Qual Life Res (2005) 14: 265–272

Brief communication

Responsiveness, longitudinal- and cross-sectional construct validity of the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) in Dutch children with asthma

H. Raat[1,2], H.J. Bueving[3], J.C. de Jongste[4], M.H. Grol[5], E.F. Juniper[6] & J.C. van der Wouden[3]
[1]*Department of Public Health, Erasmus MC – University Medical Center Rotterdam (E-mail: h.raat@erasmusmc.nl);* [2]*GGD – Municipal Health Service, Rotterdam;* [3]*Department of General Practice;* [4]*Department of Pediatric Pulmonology, Erasmus MC – University Medical Center Rotterdam;* [5]*Department of Pediatric Pulmonology, University Hospital and University of Groningen, The Netherlands;* [6]*Department of Clinical Epidemiology and Biostatistics, McMaster University Medical Center, Hamilton, Ontario, Canada*

Accepted in revised form 19 February 2004

Abstract

Objective: Health-related quality of life is an important measure in evaluations of the management of childhood asthma. In this study, we assessed psychometric properties, responsiveness, and longitudinal and cross-sectional construct validity of the Dutch version of the 23-item Pediatric Asthma Quality of Life Questionnaire (PAQLQ). *Methods*: The study group consisted of 238 6–18-year olds with asthma, with complete respiratory symptom diaries in the course of one winter season; each child had one (or more) PAQLQ measurement(s) concerning one (or more) week(s) with relatively many symptoms (n = 238). Each child also had one PAQLQ measurement concerning another week with relatively few symptoms (n = 238). The PAQLQ scores of the 238 children for a week with few symptoms (the symptom diary scores remained below a predefined level everyday) were compared with their PAQLQ scores for another week with many symptoms (on day 1 of that week, symptom diary scores had been above the predefined level). Additionally, in a subgroup of the study group that had experienced two or more 'weeks with many symptoms' (n = 101), we compared the PAQLQ-scores for two different weeks with many symptoms of these children. *Results*: Only the domain Emotions showed a ceiling effect (>25% had the maximum score). All Cronbach's α's of the PAQLQ total score and domains were >0.70, except for Activities ($\alpha = 0.54$). Mean PAQLQ-scores were significantly different ($p < 0.01$; n = 238) between one week with few symptoms and another week with many symptoms. Contrary, in the subgroup of children with PAQLQ-measurements regarding more than one week with many symptoms (n = 101), mean PAQLQ-scores did not differ significantly ($p \geqslant 0.05$) between 1 week with many symptoms and another week with many symptoms. These results indicate responsiveness. (Changes in) lower respiratory tract symptoms, indicative of asthma severity, correlated better with (changes in) PAQLQ scores than (changes in) upper respiratory tract symptoms, which supports the longitudinal and cross-sectional construct validity. *Conclusion*: The assessed properties of the PAQLQ linguistic validation into Dutch were similar to those originally established for the PAQLQ in Canada. This study showed that the Dutch PAQLQ has adequate psychometric properties, excellent responsiveness, and that the longitudinal and cross-sectional construct validity is supported.

Key words: Asthma, Children, Health-related quality of life, Pediatric Asthma Quality of Life Questionnaire (PAQLQ), Responsiveness, Validity

Introduction

Health-related quality of life is an important measure, complementary to clinical and physiological parameters, in evaluations of the management of childhood asthma [1–9], a very prevalent chronic condition [10]. The Pediatric Asthma Quality of Life Questionnaire (PAQLQ), developed by Juniper et al., is a widely used disease-specific health-related quality of life measure for children and adolescents aged 7–17 years [3, 11]. It has three domains: symptoms (10 items), activity limitations (5 items), and emotional function (8 items) [3]. All items have seven response options. Usually, the mean item score (or change in mean score) is reported per domain and for the whole instrument. Scores range from 1 to 7, where higher scores indicate better quality of life [3].

The PAQLQ was first applied in Canada and has since been used in several other countries [3, 12–15]. A PAQLQ linguistic validation into Dutch was performed following a rigorous process including two independent forward and backward translations and a cognitive debriefing on 10 children with asthma [16–18].

