Reliability and validity of the Sinhala version of the PedsQL™ 3.0 Asthma Module in early adolescents with asthma in a district of Sri Lanka

M N Danansuriya[1], L C Rajapaksa [2], J W Varni[3],

Abstract:

Objective:
To examine the psychometric properties of the Sinhala version of the Pediatric Quality of Life Inventory™ (PedsQL™) 3.0 Asthma Module among adolescents with asthma in Sri Lanka.

Methods:
The PedsQL™ 3.0 Asthma Module patient self-report and parent proxy-report were translated into Sinhala and conceptually validated. A cross-sectional study was conducted among 140 adolescents (12-15 years), with physician diagnosed asthma and their caregivers (n=140). Reliability was assessed with Cronbach's alpha. Validity was evaluated by examining scale structure, by exploring interscale correlations and comparing across known groups.

Results:
PedsQL™ Asthma Module - Sinhala version was acceptable with minimal missing responses. All scales showed satisfactory reliability with 0.87 for the total scale scores for both patient and parent reports. Overall results of the multitrait scaling analysis confirmed the scale structure. Construct validity was confirmed by the inter-scale correlations between the domains for teen self-report and between teen and parent reports. The PedsQL™ Asthma Module showed convergent validity with PedsQL™ 4.0 Generic Core Scales and was able to discriminate adolescents with controlled and uncontrolled asthma

Conclusion:
The PedsQL™ 3.0 Asthma Module- Sinhala version is a reliable and valid instrument to measure asthma-specific health related quality of life among adolescents with asthma in Sri Lanka.

Key words: PedsQL™, Asthma, Sri Lanka, Adolescents, Health related quality of life

Introduction:

Asthma is one of the common chronic diseases affecting children globally and in Sri Lanka [1-5]. Asthma has been identified as the 3rd leading disease in the assessment of the burden of diseases in Sri Lanka [6] and a major reason for school absence among primary school children [7].

Not only the presence of asthma but also its management strategies impose a significant impact on individual's quality of life [8-11]. The physical and psychosocial consequences of having a chronic illness like asthma are more profound among adolescents due to the nature of "adolescence" [12]. Health professionals routinely rely on clinical or physiological measures and often fail to identify or address the psychosocial issues related to disease. The importance of including a measure which captures the total impact of the disease on an individual encompassing his/her perceptions of wellbeing in outcome evaluation is increasingly recognised. Health Related Quality of Life (HRQOL) measures have been used to capture the effects of an illness on the well being of individuals in health care practice and research [13]. In evaluating HRQOL aspects of asthma, disease-specific measures are considered over generic measures as those tools provide details on the distinctive impact of the disease and its management on an individual's life [14, 15]. Lack of a culturally validated tool has been a limiting factor in measuring the impact of asthma on adolescent's HRQOL in Sri Lanka. Therefore, this study has been planned to examine the psychometric properties of an asthma-specific HRQOL instrument with the objective of future application in clinical and research settings.

The Pediatric Quality of Life Inventory™ (PedsQL™) 3.0 Asthma Module (Available from: http://www.pedsql.org/) was selected considering its brevity, modular approach and the availability of age appropriate versions in both self-report and parent proxy-report versions [16] . Our objective was to assess the psychometric validity and reliability of the Sinhala version of PedsQL™ 3.0 Asthma Module in a sample of adolescents with asthma in Sri Lanka. To our knowledge, this is the first assessment of an asthma-specific HRQOL instrument in a sample of adolescents in Sri Lanka.

1. Consultant Community Physician ,Family Health Bureau, Colombo
2. Professor in Community Medicine (Retired) University of Colombo
3. Professor and Vice Chair for Research Department of Paediatrics, College of Medicine ProfessorDepartment of Landscape Architecture and Urban Planning,College of Architecture, exas A&M University, College Station, TX, USA

Methods

Participants and settings

This study was conducted between January and April 2008. The sample size was estimated based on testing the hypothesized scale structure using multivariate analysis techniques. The minimum sample size required for this 28-item instrument is 140 asthma patient-parent pairs [17]. Asthma patients aged 12-15 years were accrued from asthma clinics from four university hospitals in Sri Lanka. Physically/mentally disabled; presence of other co-morbidities; unable to understand the Sinhala Language were excluded. The questionnaires were given during the clinic waiting time, in the presence of a trained research assistant (RA) after obtaining the informed verbal consent from the parent/guardian and the adolescent. They were asked to complete the questionnaire independently and discussions were discouraged. This study was approved by the Ethics Committee of the Faculty of Medicine, University of Colombo, Sri Lanka.

