also been reported in previous studies.[14]

The predominance of male children had been reported previously in various studies, and probably reflects a greater prevalence of asthma among males in the pediatric population.[1,6,15] Regarding asthma severity, GINA treatment steps 3 and 4 were more prevalent, reflecting the reality of a tertiary healthcare environment.[6,16] Nonetheless, we were able to assess patients of all severity levels in this study.

Allergic rhinitis was the most prevalent comorbidity associated to asthma, present in 75% of studied patients. Similar observations have been reported by various authors.[15,17]

Assessment of the instrument's properties

Both apparent and content validation may be considered general proprieties of a questionnaire, and PedsQL Asthma has shown to have both: it is able to measure the QL of interviewed children and to relate it to limitations caused by asthma. Construction validation has been assessed by comparing PedsQL Asthma to PAQLQ, with a

moderate correlation ($r=0.66$ and $r=0.64$) identified between the questionnaires. The instrument's internal consistency showed α C values above 0.8 for both versions, agreeing with previous validations of PedsQL Asthma in other languages.[8,14]

The Portuguese versions of PedsQL Asthma Children and Parents showed moderate correlation with the already validated Portuguese version of PAQLQ. A moderate correlation is expected, since these instruments have different domains and cover different aspects of the disease. After dividing the scores of both questionnaires (PedsQL and PAQLQ) in five groups, both instruments have shown moderate concordance levels (according to the Kappa index), supporting the construction validation of PedsQL Asthma Portuguese version.

It is important to have more than one validated instrument to assess QL in asthmatic children, and this new instrument may fill gaps in the previous one, such as the possibility to be applied to both children/adolescents and parents.

The Asthma domain of PedsQL Children had a moderate correlation to PAQLQ's total score, and a strong correlation to PAQLQ's Activities, Symptoms and Emotional domains. Similar results were found when using the original version of this instrument. [8]

A moderate correlation was found between PedsQL Asthma and the Asthma Control Test (ACT or C-ACT). This had previously been found in other studies comparing a QL questionnaire to asthma control tests.¹⁸ High correlations were found between ACT/C-ACT and the Asthma domain of PedsQL, probably because this

domain deals with actual symptoms and exacerbations of the disease in a similar way than the control tests.

When analyzing the correlations between children's and parents' answers to PedsQL Asthma questionnaires, the highest values were found for the age range between 5-7 years old, while the lowest correlations were found for adolescents. Some authors had already observed low correlations between adolescents' answers and their parents' perception.[18]

We have found moderate and strong correlations between children's and parents' total scores in PedsQL Asthma for the Asthma and Concerns domains and weaker correlations in the Treatment and Communication domains. Similar results were found when using the original and the Chinese versions of PedsQL Asthma.[8,14] These findings support the importance of including both children's self-assessments and parent-directed questionnaires, since each of may present important, differing and complementary perspectives of a child's QL.[10]

When comparing parents' and children's answers in the different domains of PedsQL Asthma, we observed significantly higher values for parents in relation to children in the Treatment domain. This may be explained by parents' perception being based mainly on visible and easily perceptible clinical manifestations of asthma, such as coughing, dyspnoea and nighttime awakenings, while the Treatment domain also includes a number of subjective questions like fear of treatment and of doctor consultations.[19] Such divergences point to the need of measuring the perspective of both parts.

In the separate analysis by age group, patient and parent/adult scores in the Treatment domain showed larger differences in results for children aged 5-7 years old and adolescents (13-18 years old). This finding may be related to adolescents having greater difficulty in expressing their fears and urges to their parents.[19]

We found significant differences between QL scores of different age classes, with highest values for the 5-7 year-old children. This may be due to a reduction of QL in the emotional dimension after s entering preadolescence, period characterized by transitions in the school context, new development tasks, more responsibilities, new social and relationship challenges and also physical challenges, all of which may lead to social and emotional instability.[20]

It has been reported in the past that 8 year-old children tend to have lower QL than adolescents, since the latter are more physically capable and can perform various activities with more independence. Therefore, this age-group transition may be an important benchmark for efforts to promote the QL of these children.[20]

PedsQL Asthma's reproducibility was assessed by applying the questionnaire at two distinct times in patients whose health conditions was considered stable. In order to test the questionnaire's reproducibility, we also grouped results into five groups, as recommended in the Mapi research manual[11], and we verified that the answers maintained the same classification in almost the whole sample. This finding allows us to conclude that this instrument is reproducible, since it has been able to show the same result in clinically stable patients after repeated applications.

Possible limitation of this study is that we were unable to achieve a significant

sample of patients with important changes (3 points or higher) in the ACT/C-ACT tests, thus preventing assessment of the questionnaire's responsiveness. Moreover, all assessed patients were from the same health center. Therefore, despite the diversity seen in asthma severity, socioeconomic and cultural levels in our sample, we cannot assert as a fact that the group studied here is representative of the Brazilian population as a whole. The consecutive, nonrandom patient selection method may be a further limitation of this study and a source of potential biases. Nevertheless, we conclude that the Portuguese translation of the PedsQL Asthma instrument did not produce structural changes in the original questionnaire, and that its adaptation and validation for the Brazilian culture did not impair its original properties.

The translated instrument had moderate to high correlations to a previously validated and widely used test for assessing of the quality of life of asthmatic children and adolescents.

CONCLUSIONS

The Portuguese version of PedsQL Asthma, adapted for Brazilian culture, can be easily and quickly applied, and has been shown to be useful for evaluative purposes, as well as being reproducible when applied on stable patients. This instrument can therefore be considered a valid instrument for the assessment of the quality of life of asthmatic children and adolescents.

DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Table 1: Demographic and clinical characteristics of the patients and demographic characteristics of the parents.

