ASIAN PACIFIC JOURNAL OF ALLERGY AND IMMUNOLOGY (1999) 17: 155-161

Pediatric Asthma Quality of Life Questionnaire: Validation in Children from Singapore

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SUMMARY **"Quality of Life" is a multidimensional measure encompassing the physical, emotional and social functioning of the child. The asthma specific questionnaire contains 23 questions (items) in three areas (domains) of activity, symptoms and emotions. The objective of the present study was to validate the Paediatric Asthma Quality of Life Questionnaire "PAQLQ"(copyright 1991 McMaster University). If the questionnaire is valid, a change in the child's asthma will be accompanied by a change in the "Quality of Life" questionnaire score. The questionnaire was administered twice over four weeks and the child's asthma status was assessed concurrently. Two groups were thus identified; Group A = unchanged asthma, Group B = changed asthma. Forty-seven children, aged 7 to 14 years, completed the study. Reliability of the questionnaire shows an intraclass-correlation coefficient of only 0.71. Cross-sectional construct validity was demonstrated by a significant correlation between the whole questionnaire and the clinical asthma score ($p < 0.001$) but not in the separate domains. Longitudinal construct validity was also demonstrated by the significant correlation between change in the total questionnaire score, but not separate domains, with change in the child's asthma score ($p < 0.05$). Responsiveness was shown by a significant difference in the magnitude of the change in the questionnaire score between the two groups ($p < 0.001$), but again not in the separate domains. It was concluded that the questionnaire was validated as a whole but not in as convincing a manner, as has been done by others, and we are therefore in a position to advise caution in its application in our population.**

There has been tremendous interest in the measurement of "Quality of Life" in chronic disorders in both adults and children over the last two decades.[1-8] It is now an accepted; some argue an essential, endpoint in medical research in adults and is appearing more commonly in research relating to children.[9]

The term "Quality of Life" is in everyday usage in the English language. It is however, extraordinarily difficult to define the term to everyone's satisfaction. We accept the definition of Gill and Fernstein that "Quality of Life", is a multidimensional measure encompassing the physical, emotional and social functioning of the child. It should measure the uniquely personal perspective of an individual on his/her health status and encompass the non-medical aspects of his/her life.[10] Numerous generic Quality of Life questionnaires have been developed for a wide spectrum of conditions, covering oncology, cardiovascular and respiratory ailments and treatment modalities in order to measure this variable.[11]

Why should we measure "Quality of Life", in Pediatrics at all? It is recognized that survival data, alone, does not provide sufficient information in order to make treatment decisions, especially in chronic conditions where there is considerable morbidity but very rarely mortality. In addition, treatment plans for chronic conditions need to take into account the individual's own personal view of their

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illness and the impact that it has on their daily life. Asthma is the most common chronic disease in childhood and the prevalence is said to be increasing worldwide[12-14] and is, therefore, understandably, a focus for quality of life assessment.

In the past, a doctor took a comprehensive medical and social history to assess the impact of asthma on a child's life.[15] When done well, it provided an invaluable resource to the doctor. What it did not provide was a numerical value for use in follow-up or research. "Quality of Life", assessment may provide a way of comparing this variable over a period of time. Furthermore, pharmaceutical companies are now using "Quality of Life" assessment as an endpoint in research, to demonstrate drug efficacy.

The aim of this study was to examine the feasibility and usefulness of measuring Asthma Related Quality of Life in the children who attend our Children's Asthma Clinic, at the National University Hospital in Singapore. In order to do this; we used the easily accessible Paediatric Asthma Quality of Life Questionnaire, (copyright@1991 McMaster University).[16,17] Juniper *et al.*[18] developed and validated this questionnaire in North America and this has since been replicated in Europe. We set out to validate the questionnaire, when used in our paediatric population with asthma, in order to determine the potential for the questionnaire to be used in our future clinical practice and research.

MATERIALS AND METHOD

Children eligible for inclusion in the study had to be aged between 7 and 17 years, have a diagnosis of asthma for at least the preceding twelve months and able to read English. Children were excluded if they had other illnesses, which were likely to affect their quality of life or had recurrent chest infections requiring therapy with antibiotics. Parental consent was obtained and our hospital ethics committee approved the study.

