

Validity of the Pediatric Asthma Quality of Life Questionnaire in Polish children

Iwona Stelmach¹, Daniela Podlecka¹, Paweł Majak¹, Joanna Jerzyńska¹, Rafał Stelmach², Anna Janas², Jan Krakowiak³ & Włodzimierz Stelmach³

¹Department of Pediatrics and Allergy, Medical University of Lodz, Lodz, Poland; ²Institute of Dental Surgery, Faculty of Medicine and Dentistry, Medical University of Lodz, Lodz, Poland; ³Department of Social and Preventive Medicine, Medical University of Lodz, Lodz, Poland

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Correspondence

Iwona Stelmach, MD, PhD, Prof.,
Department of Pediatrics and Allergy, N.
Copernicus Hospital, 62 Pabianicka Str.
93-513 Lodz, Poland.
Tel.: ++48426895972
Fax: ++48426895973
E-mail: alergol@kopernik.lodz.pl

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Abstract

Background: Although the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) was translated for use in Polish asthmatic children, it is necessary to confirm that its validity, reliability, and the accuracy of the responses are not influenced by culture difference. Therefore, the objective of this study was to validate the Polish version of the Pediatric Asthma Quality of Life Questionnaire.

Methods: This was a 9-week period cohort study. The patients were interviewed using the PAQLQ on four occasions: at baseline, 1 wk after inclusion, and after 5 and 9 wk. At each clinic visit, lung functions test and NO measurements were performed. Asthma control (according to GINA) was assessed throughout the study.

Results: One hundred and one patients completed the study. At all visits, moderate correlations (from $r = -0.51$ to -0.68) between all PAQLQ domains and the asthma diary were observed. We noticed a significant improvement in the understanding of the questions during the last visit compared to baseline. The gradient of correlation coefficients between the symptoms domain of PAQLQ and asthma diary was observed across study visits. The standards of reliability defined by Cronbach's α -coefficient (from 0.75 to 0.91) were fulfilled in all domains of the questionnaire, at all visits. We found a higher increase in PAQLQ score in patients who obtained asthma control compared to those who lost control during the study. There was no relation between PAQLQ and FeNO. At all visits, moderate correlations (from $r = -0.51$ to -0.68) were shown between all PAQLQ domains and the asthma diary.

Conclusions: We showed that Polish version of PAQLQ is valid and reliable among our study group. Moreover, as far as clinical practice is concerned, PAQLQ seems to be a useful tool for monitoring asthma in children especially based on the physician's grading of asthma severity according to GINA guidelines.

Quality of life assessments are used to measure the effectiveness of medical treatment and other interventions in improving patient functioning and adaptation to a chronic illness (1, 2). Asthma can impair children's participation in play, leading to social and emotional consequences, and finally result in the impairment of the Quality of Life (QOL) in children. Symptoms of childhood asthma are generally reported to correlate poorly with objective measurements (3), but distinction is usually not made with respect to asthma symptom. The Pediatric Asthma Quality of Life Questionnaire (PAQLQ) is the only available questionnaire referring to typical childhood issues and specifically developed and validated to measure

asthma control (4). It was developed by Juniper in English and has been translated and validated in many countries. It has been shown recently that PAQLQ results reflect clinical manifestations of asthma in children more accurately than objective measurements (5). Although PAQLQ was translated for use in Polish asthmatic children, it is necessary to confirm that its validity, reliability, and the accuracy of the responses are not influenced by culture difference. For this purpose, we conducted the present study. There is little agreement among researchers if a child's QOL can be used to classify asthma severity or to monitor treatment. However, it is believed that the use of a standard quality of a questionnaire will enable

clinicians to focus on the important dimensions of patient care, allowing them to develop a more relevant medical plan. Therefore, we tried to determine a correlation between the domains of the questionnaire and physical indicators of inflammation, such as fractional exhaled nitric oxide (FeNO) and lung function.

The first objective of this study was to validate the Pediatric Asthma Quality of Life Questionnaire among asthmatic children in Poland. Secondly, we sought to determine whether there is a correlation between the domains of the questionnaire and FeNO and Δ FEV1 in bronchial reversibility test.