Measures

The 28-item multidimensional PedsQL™ 3.0 Asthma Module includes four scales: (1) Asthma symptoms (11 items), (2) Treatment problems (11 items), (3) Worry (3 items) and (4) Communication (3 items). It has parallel child self-report and parent proxy-report formats for separate age groups. Questions ask how much of a problem each item has been during the past month and responses are made on a 5-point scale ranging from 0 (never a problem) to 4 (almost always a problem). Items are reverse scored and linearly transformed to a 0 -100 scale; higher scores indicate better HRQOL. According to the instructions given with the instrument, scale scores are computed as the sum of the items divided by the number of items answered (accounting for missing data). If more than 50% of the items in the subscale are missing, the scale score is not computed [16, 18]. The teen version (ages 13-18 years) selected for the present study. The PedsQL™ $^{3.0}$ Asthma Module was translated into Sinhala and conceptually validated according to international guidelines which included forward, backward translations and cognitive interviews with the target group [19, 20]. Experts' comments were sought when necessary. There were administered additional items on basic socio-demographic information; present and past medical history; current treatment details; questions on asthma control during the previous month measured with the Asthma Control Test (ACT); details of school absence and frequency of visits to a health facility during the previous month.

Statistical Analysis

Feasibility and acceptability of the questionnaires were assessed by the percentage of missing data, rate of completion of scales and items. The range of measurement was based on the percentage of scores at the extremes of the scaling range, that is, the maximum possible score (ceiling effect) and the minimum possible score (floor effect) [21]. Surveys with small floor or ceiling effects (1% to 15%) are considered to meet acceptable measurement standards, while surveys with moderate floor or ceiling effects (> 15%) are considered less precise in measuring latent constructs at the extremes of the scale [22]. All items in the PedsQL™3.0 Asthma Module were reviewed by a panel of experts, consisting of clinicians and representatives from the target group.

Reliability of the PedsQL™3.0 Asthma Module was examined through Cronbach's alpha internal consistency reliability. Construct validity was examined with multi-trait scaling analyses to assess the extent to which the items of instrument loaded into the hypothesized multi-item scales based on the evaluation of item-scale correlations [18, 23]. Item convergence was defined as a correlation of 0.40 or greater between an item and its own scale (corrected for overlap). Item discrimination was based on a comparison of the magnitude of the correlation of an item with its own scale compared with other scales. Scaling successes were defined as those cases in which an item correlated significantly higher (> 1.96 standard errors) with its own scale (corrected for overlap) than with another scale [18, 23]

Convergent and discriminant validity was established by assessing the inter-scale correlations between the domains of the teen self-report version. Conceptually related scales (e.g., symptoms and treatment scales) were expected to show higher correlations. Cross informant variance was established by examining parent/teen inter-correlations [16, 24]. It was expected that more observable domains (i.e., symptoms) would show higher teen-parent correlations [16, 25].

Convergent validity was further examined for the PedsQL™ 3.0 Asthma Module by analysing the inter-correlations between the PedsQL™ 4.0 Generic Core Scales Total scale scores. Higher asthma symptom scores were expected to correlate significantly with higher total scale scores of the PedsQL™ 4.0 Generic Core Scales [16, 26]. We also anticipated that adolescents who missed more school days and those who had more visits to health facility during the previous one month would report lower asthma total scores [25, 27].

To demonstrate the discriminatory capacity of the PedsQL™ 3.0 Asthma Module, scale scores were compared between the two groups which were hypothesized to differ with regard to asthma control during the previous month. Higher asthma scores were expected with better asthma control [13]. Asthma control was evaluated using the asthma control test (ACT) **(available from:** http://www.asthmacontrol.com/pdf/ **).** ACT was selected considering its brevity and simplicity. Each question was given 5 points and the total mark allocated was 25. Those who scored 19 marks or above were considered to have "controlled asthma" and those who obtained below 19 marks were considered as "uncontrolled asthma".

Hypothesized relationships were examined using Spearman rho and Mann-Whitney U-test. Correlation effect sizes were designated as small (0.10-0.29), medium (0.30-0.49) and large (>=.50) [28]. Inter-correlations were expected to demonstrate medium to large effect sizes (≥0.30) [16, 26]. Statistical analysis was conducted using SPSS for Windows (SPSS, Inc., Chicago, IL).