The study design consisted of a 4-week cohort study with assessments at 1 and 4 weeks. The Paediatric Asthma Quality of Life Questionnaire (PAQLQ) was administered on the two assessments by the same trained interviewer. The child was interviewed without the caregiver present. The initial interviews were conducted, in a quiet room, in the children's clinic. Spirometry was done at the first interview but, unfortunately, not repeated at the second interview because the majority of these were done at the child's home.

The Paediatric Asthma Quality of Life Questionnaire (PAQLQ)

The PAQLQ contains 23 items in 3 domains: activity limitation (n = 5), symptoms (n = 10) and emotional function (n = 8).

In the activity domain, the child chose 3 activities, from a list, which were important to him/herself and limited because of asthma. The list of choices was slightly modified to suit a tropical climate. Skiing, tobogganing, ice-skating and climbing were changed to roller-blading/skating, skateboarding, gymnastics and long distance running. Ball hockey, football and "playing at recess" are not common activities in Singapore schools and therefore were replaced by badminton, school physical exercise (PE) and training for the National Physical Fitness Award, respectively. The term "irritable" was replaced by the term "easily angered".

The clinical asthma control score

This was a composite of asthma symptoms and β2-agonist use during the preceding week. One point is scored for each criterion fulfilled, on one or more days in the week. The criteria are: awoken by symptoms at night; awoken with symptoms in the morning; presence of sputum; limitation of activities; β2-agonist use more than 4 times per day and if the peak expiratory flow rate is less than 70% of the predicted value.

The Global Rating of Change Questionnaire

This assessed caregivers and children, individually, by simply asking about changes in their quality of life since the last clinic visit. Responses were scored on a 15-point scale ranging from: -7 (a very great deal worse), 0 (no change) to +7 (a very great deal better). It was administered on the second assessment.

Statistical analysis

To validate that the PAQLQ is a reliable tool in our population, it was assessed for discriminative and evaluative properties.

The discriminative properties were designed to distinguish between subjects at a single point in time. High reliability was measured by yielding the same results, in repeated applications, in an unchanged (clinically stable) population. It is demonstrated by showing a high ratio of differences in scores between patients (cross sectional comparison scores at first inter-

view) to that of scores within patients (paired comparison at first and second interview in the unchanged group). This is known as the intraclass correlation coefficient, which at best has a value of 1.

Cross-sectional construct validity was measured by the correlation between established rating scales and the PAQLQ. In this case, there is no accepted gold standard rating scale, therefore, the PAQLQ is being tested against the clinical asthma score, and the global rating of change for both child and caregiver.

Evaluative properties of the questionnaire were assessed by the responsiveness and the longitudinal construct validity, ie. ability to detect important changes, even if they are small.

To determine the clinical significance of the PAQLQ score, we calculated the minimal clinical important difference, which is the mean difference in scores in those who scored between -3, -2, +2 or +3 on the global rating of change. These global rating of change scores were taken as the "smallest difference, which patients perceive as beneficial and would mandate, in the absence of excessive cost, a change in the patient's management".[20]

Statistical analyses were carried out using SPSS for Windows (v9.01). Pearson correlation was used to determine the relationship between continuous variables, and Student *t*-test to compare means between groups.

RESULTS

We recruited 55 children of whom 47 completed the 2 interviews. Eight children who failed to complete the study did so for non-medical reasons and did not differ from the children who completed the study. The children were separated depending on whether or not their asthma remained stable. The asthma status was assessed on the basis of the change in score of the clinical asthma control score and the global rating of change scores given by the child and by the caregiver. Nineteen children were placed in Group A (unchanged), as their asthma was judged to be stable, over the 4-week study period, and 28 in Group B (changed) as their asthma changed over the time, either as a result of natural fluctuations in asthma or due to a change in inhaled medication. The demographic profile was similar between groups A and B; however, Group B had a higher proportion of children with more severe asthma (Table 1). There was improvement

Table 1. Group A & B. Distribution of the variables of sex, race, age, social class and classification of asthma

Category	Group A (unchanged)	Group B (changed)
n (47)	19	28
Sex: M/F	14:5	21:7
Race: C/M/ I	10:4:5	13:10:5
Age (mean ± S.D., years)	9.84 ± 2.00	9.96 ± 1.87
Social Class 1:2:3	11:4:4	10:9:9
Classification of asthma MI:MP:Mod P	12:3:3	11:7:10

M = Male, F = Female; M = Malay, C = Chinese, I = Indian
MI = Mild Intermittent, MP = Mild Persistent, Mod P = Moderate Persistent
Social classes 1 = legislators, managers, professionals (doctors)
2 = technicians, associate professionals (nurses)
3 = clerical workers and others (ref 24).