This study aims to evaluate the Dutch PAQLQ by assessing:

(1) psychometric properties (score distributions to assess *floor and ceiling effects*; *internal consistency* of the domains; *test–retest reliability*);
(2) evaluative properties (ability to detect changes between periods with differences in reported respiratory symptoms as indicator of *responsiveness*; correlation coefficients between changes in reported respiratory symptoms plus other indices of severity and changes in PAQLQ scores as indicator of *longitudinal construct validity*) [19];
(3) discriminative properties (correlation coefficients between the level of reported respiratory symptoms plus other indices of severity at a point in time and PAQLQ scores at that time as indicator of *cross-sectional construct validity*) [19].

The PAQLQ cross-cultural adaptation into Dutch will be regarded as successful when the PAQLQ measurement properties are similar to those that were originally found in Canada and other countries [3, 12–15, 20].

Methods

Study population and data collection

The study group consisted of 238 6–18 year olds with asthma, with complete respiratory symptom diaries and multiple (at least 2) PAQLQ measurements during one winter season (1999–2000 or 2000–2001). Each PAQLQ measurement of a certain child in the study related to a different period of 7 days (i.e. 'week') during the winter season that the child participated. Each of the 238 children with asthma in the study had at least one PAQLQ measurement concerning a week with relatively many symptoms; and, additionally, all of the 238 children had one PAQLQ measurement concerning a week with relatively few symptoms (see below for definitions of many/few symptoms). The study population was drawn from 696 children with asthma selected from 144 general practices who participated in a randomized double-blind placebo-controlled trial of influenza vaccination [21]. During the year previous to inclusion, all had used asthma maintenance therapy or more than 52 doses of relief medication.

Socio-demographic variables, age at asthma onset, history of allergy, medication and FEV_1 were assessed at inclusion; we divided FEV_1 by predicted values to obtain FEV_1-% predicted [22]; the results are shown in Table 1. Upper- and lower respiratory tract (URT and LRT) symptoms and use of beta-agonists were recorded in the respiratory symptom diaries. URT symptoms included sneezing, runny/stuffy nose, burning/watery eyes, sore throat, hoarseness, fever/shivering, headache, and myalgia. LRT symptoms included cough and wheeze during day and night, difficult breathing or shortness of breath. The LRT symptoms are considered by clinicians to be related to the illness severity of asthma, while URT symptoms are considered to reflect the presence of infections, mostly of viral origin [21]. The URT and LRT symptoms, as listed per day in the diaries, were scored from 1 (mild) to 3 (severe); not fit to go to school/work because of symptoms was scored as 2 [21]. Per day, the symptoms-diary scores were summated separately for URT and LRT

Table 1. Characteristics of the study group (n = 238)

Variable	N	% of participants	Mean (SD)
Age group (years)			
6–10	137	57.6	
11–14	68	28.6	
15–18	33	13.9	
Mean (SD)			10.8 (3.2)
Gender			
Girls	121	50.8	
Mean age (years) at asthma onset (SD)			3.3 (3.5)
FEV_1 % predicted (*at inclusion*)			
$<80\%$	51	21.8	
$\geqslant 80\%$	183	78.2	
Mean (SD)			88.7% (13.7)
FEV_1 % predicted (*at a day with symptoms-diary-score below the predefined level*)			
$<80\%$	40	17.5	
$\geqslant 80\%$	189	82.5	
Mean (SD)			92.9% (14.2)
FEV_1 % predicted (*at a day with symptoms-diary-score above the predefined level*)			
$<80\%$	75	34.2	
$\geqslant 80\%$	144	65.8	
Mean (SD)			84.5% (19.2)
Child has history of allergy			
Yes	127	53.3	
Child has used inhalation steroids during 12 months prior to inclusion			
Yes	221	92.9	
Child born in the Netherlands			
Yes	236	99.2	
Parents sharing household			
Yes	224	94.1	
Educational level of mother			
Elementary school	7	3.0	
Secondary education	188	80.7	
Higher education/university	38	16.3	

symptoms; higher diary-scores indicate the presence of more reported respiratory symptoms on that particular day [21].