Results

A total of 152 teen-parent pairs were recruited serially according to inclusion and exclusion criteria. Eight patients/parents (5.0%) refused to participate due to personal reasons and the questionnaire was read out for three parents and one adolescent due to language barriers and vision problems. Twelve teen-parent pairs mentioned above were removed in the analysis due to incomplete information, leaving 140 as the sample (92.1%). All teens were attending school. The majority were Sinhalese (87.1%) and males (54.3%). The mean age was 13.24 years (SD=1.04) (Table 1). The mean age for boys was 13.26 (SD=1.0) and for girls, 13.10 years (SD=1.14). According to the ACT scores, a majority (55.7%) had uncontrolled asthma during the previous month. Nearly 68% was on regular inhaler treatment for asthma.

Nearly 75% of the parent respondents were mothers and 44.3% were in the age group of 35-44 years. Sixty three percent of the parents were housewives (63.6%) and 43.6% had studied up to G.C.E. Ordinary level.

The adolescent patients with asthma took between 5 to 7 minutes for completion of the PedsQL™ 3.0 Asthma Module. There was a high response rate at the scale level; and missing values ranged from none to 0.7% for the teen patient's self-report. The item level missing values ranged from none to 32%. A higher level of missing values was observed with inhaler use "having trouble using my inhaler" (22.9%) and "don't like to carry my inhaler" (22.9%). The reason could be due to only 68% of the sample being on regular inhaler medication. Lack of a pet could have made 7.1% of the sample to avoid responding for the item on "hard to play with pets". Following exclusion of the above 3 items, the range of missing items was to none to 2.1%.

Parents spent about 5-10 minutes to complete the questionnaire. There was a high response rate at scale level. The item level missing values for parent reports ranged from none to 23.6% and followed a similar pattern observed with teen reports. Worry and Communication domains showed ceiling effects while none of the domains showed floor effects for either patient self-report or parent proxy-report.

Reliability values for PedsQL™ 3.0 Asthma Module was 0.87 for teen self-report and 0.87 for parent proxy-report, exceeding the recommended minimum alpha coefficients of 0.70 for group comparisons (Nunnally and Bernstein, 1994) (Table 2).

Item-convergent validity was confirmed for 21 items of the total 28 items (75%). Only one scale (Communication) of the four hypothesized scales showed 100% item convergent validity. Item-discriminant validity was noted in 74 of 84 tests (88.1%) while scaling success was observed in 76.2% of tests (Table 3).

Inter-scale correlations showed that conceptually related scales (e.g., symptoms and treatment scales) correlate significantly with one another (>0.50) and the more observable Asthma Symptoms Scale had the highest inter-correlations between teen and parent reports (ρ=0.72) (Table 4). Medium to large sized correlations were noted between the symptoms scale (ρ=0.45) and the treatment scale (ρ=.55) of the PedsQL™3.0 Asthma Module with the total score of the PedsQL™4.0 Generic Core Scales (Table 4). Significant medium sized correlations were demonstrated between Asthma Symptoms Scale score and school days missed (ρ= -0.39, p<0.01) and number of visits to health facility (ρ= -0.36, p<0.01) during the previous one month. A similar pattern was observed with the Asthma Module total score, with Spearman ρ of -0.30 (p<.01) and -0.42 (p<.01), respectively.

The study sample was dichotomized according to asthma control in the last month. There were 57 patients with controlled asthma (scored≥19) and 78 with uncontrolled asthma (scored <19). As seen in Table 5, adolescents with uncontrolled asthma reported significantly lower PedsQL™ Asthma Module scale scores in all domains compared to those with controlled asthma.

Discussion :

Table 1 : Socio-demographic characteristics of study participants (N=140)

	N	%
Sex		
Male	76	54.3
Female	64	45.7
Grade		
7	29	20.7
8	49	35.0
9	38	27.1
10	24	17.1
Race		
Sinhala	122	87.1
Tamil	4	2.9
Muslim	14	10.0
Mean Age	13.2yrs (SD=1.04)	
Visits to health facility during past 1month		
None	71	50.7
Once	34	24.3
Twice	24	17.1
Three times	8	5.7
Four times	2	1.4
Not mentioned	1	0.7
Caregiver		
Mother	103	73.6
Father	21	15.0
Others	16	11.4
Care giver Educational Level		
No schooling	3	2.1
Primary	5	3.6
Secondary	43	30.7
Passed O/L	61	43.6
Passed A/L	23	16.4
Higher Education	5	3.6