Materials and methods

Subjects

One hundred and ten patients from the Pediatric Allergy Clinic were enrolled; all of them were diagnosed with atopic asthma (asthma as defined by GINA guidelines) (6) at least 6 months before. Patients aged between 7 and 17 yr were eligible.

Inclusion criteria

The patients experienced asthma symptoms during the week prior to enrollment with a score lower than 6.5 on the symptom domain of the Pediatric Asthma Quality of Life Questionnaire (7.0 = no impairment and 1.0 = severe impairment) (see Quality of Life Outcome Measures).

Exclusion criteria

Children with illnesses other than asthma but which might have an impact on health-related QOL (HRQOL), including children who suffered from recurrent chest infections requiring treatment with antibiotics, and those unable to perform reliable peak expiratory flow rates at home or requiring oral steroids during the previous 2 wk, were excluded from the study.

All patients were able to communicate directly with the interviewer and were capable of performing a reliable maneuver of PEFR and spirometry. A primary caregiver, usually a parent, accompanied each child to every clinic visit. The study was conducted between March 2007 and October 2009. The parents and patients (when appropriate) signed an informed consent. The study was approved by the Ethics Committee of the Medical University of Lodz, Poland.

Study design

This was a 9-week period cohort study. The patients visited the clinic at enrollment, at week #1, #5, and #9 (1, 4). At enrollment, they received instructions on how to record their symptoms and beta-agonist use, how to use the peak flow meter to measure lung function, and how to record values in their asthma diaries. Each patient received an asthma diary and a portable peak flow meter for recording morning PEFR

at home, 1 wk before each follow-up clinic visit. The patients were interviewed using PAQLQ by the same interviewer at all four visits, without the parents being present. At each clinic visit, there were two procedures performed: NO measurements and spirometry (one before bronchodilator administration and the other 20 min after it).

Asthma control evaluation

For the assessment of asthma control, long-term treatment objectives identified by the GINA working group (6) were adopted. A child was considered either under control or not under control in week #1 and #5 according to the guidelines (6–8). The patients whose asthma was adequately controlled continued to take their established asthma medications throughout the study. We considered asthma to be inadequately controlled when one or more of the following were present: incidents of night-time awakenings because of asthma symptoms, persistent waking with the symptoms in the mornings, limitation of normal daily activities, and/or a need for more than two puffs of an inhaled short-acting bronchodilator a day. The patients whose asthma was not adequately controlled at week #1 or #5 were referred to their asthma doctor to increase their controller medications.

Outcome measures

Pediatric Asthma Quality of Life Questionnaire

Health-related quality of life was assessed with the Polish version of PAQLQ by Juniper (4). PAQLQ is a disease-specific questionnaire consisting of 23 questions grouped into three domains:

1. Symptoms: questions 1, 3, 5, 7, 9, 11, 13, 15, 17, 20.
2. Emotional function: questions 2, 4, 6, 8, 10, 12, 14, 18.
3. Activity limitations: questions 16, 19, 21, 22, 23.

At each visit, the patients produced oral answers to questions concerning impairments that they had experienced during the week preceding the visit. The questions were read out by a trained interviewer. Responses to each item in the PAQLQ were demonstrated on a 7-point scale, where 1 represented severe impairment and 7 represented no impairment (4). The same rule was adopted for subgroups of questions. Individual items within the PAQLQ score were of equal importance, and the results were expressed as the mean score per item for each of the domains as well as for the overall quality of life. At each follow-up visit, the patients were shown their score from the previous visit. Differences in the PAQLQ score ≥ 0.5 were considered significant.

Assessment of the understanding of the questions

The understanding of the questions was categorized according to the following rule: (i) low level: great difficulty in understanding the question, (ii) moderate level: some difficulty in understanding the question, (iii) high level: the question fully understood. If the children had any difficulty understanding the content of the questions or the procedure of answering them, the physician present during the interview provided necessary explanations. The questions that proved

problematic for a relatively large number of children were classified as moderate level of understanding; the questions that did not require explanation at any time were classified as high level of understanding.

Asthma diary

Asthma diary is a tool based on the asthma control questionnaire by Juniper (1).