If URT or LRT scores totaled 4 or more on a certain day, participants were instructed to phone the research nurse, who – within 48 hours – assessed FEV_1-% predicted [22] and – after 7 days – assessed the PAQLQ for the preceding week (*referred to as a period with many symptoms*). The participants were also visited for 'baseline' assessments of FEV_1-% predicted [22] and PAQLQ evaluation over *a period with few symptoms* (7 consecutive days during which symptom diary scores were below 4 URT/LRT-points on all days).

Pairs of PAQLQ scores, made up of a period with few and a period with many respiratory symptoms, were established and assessed for the 238 participating children, with random selection of the period with many symptoms in the event a child had reported experiencing two or more periods with many symptoms. Additionally, in the study group of 238 children with asthma, a subgroup of 101 children was distinguished from

whom two (or more) different PAQLQ measurements of weeks with many symptoms had been obtained; two periods/measurements were randomly selected if a child had reported three or more periods with many symptoms. We evaluated pairs of PAQLQ-scores relating to two different periods with many symptoms for these 101 children.

Analysis

We assessed PAQLQ score distributions to evaluate *floor and ceiling effects*, arbitrarily defined as >25% of the respondents having the maximum respectively minimum score [23], and Cronbach's α's as measure of *internal consistency* of the domains [24]. *Test–retest reliability* was evaluated preliminarily by Intraclass Correlation Coefficients (ICCs) [25] between scores at two periods with many symptoms (n = 101; see Discussion). *Responsiveness* was evaluated by assessing the mean change in PAQLQ scores between a period with few and a period with many symptoms (n = 238). This was contrasted with the mean change between two periods with many symptoms (n = 101). Mean change was tested by two-sided Wilcoxon's signed ranks tests. Cohen's effect size was used to indicate the relative magnitude of change: d = [Mean(a) – Mean(b)]/SD concerning a period with many symptoms, respectively the 2nd measurement[1]. [26]. The mean change between few versus many symptoms was compared with the change between two periods with many symptoms; this was tested by two-sided Mann–Whitney U tests (unpaired test; all included children) as well as by two-sided Wilcoxon's signed ranks test (paired test restricted to the data concerning the subgroup of 101 children with multiple measurements). *Longitudinal construct validity* was evaluated by assessing Spearman rank order correlation coefficients between the change in URT/LRT-symptoms/beta-agonist use/FEV_1-%predicted and PAQLQ changes (n = 238). *Cross-sectional construct validity* was evaluated by assessing Spearman rank order correlation coefficients between URT/LRT diary-scores/beta-agonist use/FEV_1-%predicted and PAQLQ scores. This was performed for measurements relating to both periods with few symptoms (n = 238) as well as periods with many symptoms (n = 238); so, with regard to 476 measurements.

All analyses were done in SPSS, Version 10.0. Parents/children gave informed consent; the Medical Ethical Committee of Erasmus MC approved the study.

Results

Psychometric properties

There was no evidence of any ceiling or floor effect for the PAQLQ total score and the domain scores, except for the Emotional function domain (Table 2). Cronbach's α's of the PAQLQ overall score and the domain scores were all above 0.70 indicating excellent internal consistency, except for Activities ($\alpha < 0.70$) (Table 2). Test–retest ICCs between two periods with many symptoms, were generally low (defined as <0.50) or moderate (0.50–0.75), and one time excellent (>0.75) [27] (Table 3A).

Responsiveness

The mean change in PAQLQ scores between a period with few and a period with many symptoms was fairly stable across three age groups (total score: 0.79–1.11 points difference) (Table 3). The corresponding effect sizes ranged from 0.80 to 1.19 (indicating large effects), except for Emotions (0.40–0.50). PAQLQ-score changes between a period with few and one with many symptoms (n = 238) were significantly larger than PAQLQ-score changes between two periods with many symptoms (n = 101) ($p < 0.01$), indicating excellent responsiveness.