Table 2 Reliability of PAQLQ scores in children with stable asthma (Group A)

Domain	Within subject standard deviation	Between-subject standard deviation	Intraclass correlation coefficient
Overall QOL	0.51	0.81	0.71
Symptoms	1.10	1.06	0.48
Activities	0.78	1.02	0.63
Emotions	0.87	0.86	0.50

in the asthma status in 27/28 children in group B. Twenty-two children had a change in their inhaled corticosteroid medication during the study period; eleven in Group A and eleven in Group B.

The intraclass correlation coefficient is shown in Table 2. The highest value; 0.71 was obtained with the overall PAQLQ scores. There was significant correlation between total PAQLQ scores and the overall clinical asthma control scores (cross sectional construct validity) (Table 3). Of the individual components, only FEV1 and β2-agonist use, in the second interview, showed significant correlation. Furthermore, there were significant correlations when the change in the PAQLQ score was compared with the global rating of change (longitudinal construct validity) for both child and caregiver, and the change in clinical asthma score ($p < 0.001$) (Tables 4 and 5). The separate PAQLQ domain scores followed the same trend but did not demonstrate a statistically significant relationship.

The PAQLQ responsiveness was demonstrated because the total scores for groups A and B were significantly different. The separate domains followed the same trend but only the emotion domain showed a significant difference (Table 6). However, within Group A

Table 3 Correlation between PAQLQ scores with clinical asthma scores (cross sectional construct validity)

	PAQLQ Score	
Asthma Parameters	**Overall 1st visit**	**Overall 2nd visit**
Clinical asthma control	0.580[2]	0.370[1]
Spirometry (FEV1)	0.379[1]	Not recorded
β-agonist use	0.212	0.250[1]
PEFR (%)	0.160	0.146

[1]Significant ($p < 0.01$); [2]Significant ($p < 0.001$).

Table 4 Correlation between global rating of change and change in PAQLQ scores (longitudinal construct validity)

Mean Change in quality of life score per question	Global rating of change				
	-1, 0 and 1 (n = 15)	**-3, -2, 2 and 3** (n = 11)	**-5, -4, 4 and 5** (n = 14)	**-7, -6, 6 and 7** (n = 7)	**Significance**
Overall QOL (23)	0.5	0.82	1.35	1.79	$p < 0.001$
Symptoms (10)	1.18	2.07	1.76	1.31	$p < 0.382$
Activities (5)	0.88	1.05	1.28	1.57	$p < 0.339$
Emotions (8)	0.91	1.43	1.5	1.11	$p < 0.342$

Table 5 Correlation between change in PAQLQ scores and global rating of change and clinical asthma score (longitudinal construct validity)

	Change in PAQLQ			
	Overall	**Symptoms**	**Activities**	**Emotions**
Clinical asthma score	0.295[1]	0.46	0.76	0.59
Global rating of change	0.392[2]	0.176	-0.092	0.232
Caregiver's Global rating of change	0.359[1]	0.318[1]	0.152	0.265

[1]Significant ($p < 0.05$); [2]Significant ($p < 0.01$).

Table 6 Evaluation of responsiveness: ability of the PAQLQ to detect change

	Change in PAQLQ		
Domain	**Group A** (unchanged)	**Group B** (changed)	***P* value**
All patients	(n = 19)	(n = 28)	
Overall QOL	0.54 (12.6)	1.33 (30.8)	$p < 0.001$
Symptoms	1.3 (13)	1.77 (17.7)	$p < 0.193$
Activities	1.04 (5.2)	1.21 (6.05)	$p < 0.472$
Emotions	0.93 (7.47)	1.45 (11.6)[1]	$p < 0.048$

(unchanged), a statistically significant difference in the PAQLQ scores between the first (mean [SD] = 123.5 [18.7]) and second (mean [SD] = 136.0 [19.6]) assessment was also demonstrated ($p < 0.001$).

In our study, the minimal clinical important difference in PAQLQ score was found to be 0.82, but there was a lack of consistency across the separate domains, with a higher value for symptom (2.07) and emotion (1.43) domains. For moderate changes in quality of life (global ratings = 4 and 5) the mean change in score for overall quality of life was 1.35, with consistency across the domains. For large changes (global rating = 6 and 7), the mean change was 1.79, with consistency across the domains (Table 4).