The asthma diary card employed in this study included daytime symptoms (completed at bedtime), incidents of nocturnal awakening (recorded in the morning upon awakening), and the number of puffs of as-needed β_2 -agonist. Daytime asthma symptoms and nocturnal awakenings were marked subjectively as follows: 0 = no symptoms during the day/night; 1 = very mild symptoms during the day/night; 2 = mild symptoms during daily activities/disturbing the night; 3 = moderate symptoms affecting daily activities/several sleep disturbances; 4 = quite severe symptoms during the day/frequent night disturbances; 5 = severe symptoms during the day/a great number of night disturbances; and 6 = very severe symptoms during the day/unable to sleep because of asthma. The use of β_2 -agonists was graded as follows: 0 = none; 1 = 1–2 puffs most days; 2 = 3–4 puffs most days; 3 = 5–8 puffs most days; 4 = 9–12 puffs most days; 5 = 13–16 puffs most days; and 6 = more than 16 puffs most days. The minimum score for each day was 0 (no symptoms during the daytime, no symptoms at night, and no use of β_2 -agonists). The maximum score was 36 (severe symptoms during the day and night, and the usage of the β_2 -agonists more frequent than 16 puffs most days) (1).

Clinical assessments

Lung function measurements

Pulmonary function testing was performed with a Master Screen unit (Erich Jaeger GmbH, Hochberg, Germany). Predicted values for all lung function variables were based on a previous study of healthy controls, provided by the manufacturer of the lung function test equipment (9, 10). Flow-volume curves were performed according to American Thoracic Society standards (11). The highest of three successful measurements taken was used in the study. The results were expressed as the percentage of a predicted value. Reversibility test was performed after the administration of salbutamol (200 μ g). Any changes in FEV₁, prebronchodilatory FEV₁, and PEF in comparison with baseline values (expressed in percentage terms) were taken into consideration in the overall analysis.

Nitric oxide measurement

The nitric oxide (NO) measurements were performed according to ERS/ATS recommendations (12) with a chemiluminescence analyzer (model 280i nitric oxide analyzer; Sievers, Boulder, CO, USA) and defined in parts per billion. The analyzer provides an on-line continuous measurement of NO in a single exhalation with a detection range of 0.1–500 ppb. Environmental NO was measured before and after each test,

and it never exceeded 5 ppb. All subjects were tested in the sitting position, without wearing a nose clip. The subjects exhaled at a constant flow rate (50 ml/s) from total lung capacity to residual volume without breath holding. They maintained a constant mouth pressure (17 cm H₂O) by monitoring a visual display to eliminate contamination from nasal NO. Dead space and nasal NO (reflected by the NO concentration peak during exhalation) as well as NO from the lower respiratory tract (determined by the plateau value after the peak) were recorded automatically using manufacturer's software. Three FeNO measurements of the plateau phase were obtained, with <10% variation. The mean value of three successive reproducible recordings was retained for statistical analysis.

Statistical analysis

To assess the validity of PAQLQ, the following properties of the questionnaire were analyzed:

1. Psychometric properties (referring to score distributions) – We checked whether the ceiling and floor effects occur with regard to PAQLQ and assessed its internal consistency using Cronbach's α -coefficient.
2. PAccuracy (validity) – It was determined by Pearson's or Spearman's rank correlation coefficients as appropriate.
3. PResponsiveness (referring to the ability of the instrument to detect changes of scores.) – It was assessed using Kruskal–Wallis test to determine the total difference in PAQLQ scores between the participants who obtained, maintained, or lost asthma control during the study.

All statistical calculations were performed using StatSoft Statistica for Windows, release 6.0 (StatSoft, Inc., Tulsa, OK, USA). A p-value of <0.05 was considered statistically significant.

Results

Demographics and baseline characteristics

One hundred and one patients completed the study. Nine patients withdrew the consent before week #1. Detailed characteristics of the participants are shown in Table 1. Sixty-four patients remained controlled during the period of the study, and 37 patients were classified as uncontrolled.

Ease of questionnaire administration

The interview lasted 20 min on average at a baseline visit and 10 min at each follow-up visit. We showed a significant improvement in the understanding of the questions during the last visit compared to baseline. The level of the understanding of the questions is explained in method section and presented in Table 2.