Longitudinal and cross-sectional construct validity

All correlation coefficients assessing construct validity in Table 4 were in the expected direction; however, all were either small (defined as <0.50) or moderate (0.50–0.75) [27]. (Changes in) lower respiratory tract symptoms, indicative of asthma severity, correlated better with (changes in)

[1]Following Cohen's guidelines, $0.2 \leq d < 0.5$ indicates a small effect, $0.5 \leqslant d < 0.8$ a moderate effect, and $d \geqslant 0.8$ a large effect [26].

Table 2. Score distribution and internal consistency of the PAQLQ domains with regard to a period with relatively few and a period with relatively many respiratory symptoms (n = 238)

PAQLQ domains	Mean (SD)	Range	% max. score[a]	% min. score[b]	25th %tile	50th %tile	75th %tile	Cronbach's α
Seven days with few symptoms: All 7 days had symptoms-diary-scores below[c] the predefined level (n = 238)								
Symptoms	6.09 (0.89)	2.50–7.00	12.6	0.0	5.76	6.30	6.70	0.86
Activities	5.67 (1.21)	1.20–7.00	16.0	0.0	4.99	6.00	6.67	0.61
Emotions	6.66 (0.68)	2.25–7.00	53.4[e]	0.0	6.63	7.00	7.00	0.86
Total PAQLQ score	6.19 (0.79)	2.61–7.00	8.8	0.0	5.85	6.42	6.78	0.88
Seven days with many symptoms: Day 1 had symptoms-diary-score above[d] the predefined level (n = 238)								
Symptoms	5.02 (1.22)	1.30–7.00	0.8	0.0	4.30	5.20	6.00	0.88
Activities	4.60 (1.25)	1.00–7.00	3.4	0.4	3.75	4.60	5.50	0.54
Emotions	6.22 (0.94)	2.25–7.00	25.2[f]	0.0	5.88	6.50	7.00	0.85
Total PAQLQ score	5.35 (0.99)	2.30–7.00	0.4	0.0	4.81	5.52	6.09	0.89

[a,b] Percentage of respondents with highest/lowest possible score (ceiling/floor).
[c] Summated upper- and lower respiratory tract (URT and LRT) symptom score-points per day were 3 or lower for URT as well as LRT symptoms on all 7 days.
[d] Summated upper- and/or lower respiratory tract (URT and LRT) symptom score-points were 4 or higher on the first day of the seven days for which the PAQLQ was completed.
[e] Profound ceiling effect (>50% of the participants had the highest possible score).
[f] Ceiling effect (>25% of the participants had the highest possible score).

PAQLQ scores than did (changes in) upper respiratory tract symptoms, which supports the longitudinal and cross-sectional construct validity. The Symptoms PAQLQ-domain showed the highest correlation coefficients with all indicators, except for FEV_1-%predicted.

Discussion

Evaluation of measurement instruments, including cross-cultural validation, is a continuous endeavor requiring studies in diverse clinical populations across countries [20]. This study, performed in a relatively large sample of children with asthma, supports the cross-cultural validity of the Dutch version of the PAQLQ. It showed psychometric properties and indicators of responsiveness and construct validity of the Dutch PAQLQ that were similar to those originally established for the PAQLQ in Canada [3] and later in other countries [12–15].

Limitations of our study include the sample and assessment of test–retest reliability and responsiveness. The study population that was sampled from general practices consisted mainly of moderate cases of asthma; we do not know the results in – sometimes more heterogeneous – hospital-based populations. The evaluation of PAQLQ test–retest reliability was only preliminary, as some of the children may not have been in a stable clinical state during one or both of the two different periods, each with many symptoms, that were evaluated; this may have contributed to the relatively low test–retest ICCs [3]. In order to evaluate the responsiveness of the PAQLQ, we contrasted PAQLQ mean score differences within pairs of weeks (per child, for all children in the study group) where 1 week of the pair had many and the other week had few reported diary-symptoms with, in a subgroup of the same children, the PAQLQ mean score differences within other pairs of weeks (per child in the subgroup) where both weeks within a pair had many reported diary-symptoms. In future studies, for the evaluation of responsiveness, we recommend adding other measures of disease stability than the number of reported diary-symptoms. Overall the measurement properties of the Dutch version of the PAQLQ were adequate and there were only two results that gave rise to some concern. (1) The Emotions domain showed ceiling effects, which may, to some degree, limit its use in detecting changes and describing health. (2) The internal consistency of the Activities domain was suboptimal in our sample (Cronbach's $\alpha < 0.70$), which may have contributed to the relatively low test–retest ICC in the youngest subgroup; we propose