Patients - Variables (N=200)		N(%)
Gender	Female	87 (43,5%)
Asthma control classification (ACT/C-ACT)	Not controlled (≤ 19)	78 (39%)
Asthma Step (GINA)	step 1	35 (17,5%)
	step 2	23 (11,5%)
	step 3	58 (29%)
	step 4	72 (36%)
	step 5	12 (6%)
Associated diseases	Allergic Rhinitis	150 (75%)
	Atopic Dermatitis	35 (17,5%)
	Allergic Conjunctivitis	16 (8%)
Body mass index	Extreme Thinness + Thinness	9 (4,5%)
	Eutrophic	121 (60,5%)
	Risk of overweight + overweight	50 (25%)
	Obesity + Severe obesity	14 (7%)
Parents and Responsible (N=200)		N(%)
Gender	Female	186 (93%)
Residence area	Urban	200 (100%)
Schooling	Elementary school (complete + incomplete)	85 (42,5%)
	High school (complete + incomplete)	92 (46%)
	Superior education (complete + incomplete)	21 (10,5%)
	$\leq 350\$$	30 (15%)

Familial income (dollars/month)	350 a 1000\$ ≥ 1000\$ NR	106 (53%) 10 (5%) 54 (27%)
NR- No response		

Table 2: Values of Cronbach's alpha coefficient (α_C) of PedsQL Asthma Children and PedsQL Asthma Parents separated by domains and age groups.

Internal Consistency - α_C		
Domains	Child	Parents
Problems with asthma	0.82	0.84
Problems with treatment	0.72	0.76
Concern issues	0.85	0.92
Problems with communication	0.92	0.91
Age Groups	Child	Parents
2-4 years	-	0.87
5-7 years	0.88	0.91
8-12 years	0.85	0.89
13-18 years	0.89	0.92

α_C – Cronbach's alpha coefficient

Table 3: Correlation coefficients between the domains of PedsQL Asthma Children (PC) and Parent (PP) and the domains and the total scores of the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) and the Asthma Control Test (ACT) and Childhood asthma Control Test (C-ACT).

PedsQL: domains			PAQLQ				ACT/ C-ACT
			Symptoms	Activities	Emotional	Total	
Asthma	PC	r	0.78 (0.71-0.84)	0.77 (0.77-0.83)	0.70 (0.61-0.77)	0.64(0.54-0.76)	0.73 (0.65-0.80)
		p	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	PP	r	0.75 (0.68-0.80)	0.72 (0.65-0.78)	0.70(0.62-0.76)	0.53(0.42-0.62)	0.76(0.70-0.81)
		p	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Treatment	PC	r	0.32(0.17-0.46)	0.38(0.23-0.51)	0.37(0.22-0.50)	0.34(0.19-0.47)	0.33(0.18-0.50)
		p	< 0.001	< 0.001	< 0.001	< 0.001	0.05
	PP	r	0.42(0.30-0.53)	0.43(0.31-0.54)	0.44(0.32-0.55)	0.33(0.20-0.45)	0.43(0.31-0.54)
		p	< 0.001	< 0.001	< 0.001	< 0.001	0.001
Concern	PC	r	0.34(0.19-0.47)	0.36(0.21-0.49)	0.27(0.12-0.41)	0.40(0.26-0.53)	0.18(0.02-0.33)
		p	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	PP	r	0.37(0.24-0.48)	0.40(0.28-0.51)	0.40(0.28-0.51)	0.38(0.26-0.49)	0.24(0.11-0.37)
		p	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Communication	PC	r	0.25(0.09-0.39)	0.24(0.08-0.39)	0.20(0.04-0.35)	0.23(0.07-0.38)	0.16(0.0-0.31)
		p	0.001	0.007	0.003	0.001	0.001
	PP	r	0.25(0.12-0.38)	0.25(0.12-0.38)	0.22(0.08-0.35)	0.26(0.13-0.38)	0.24(0.11-0.37)
		p	0.001	0.004	0.001	0.001	0.005

Strong correlations (> 0.7) highlighted in bold; r: correlation coefficient (95%confidence interval)

Table 4: Correlation coefficients between total scores of PedsQL Asthma Children (PC) and Parent (PP) with the notes of the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) as well as the Asthma Control Test (ACT) and Childhood Asthma Control Test (C-ACT), divided by age groups.

		PedsQL Child	PedsQL Parents	PAQLQ	ACT C-ACT
PedsQL Child	5-7 years r	-	0.76 (0.61- 0.86) (p <0.001)	0.79 (0.66- 0.88) (p <0.001)	0.70 (0.52- 0.82) (p <0.001)
	8-12 years r	-	0.63 (0.43- 0.77) (p <0.001)	0.63 (0.43- 0.77) (p <0.001)	0,24 (-0.04- 0.49) (p 0.15)
	13-18 years r	-	0.54 (0.31- 0.71) (p <0.001)	0.51 (0.27- 0.69) (p <0.001)	0.49 (0.25- 0.68) (p <0.001)
PedsQL Parents	5-7 years r	0.76 (0.61- 0.86) (p <0.001)	-	0.74 (0.58- 0.84) (p <0.001)	0.67 (0.48- 0.80) (p <0.001)
	8-12 years r	0.63 (0.43- 0.77) (p <0.001)	-	0.58 (0.36- 0.74) (p <0.001)	0.44 (0.19- 0.64) (p 0.02)
	13-18 years r	0.54 (0.31- 0.71) (p <0.001)	-	0.54 (0.31- 0.71) (p <0.001)	0.50 (0.26- 0.68) (p <0.001)

Legend: Strong correlations highlighted in bold; r: correlation coefficient (95% confidence interval)