Psychometric properties

There was no evidence of the ceiling and floor effects for PAQLQ scores (Table 3). Reliability of PAQLQ was assessed

Table 1 Baseline characteristics

Gender M/F	75/26
Age [yr] mean $\pm$ s.d.	9.9 $\pm$ 2.6
Asthma diary [points], median (interquartile range)	6.2 (5.2–6.6)
FeNO [ppb], median (interquartile range)	16.8 (11.3–25)
FEV1 [% change]*, median (interquartile range)	4.4 (–1.6 to 12.3)
FEV1 [% predicted], mean $\pm$ s.d.	97.7 $\pm$ 13.6
PEF1 [% predicted], mean $\pm$ s.d.	85.0 $\pm$ 15.6
Asthma control	
Inadequately controlled	27
Controlled	74
Asthma treatment steps according GINA	
Second	23
Third	54
Forth/fifth	24

*% change from baseline in bronchial reversibility test.

Table 2 Comparison of the understanding of the questions between the baseline and the last study visit. Data are presented separately for each domain with the total number of questions (categorized according to the level of understanding) that the participants were asked

Domain	Level of questions' understanding	Visit		p-level (chi-square test)
		Baseline	Last	
Symptoms domain	Low	40	16	<0.001
	Moderate	228	114	
	High	732	870	
Activities domain	Low	14	4	<0.001
	Moderate	128	69	
	High	358	427	
Emotions domain	Low	26	18	<0.001
	Moderate	190	93	
	High	584	689	

via the analysis of its internal consistency. Cronbach's α -coefficients for all domains and at all visits ranged from 0.75 to 0.91, which indicates good reproducibility in asthmatic children.

Validity of PAQLQ

Correlations between PAQLQ scores in clinical assessments are presented in Table 4. At all visits, significant correlations (from $r = -0.51$ to -0.68) were shown between all PAQLQ domains and the asthma diary. Gradient of correlation coefficients between the symptoms domain of PAQLQ and the asthma diary was observed across study visits (see Table 2). We observed correlations between all PAQLQ domains and FEV1% predicted value at week #1 (visit 2) and a FEV1% change (in bronchial reversibility test) at week #9 (visit 4); activities domain also correlated with PEF at visit 2. We did not find any correlation between PAQLQ and FeNO nor between any other PAQLQ domains and clinical parameters. Finally, we found that PAQLQ scores and asthma control in children are strongly related. (Table 5). We observed that children with better control of asthma had higher PAQLQ scores at all visits in all three domains.

Table 4 PAQLQ validity among all patients presented as correlation coefficients (Spearman rank)

	Asthma quality of life scores in children		
	Symptoms	Activities	Emotions
Visit 2			
Asthma diary	–0.54**	–0.56**	–0.51**
FeNO	–0.16	–0.13	–0.11
FEV1 % change†	–0.07	–0.12	–0.11
FEV1	0.23*	0.30**	0.21*
PEF	0.19	0.30**	0.19
Visit 3			
Asthma diary	–0.57**	–0.55**	–0.63**
FeNO	–0.12	–0.02	–0.08
FEV1 % change†	–0.02	–0.10	0.00
FEV1	0.15	0.24*	0.19
PEF	0.10	0.13	0.09
Visit 4			
Asthma diary	–0.62**	–0.68**	–0.54**
FeNO	–0.05	–0.03	–0.17
FEV1 % change†	–0.20*	–0.20*	–0.20*
FEV1	0.18	0.12	0.15
PEF	0.12	0.11	0.08

* $p < 0.05$; ** $p < 0.01$, †% change from baseline in bronchial reversibility test.

Table 3 Score distribution and internal consistency of PAQLQ domains at the last visit

	Mean	SD	%max*	%min†	Range	25th	50th	75th	Cranbach's alpha
Symptoms	58.5	10.3	7.9	1.0	23–70	52	62	66	0.85
Activities	29.9	4.9	14.9	1.0	11–35	28	31	33	0.78
Emotions	48.3	8.2	14.9	1.0	21–56	47	51	54	0.79

*, † percentage of respondents with the highest/lowest possible score (ceiling/floor).