Table 3. Responsiveness: assessment of the change as measured by the PAQLQ between two periods. (A) At day 1, both periods had a symptoms-diary-score above[a] the predefined level (n = 101; a subgroup of the whole study group of children with asthma that had at least 2 PAQLQ measurements concerning different weeks with many symptoms); (B) One period had diary-symptom-scores below[b] the predefined level on all 7 days; the other period had, at day 1, a symptoms-diary-score above[a] the predefined level (n = 238; these data were available for the whole study group)

	Change in quality of life scores[c]							
PAQLQ domains	(A) Comparison between 2 periods with both many symptoms				(B) Comparison between 2 periods with few vs. many symptoms			Difference A vs. B
	Mean change (SD)	*p*-Value [d]	Effect size (*d*)[e]	ICC between period 1 and 2[f]	Mean change (SD)	*p*-Value[d]	Effect size (*d*)[e]	*p*-Value[g]
All children (6–18 years)	(n = 101; i.e. a subgroup of the whole study group)				(n = 238; i.e. the whole study group)			
Symptoms	0.12 (1.28)	0.55	0.10	0.40**	1.07 (1.12)	0.00	0.88	0.00/0.00
Activities	−0.19 (1.34)	0.16	−0.14	0.40**	1.06 (1.26)	0.00	0.86	0.00/0.00
Emotions	−0.09 (0.78)	0.13	−0.11	0.56**	0.43 (0.76)	0.00	0.47	0.00/0.00
Total PAQLQ score	−0.01 (0.96)	0.57	−0.01	0.48**	0.85 (0.86)	0.00	0.85	0.00/0.00
Age 6–10 years	(n = 62)				(n = 137)			
Symptoms	−0.06 (1.22)	0.47	−0.05	0.42**	0.94 (0.93)	0.00	0.84	0.00/0.00
Activities	−0.33 (1.48)	0.08	−0.27	0.18	1.05 (1.31)	0.00	0.84	0.00/0.00
Emotions	−0.20 (0.80)	0.03	−0.25	0.57**	0.50 (0.79)	0.00	0.50	0.00/0.00
Total PAQLQ score	−0.16 (0.97)	0.10	−0.18	0.43**	0.81 (0.79)	0.00	0.84	0.00/0.00
Age 11–14 years	(n = 31)				(n = 68)			
Symptoms	0.52 (1.19)	0.03	0.45	0.34*	1.09 (1.32)	0.00	0.84	0.02/0.01
Activities	0.04 (1.00)	0.74	0.03	0.65**	1.01 (1.12)	0.00	0.92	0.00/0.01
Emotions	0.11 (0.76)	0.66	0.14	0.43**	0.27 (0.66)	0.00	0.40	0.03/0.34
Total PAQLQ score	0.28 (0.84)	0.10	0.29	0.52**	0.79 (0.89)	0.00	0.88	0.00/0.00
Age 15–18 years	(n = 8)				(n = 33)			
Symptoms	0.02 (1.81)	1.00	0.01	0.42	1.55 (1.31)	0.00	1.19	0.01/0.03
Activities	0.05 (1.28)	0.74	0.03	0.73*	1.23 (1.36)	0.00	0.80	0.05/0.35
Emotions	0.00 (0.71)	0.93	0.00	0.80**	0.50 (0.76)	0.00	0.44	0.10/0.12
Total PAQLQ score	0.01 (1.18)	0.89	0.01	0.66*	1.11 (1.03)	0.00	0.93	0.01/0.05