DISCUSSION

In this study, we were able to validate the PAQLQ, as an instrument to measure quality of life in our local children with asthma. However, the reliability of the questionnaire was less impressive than we had expected. With respect to the questionnaire's discriminative properties, the highest intraclass correlation coefficient obtained was 0.71, for the overall PAQLQ score, with less impressive results for the separate domains (Table 2). In contrast, Juniper *et al.*,[17] originators of this questionnaire, demonstrated an intraclass coefficient of 0.95 overall, with the lowest value of 0.67, for the activities' domain, compared to our lowest value of 0.48, for the symptom domain.

When our results were compared with those of Juniper *et al.*[17] the cross sectional and longitudinal construct validities, although significant, showed far poorer correlation, overall and in individual domains. There is also a concern that in our study, the PAQLQ scores, between the two interviews for group A (defined as unchanged) were significantly different, indicating that other non-asthma variables may be affecting the scores in our children. This information was not available from other studies.[17,18] Our data did support Juniper *et al.*[17] on the point that in children, over eleven years, there is no benefit in taking a proxy assessment for quality of life assessment.[19] Although the children in our study were younger, our results still showed a better correlation between the total PAQLQ score and the child's global rating of change, than the caregiver's score.

The minimal clinical important difference aims to measure clinically significant changes in quality of life, as opposed to merely statistical significance.[17,20] Guyatt *et al.*[19] initially validated "the minimal clinical important difference". The value of 0.82 per item for the overall quality of life measurement means that a difference of 19 points (0.82 x 23 questions), between the two scores, is required for the change to be considered clinically significant. This was much larger than that obtained by Juniper *et al.*[17] and Jaeschke *et al.*[20] who reported a minimal clinical important difference of 0.42 and 0.5 per item, ie. 10 points difference for the overall quality of life score.

The PAQLQ was developed and validated in Canada, and it is said that there is now no need to seek to validate the questionnaire in a foreign setting.[21] Our results dispute this point of view and indicate that questionnaires need to be validated in the population they are to be used in. Further evidence for this is given by the Child Asthma Questionnaire, which was designed in the UK, but showed substantial

differences when tested in an Australian population of children.[22]

Failure to reproduce Juniper's excellent results may have been due to insufficient power. Although we recruited a similar number of children, we were only able to follow our patients for a second visit and not a third as was done in her study.[17] Our number of observations was therefore less. This was due to both time and financial constraints.

The design of the questionnaire may have contributed to our difficulties in validation, eg. the language used to grade the responses. Children, as young as seven, are asked to differentiate between, "Quite bothered", "somewhat bothered" and "bothered a bit". These responses are unchanged from the initial adult version of the questionnaire, from which the pediatric version was modified.[23] Younger children also had difficulty understanding the concept of "last week". There is also a lack of age-specific questions, which fails to address the differences in maturity of an eight-year child compared to a 14-year-old teenager. The PAQLQ also lacks comprehensiveness because it does not address the social impact of asthma in childhood, eg. problems with school attendance, peer pressure, teenager's smoking habits or teenager's embarrassment taking medication.

There are also practical problems with the PAQLQ. The questionnaire took an average of 20 minutes to complete during the first visit and 10 minutes, on the second visit. The total time required of the family could be longer because of the time needed to obtain informed parental consent. A quiet room is also required for use by a trained interviewer. This all leads to an increase in the cost of health provision.

A further limitation of the data is the robustness of the measures that the PAQLQ is being correlated with. For example, the "clinical asthma score" is a composite of historical symptoms and is therefore dependent on the child's recall of the previous week. The "global rating of change", is not a criterion or Gold Standard of change but it was used as an anchor to calculate "The minimal clinical important difference".

In conclusion, asthma is a common chronic disease of childhood and while death from the disease is rare, the morbidity caused by it is considerable. There are obvious advantages to be gained from measurement of the impact of the disease on the child and family. Defining, standardising and quantifying a Quality of Life measurement will help clinicians determine improvements in patient care, even when this is not accompanied by an appreciable improvement in the severity of the disease state.

The science of assessing Quality of Life, in chronic medical conditions in children, is expanding and developing. It will undoubtedly become part of our clinical assessment in the future but we feel at present needs further evaluation. This study did validate the PAQLQ questionnaire but not in as convincing a manner as was previously done.[17,18] In view of this, we are in a position to say that further validation of the questionnaire in our population will be necessary and modifications may have to be implemented before it can be used for clinical or research purposes.

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