Table 5 Associations between PAQLQ domains and asthma control

	Levels of asthma control		p
	Inadequately controlled	Controlled	
Visit 2			
Symptoms	51.4 (7.8)	69.3 (0.9)	<0.001
Activities	25.4 (4.6)	34.4 (1.4)	<0.001
Emotions	42.4 (7.6)	54.8 (2.7)	<0.001
Visit 3			
Symptoms	53.1 (7.3)	69.5 (0.7)	<0.001
Activities	26.3 (5.7)	34.2 (1.8)	<0.001
Emotions	42.8 (9.4)	55.0 (2.1)	<0.001
Visit 4			
Symptoms	50.3 (7.8)	69.5 (0.7)	<0.001
Activities	25.0 (5.6)	34.6 (0.8)	<0.001
Emotions	40.0 (9.5)	55.6 (1.0)	<0.001

Longitudinal validity of PAQLQ

Table 6 shows correlations between the changes in scores of PAQLQ during visits 2 and 4 and clinical parameters. Weak correlations were found between clinical parameters (asthma diary, FEV1 and PEF) and the activities domain of PAQLQ, between FEV1 and the symptoms domain and between asthma diary and the emotions domain of PAQLQ; no other correlations were found.

Responsiveness

We compared the absolute change in PAQLQ between the participants who obtained, maintained, or lost asthma control during the study. We found a higher increase in PAQLQ score in patients who obtained asthma control compared to those who lost control during the study between week #5 and #9. This increase applied to all domains. Between week #1 and #5, the above differences were seen only in the activities domain (Fig. 1).

Table 6 Longitudinal PAQLQ validity among all patients presented as correlation coefficients (Spearman rank)

Change between visit 2 and 4 in	Asthma quality of life scores in children (change between visit 2 and 4)		
	Symptoms	Activities	Emotions
Asthma diary	-0.18	-0.26**	-0.22*
FeNO	-0.17	-0.08	-0.07
FEV1% change†	-0.07	-0.13	-0.11
FEV1	0.22*	0.24*	0.14
PEF	0.11	0.34**	0.13

*p < 0.05; **p < 0.01, †% change from baseline in bronchial reversibility test.

Discussion

We observed that PAQLQ responsiveness depends on the study period; the understanding of the questions was better toward the end of the study, at week #5 and #9. Our estimation on validity, reliability, and responsiveness appeared to be very close to other foreign trials, including the original Canadian trial (13–15). Our results confirm the link between PAQLQ score and the main clinical parameters in asthmatic school-aged children.

The Pediatric Asthma Quality of Life Questionnaire showed very good responsiveness. It was able to detect changes in patients who improved or deteriorated and was able to distinguish such patients from those who remained stable and showed a high index of responsiveness. For each visit during the trial, we found that all three domains of PAQLQ significantly correlated with the asthma diary and that all domains of the questionnaire demonstrated a weak but significant correlation with predicted FEV1 values. Our findings coincide with the results reported by Thai (13) and Spanish (15) researchers and also with the original questionnaire by Juniper (4, 16–18). A lack of correlation between PAQLQ domains and FEV1 predicted values was found in one Italian trial (14). Nevertheless, it is important to remember that a single measurement of FEV1 may not reflect child's condition during the week preceding the visit. We also found that all three domains of PAQLQ correlated weakly with bronchial reversibility test, which seems to be a more responsive parameter of asthma worsening, but that correlation was observed only during the last – week #9 – visit. The results of this study suggest that PAQLQ is not well understood at a week #1 visit in clinical practice.

A study on validity of the Swedish version of PAQLQ (19) showed a significant correlation between general PAQLQ scores and the symptoms score and also the percentage of a peak flow rate. Our findings did not show a similar correlation with the general score of PAQLQ, but we found weak correlations between: the activity limitation domain and clinical parameters (asthma diary, FEV1, and PEF), FEV1% values and the symptoms domain and finally between the emotional domain and the asthma diary. In the study of Farnik et al. (20), baseline spirometry showed correlation for lung function and Polish version of PAQLQ symptom and activity domains.