[a] Summated upper- and/or lower respiratory tract (URT and LRT) symptom score-points were 4 or higher on the first day of the 7 days for which the PAQLQ was completed.
[b] Summated upper- and lower respiratory tract (URT and LRT) symptom score-points per day were 3 or lower for URT as well as LRT symptoms on all 7 days.
[c] Scores are expressed as the difference in mean scores between the two periods: (A) Score regarding the 1st period minus score in 2nd period; (B) score regarding period with few symptoms minus score in period with many symptoms.
[d] Two-sided Wilcoxon's signed ranks test for differences between mean scale scores at two measurements.
[e] Difference of mean scores at two measurements divided by SD at the second measurement (A) respectively at the period with many symptoms (B); $0.2 \leqslant d < 0.5$ indicates a small effect, $0.5 \leqslant d < 0.8$ an intermediate effect, and $d \geqslant 0.8$ a large effect [26].
[f] Intra-class correlation (ICC) coefficients between PAQLQ scores regarding the first and second period with many symptoms as preliminary evaluation of test–retest reliability; * $p < 0.05$; ** $p < 0.01$.
[g] Two-sided Mann–Whitney *U*-test (unpaired test; all children)/two-sided Wilcoxon's signed ranks test (paired test restricted to subgroup of 101 children with multiple measurements).

to reevaluate the internal consistency of the Dutch version of the Activities domain in future studies.

This study showed that the Dutch PAQLQ has satisfying psychometric properties, excellent responsiveness, and that longitudinal and cross-sectional construct validity is supported. Issues that require attention are the consequences of the ceiling effects of the domain Emotions, the internal consistency of the domain Activities and the test–retest reliability of the Dutch PAQLQ.

Table 4. Longitudinal and cross-sectional construct validity of the PAQLQ (n = 238)

	Change in PAQLQ scores between 2 periods with few vs. many symptoms[a]			
	Symptoms	Activities	Emotions	Total PAQLQ score
Longitudinal construct validity (*Spearman rank order cor. coef.*)				
Change between 2 periods with few vs. many symptoms				
Change in upper resp. tract symptoms	−0.13*	−0.11	−0.04	−0.13
Change in lower resp. tract symptoms	−0.38**	−0.29**	−0.15*	−0.36**
Change in total number symptoms (U/LRT)	−0.31**	−0.22**	−0.09	− 0.28**
Change in β -agonist use	−0.25**	−0.18**	−0.17*	−0.24**
Change in FEV_1-%predicted	0.07	0.09	0.08	0.11
	PAQLQ scores at one point in time			
Cross-sectional construct validity (*Spearman rank order cor. coef.*)				
Combination of periods with few and many symptoms[a] (476 periods from 238 participants)				
Upper respiratory tract symptoms	− 0.46**	− 0.37**	− 0.28**	− 0.43**
Lower respiratory tract symptoms	− 0.55**	− 0.46**	− 0.35**	− 0.53**
Total number of symptoms (URT + LRT)	− 0.56**	− 0.47**	− 0.35	− 0.54**
β-agonist use	− 0.33**	− 0.24	− 0.21*	− 0.31**
FEV_1-%predicted (at day 1 of period)	0.17**	0.13**	0.16**	0.18**

[a] A period with few symptoms refers to a 7-days-period during which, on all days, the symptoms-diary-scores were below the predefined level. A period with many symptoms refers to a 7-days-period during which at the first day, symptoms-diary-scores were above the predefined level.
* $p < 0.05$; ** $p < 0.01$.

Acknowledgements

We acknowledge the careful cross-cultural adaptation of the Dutch PAQLQ by Isabelle Mear and co-workers, MAPI Research Institute, Lyon, France and Marion Grol (local coordinator) under supervision of Elizabeth F. Juniper. The Netherlands Organization for Health Research and Development (ZonMw), The Hague, The Netherlands funded the data collection within the framework of an influenza vaccination trial in asthmatic children. We thank the children, parents and general practitioners who took part in the study, and Annelies Kodde for help with statistical analyses. We are grateful to Marie-Louise Essink-Bot for her helpful comments on an earlier version of this manuscript.

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Address for correspondence: Hein Raat, Department of Public Health, Erasmus MC – University Medical Center Rotterdam, P.O. Box 1738, 3000 DR Rotterdam, The Netherlands
Phone: +31-10-408-7714; Fax: +31-10-408-9449
E-mail: h.raat@erasmusmc.nl