Table 2: Scale Descriptives for PedsQL™ 3.0 Asthma Module scales for patient self-report and parent proxy-report (N=140)

Scale	Scale Descriptive					
	Missing (%)	Median	Mean (SD)	Range	% floor/ % ceiling	Reliability Cronbach's Alpha
Self Report						
Total score	0(0.0)	78.70	77.60 (12.7)	41.9-100.0	0.0/0.7	.87
Symptoms	0(0.0)	75.00	74.18 (15.3)	36.4-100.0	0.0/ 1.4	.83
Treatment	0(0.0)	86.23	83.37 (12.9)	45.4-100.0	0.0/7.9	.74
Worry	0(0.0)	70.83	71.50 (23.2)	0.0-100.0	0.7/20.7	.72
Communication	1(0.3)	75.00	75.47 (22.3)	0.0-100.0	0.7/28.6	.85
Parent Report						
Total score	0(0.0)	81.48	79.54 (11.7)	43.5-100.0	0.0/0.7	.87
Symptoms	0(0.0)	72.72	73.17 (16.4)	22.7-100.0	0.0/3.6	.87
Treatment	0(0.0)	86.36	85.46 (10.6)	55.5-100.0	0.0/9.3	.65
Worry	0(0.0)	83.33	80.65 (20.6)	0.0-100.0	0.7/ 34.3	.79
Communication	0(0.0)	95.00	80.38 (19.2)	16.7-100.0	0.0/29.3	.81

Table 3: Item-Scale correlations for multi-trait- scaling analysis of PedsQL™ 3.0 Asthma Module scales

(corrected for overlap)

Item NO.	Symptoms	Treatment	Worry	Communication
QOL1*	**.588**[b]	.340[b]	.265[b]	.095
QOL2	**.646**[b]	.347	.174	.144
QOL3	**.557**	.405	.261	.129
QOL4	**.607**[b]	.463[b]	.278[b]	.198
QOL5	**.655**	.394	.313	.148[b]
QOL6	**.432**	.234	.098	.219[b]
QOL7	**.610**	.466	.426	.224
QOL8	.188[#]	.286***$	.157$	.082$
QOL9	**.612**	.444	.359	.226
QOL10	.311[#]	.445***$	.315***$	.241$
QOL11	**.446**[b]	.244[b]	.395[b]$	.139
QOL12	.369$	**.393**	.085	.061
QOL13	.425***$	.361[#]	.058	.068
QOL14	.217***$	.093[#]	.242***$	.051
QOL15	.339	**.511**	.358	.139
QOL16	.118$	.228[#]	.268***$	.310***$
QOL17	.512	**.391**	.426	.149
QOL18	.456$	**.479**	.191	.271
QOL19	.182[b]$	.292[b#]	.266[b]$	.111
QOL20	.464	**.630**	.405	.211
QOL21	.424	**.610**	.313	.238
QOL22	.478$	**.599**	.349	.393
QOL23	379***$	.404***$	.361[#]	.189
QOL24	382	.398	**.676**	.206
QOL25	308	.386	**.610**	.300
QOL26	168	.277	.249	**.820**
QOL27	293	.376	.345	**.707**
QOL28	243	.314	.155	**.652**

[b] = 137; all other n= 140

Item-scale correlations with own scales for item-convergent validity are shown in **bold typing.** Failed tests are shown as [#]

*** - failed tests with item discriminant validity, where an item correlated higher with a scale other than its own

$ - Scaling errors, where an item correlated with a scale other than its own, with a standard error of correlation more than 1.96 (r>1.96 SE)

Table 4: Spearman rho correlation coefficients between PedsQL™ Asthma Module and the PedsQL™ 4.0

Generic Core Scales

	Asthma Scales -Self report				Asthma Scales -Parent proxy report		
Asthma Self report	**Symptoms**	**Treatment**	**Worry**	**Comm.**	**Symptoms**	**Treatment**	**Worry**
Symptoms							
Treatment	*.65*						
Worry	*.44*	*.48*					
Comm. [a]	*.26*	*.38*	*.29*				
Parent report							
Symptoms	**.72**						
Treatment	.32	**.56**			*.50*		
Worry	.28	.26	**.47**		*.48*	*.43*	
Comm.[a]	.08*	.21	-.01*	**.50**	*.17*	*.33*	*.13**
Generic Core Scale- Self report	.46	.55	.37	.31			

N=140 except [a] =139
All correlation significant at the 0.05 level (2-tailed) except *
Hetero trait – mono method correlations are shown in *italics*
Mono trait – hetero method correlations are shown **Bold**