Estimating the ease of use of the Polish version of PAQLQ, we obtained a good average time taken for completing the questionnaire (20 min on enrollment and 10 min at each follow-up visit), which is similar to other researches. We also observed that younger children had some difficulty in interpreting the time frame as well as in differentiating between various response options on the 7-point scale. That last problem may stem from a very little difference in meaning between two close responses in Polish. That should be kept in mind especially while using the self-administered version of the questionnaire. Because of these language-related difficulties, the assistance of the interviewer was necessary in several cases. However, in the end, all children, including the youngest, were able to answer all 23 questions. Our results are the

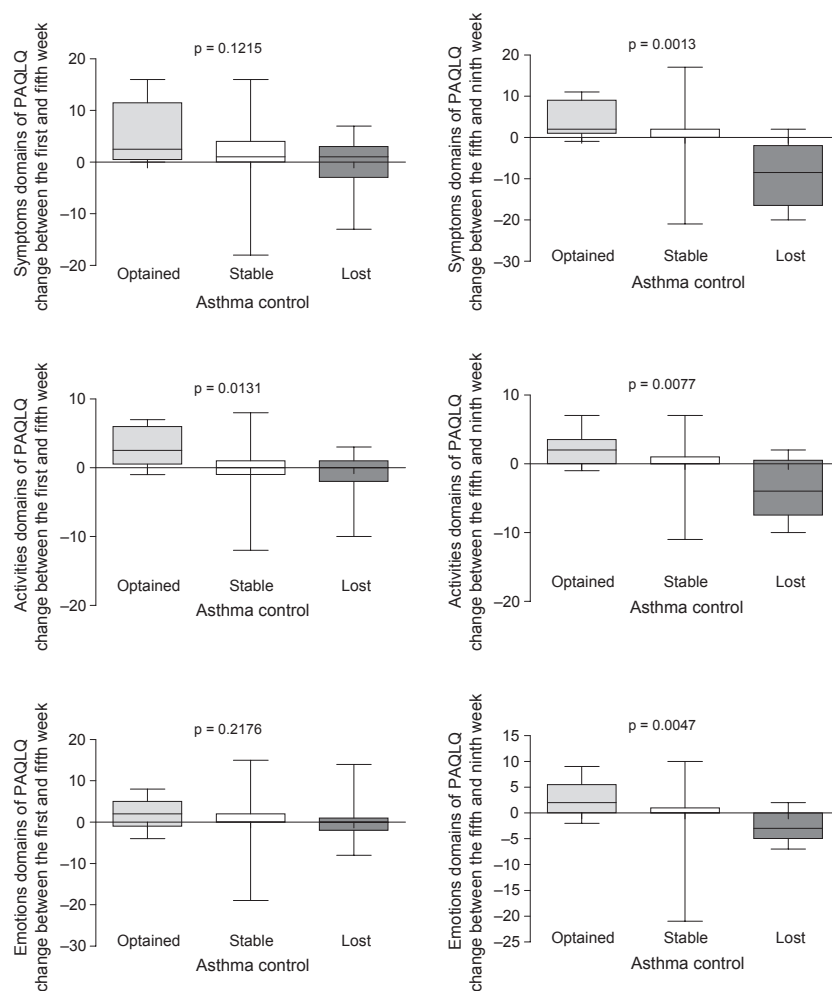


Figure 1 Comparison of an absolute change in PAQLQ between the participants who obtained, maintained, or lost asthma control during the study. Changes in PAQLQ were calculated between the first and fifth week, as well as between the fifth and ninth week of the study.

first to prove that the diagnostic value of PAQLQ increases with the frequency of use. It also accounts for the fact that PAQLQ is not well understood at week #1 visit in clinical practice, but its understanding increases with each follow-up visit.

To conclude, we showed that the Polish version of PAQLQ is valid and reliable among our study group. We suggest that PAQLQ performs well as a standardized instrument for clinical cross-sectional trials. However, PAQLQ also seems to be a useful tool in clinical practice for monitoring asthma in children especially based on the physician's grading of asthma severity according to GINA guidelines. The Polish version of PAQLQ proved to be a reliable, valid, and responsive tool for assessing QOL in Polish asthmatic children. However, some prospective modifications may be necessary,

especially taking into consideration the above-mentioned closeness of meaning between two responses on the answering scale.

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Conflict of interest

Authors declare no conflict of interest.

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