Table 5: Comparison of PedsQL™ 3.0 Asthma Module scale scores across asthma control groups

Self report	Controlled asthma (n=62) Mean (SD)	Uncontrolled asthma (n=78) Mean (SD)	Mann-Whitney U test (P value)
Symptoms	85.2 (9.9)	65.4(12.8)	<0.01
Treatment	90.2(8.5)	77.8(13.2)	<0.01
Worry	81.0(18.2)	63.9(24.1)	<0.01
Communication	82.6(19.9)	69.7(22.5)	<0.01
Total score	86.5(7.1)	70.5(11.7)	<0.01

The findings of the present study demonstrate that the PedsQL™ 3.0 Asthma Module-Sinhala version is a feasible, reliable and valid measure in evaluating asthma-specific HRQOL among adolescents with asthma in Sri Lanka. There was a high response rate at the scale level in both teen and parent reports. Absence of floor effects can be expected with the characteristics of the study sample as it did not include patients from the entire disease spectrum (i.e., patients from emergency department). If we were to include more severe patients, the percentage of the ceiling effects could have been reduced. Despite the measures taken to increase responses, there were missing data with regard to few items but most of it could be considered as "not relevant"[29].

Internal consistency reliability values exceeded the recommended minimum alpha coefficient standard of 0.70 for group comparisons for the majority of scales in both reports replicating the findings elsewhere [16, 25, 26]. The Treatment Scale for the parent proxy-report showed a reliability value of 0.65, which still can be employed for descriptive and exploratory purposes.

Overall results show that 75% of items exhibited item-convergent validity and 88.1% of items showed item-discriminant validity with 76.2% of scaling success overall, supporting the conceptual validity of the PedsQL™ Asthma Module-Sinhala version. The items which showed poor discriminant validity measured highly related and inter-dependent dimensions of HRQOL although categorized under separate scales. For example, even though the item "hard to play with pets" is categorized under the Asthma Symptom Scale, it showed higher correlation with the Treatment Scale. The adolescent may not perceive the above as a problem related to his asthma but as a problem with the management of the disease because most Sri Lankan parents impose various lifestyle restrictions including avoidance of pets [10, 11] .

The examination of inter-scale correlations between various domains of the Asthma Module showed the expected pattern in accordance with previous studies [16, 25]. The presence of low to medium sized inter-scale correlations in the matrix reinforced the findings of the multi-trait scaling analysis. The highest teen-parent concordance was reported with the more observable Asthma Symptoms Scale, replicating the findings of Greenly, Josie and Drotar (2008).

As hypothesised, inter-scale correlations between patient self–report on the PedsQL™ 3.0 Asthma Module and the PedsQL™ 4.0 Generic Core Scales showed medium-sized correlations confirming the convergent and discriminant validity of the PedsQL™ 3.0 Asthma Module. The absence of large sized correlations confirms that the domains measured by each instrument are measuring distinct components of HRQOL. However, the highest correlation was found between the PedsQL™ 4.0 Generic Core Scales total scale score and the PedsQL™ 3.0 Asthma Module Treatment Scale score, but not between the Generic Core Scales–total score and the Asthma Symptoms Scale –total score as hypothesized and previously reported [16]. The reason may be that asthma treatment has a greater impact on overall general HRQOL among Sri Lankan children with asthma compared to asthma symptoms.

The PedsQL™ Asthma Module scores had a significant correlation with school absence during the previous month. Similar associations have been reported by [25]. The present study also demonstrated a significantly higher Asthma Module scores among children who had less number of visits to health facility during the previous month, further confirming the construct validity of the instrument. Known-group discriminate validity comparisons demonstrated that the instrument discriminates between clinically different groups of controlled and uncontrolled asthma in agreement with the previous literature [25, 30].

The generalizability of the findings of the present study is limited by the sample characteristics, specifically because the sample was restricted to adolescents 12-15 years old and to those who could understand the Sinhala language. Further limitations include that school absence and visits to health institutions could be due to asthma related and non-asthma related causes. Further, we did not measure responsiveness of the scale due to limitation of resources. The findings may not be relevant to adolescents with more severe forms of asthma as our sample consisted of adolescents attending clinic and did not include adolescents in emergency rooms.

Conclusion :

The overall study results confirm that the Sinhala translations of the PedsQL™ 3.0 Asthma Module is a feasible, reliable and valid instrument for measuring asthma-related quality of life among adolescents in Sri Lanka.

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