

Original Article

Health related quality of life instrument for preschool aged children in Sri Lanka: validation study

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Abstract

Background and Objectives

Health related quality of life of children encompasses the clinical status and the perception of health. The aim of the study was to adapt and validate the TAPQOL health related quality of life instrument for children in the age group of 3 to 4 years in Sri Lanka.

Methods

The English TAPQOL was adapted to the Sinhala language using a modified Delphi technique. A community based cross-sectional descriptive study was conducted among 492 children in the age range of 3 to 4 years in the Colombo District. A multistage cluster sampling method was used to select children. Mothers of children were interviewed using a structured questionnaire which included the adapted tool. In the analysis, factor extraction, reliability and discriminant validity were tested.

Results

Response rate was 94.9% (n=467). For factor extraction, 44 items were extracted and arranged into 12 subscales. Subscales represented different dimensions of health. All subscales had less than 2% of missing values indicating high acceptability. Cronbach's alpha was more than 0.7 in eleven subscales. High correlations were observed for test-retest reliability for responses 2 weeks apart. The instrument showed satisfactory discriminant validity with preterm born children obtaining low scores in eleven subscales compared to the term born group.

Conclusions and recommendations

The TAPQOL questionnaire could be used in the community setting for preschool aged children to assess health related quality of life.

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Introduction

Advances in medical interventions have led to improvements in mortality, morbidity and quality of life. Health related quality of life (HRQOL) is the "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" [1]. Researchers, clinicians and public health professionals measure health related quality of life using pre-validated quality of life questionnaires (instruments).

Generic and disease specific questionnaires are used to assess the HRQOL of children. Generic questionnaires assess the basic dimensions of health whereas disease specific instruments pay additional attention to the outcome of that illness.

Assessment of the HRQOL of children poses specific challenges. Due to their limited development in cognitive and emotional dimensions and lack of understanding of their own health status, preschool aged children cannot provide the self-assessment on their HRQOL [2,3]. So, parents of preschool children become proxy assessors of their children's health. Moderate to good agreement was observed between parent proxy and child reporting in previous studies which had evaluated parent and child agreement on HRQOL assessment [4].

Sri Lanka is a lower and middle income country with good health outcome indicators for preschool aged children [5]. These quantitative assessments are robust but less sensitive to patient needs, perceptions and socio economical contexts [6]. It is timely for health workers to utilize outcome measures with qualitative and perception-based assessments for preschool aged children. But there are no validated instruments to assess the quality of life of preschool aged children in Sri Lanka. A validated instrument would contribute to enriching the quality of the existing, well established child health programme by adding a quality of life dimension to it. A validated tool will be useful to assess the outcome of interventions for preschool aged children.

There are many instruments used globally to assess the HRQOL of preschool aged children. Following a desk review and an expert panel discussion, the quality of life questionnaire for preschool aged children (TAP QOL) owned by the Netherlands organization for applied scientific research academic medical center (TNO AZL) was considered the most suitable for the validation process. The tool was selected for its holistic nature, simplicity and appropriateness for preschool aged children. The aim of the study was to adapt and validate the TAPQOL health related quality of life instrument for children in the age group of 3 to 4 years in Sri Lanka

Methods

TNO AZL quality of life questionnaire for preschool children was developed by Fekkes et al, at the Leiden University Medical Center in Netherlands. The TAPQOL original instrument has 43 items grouped into 12 subscales. The subscales are groups of items describing different aspects of quality of life of a child and they represent the domains of health, physical, emotional, cognitive and social health [7]. Each item in the physical and cognitive domains consists of two questions. The first question inquires whether the child has had a "symptom" or "functional limitation" during the last 3 months and its frequency. The second question inquires regarding any negative perception felt at that time due to the symptom / functional limitation. In scoring, both questions are combined to give a single score. Responses given in both parts are combined to calculate the item score. Each item in the emotional and behavioural domains has a single question. It inquires about the functional limitation of the child and its frequency. A direct score is assigned for the response. The recall period is 3 months [8].

Adaptation of the TAP QOL questionnaire (English version) to the Sinhala language:

A panel of fifteen experts reviewed the original tool in the English language for its appropriateness to the local setting. The expert panel consisted of public health specialists, clinicians, a child psychiatrist, sociologists and parents of 3 years old children [9]. Figure 1 presents the steps in the adaptation process.

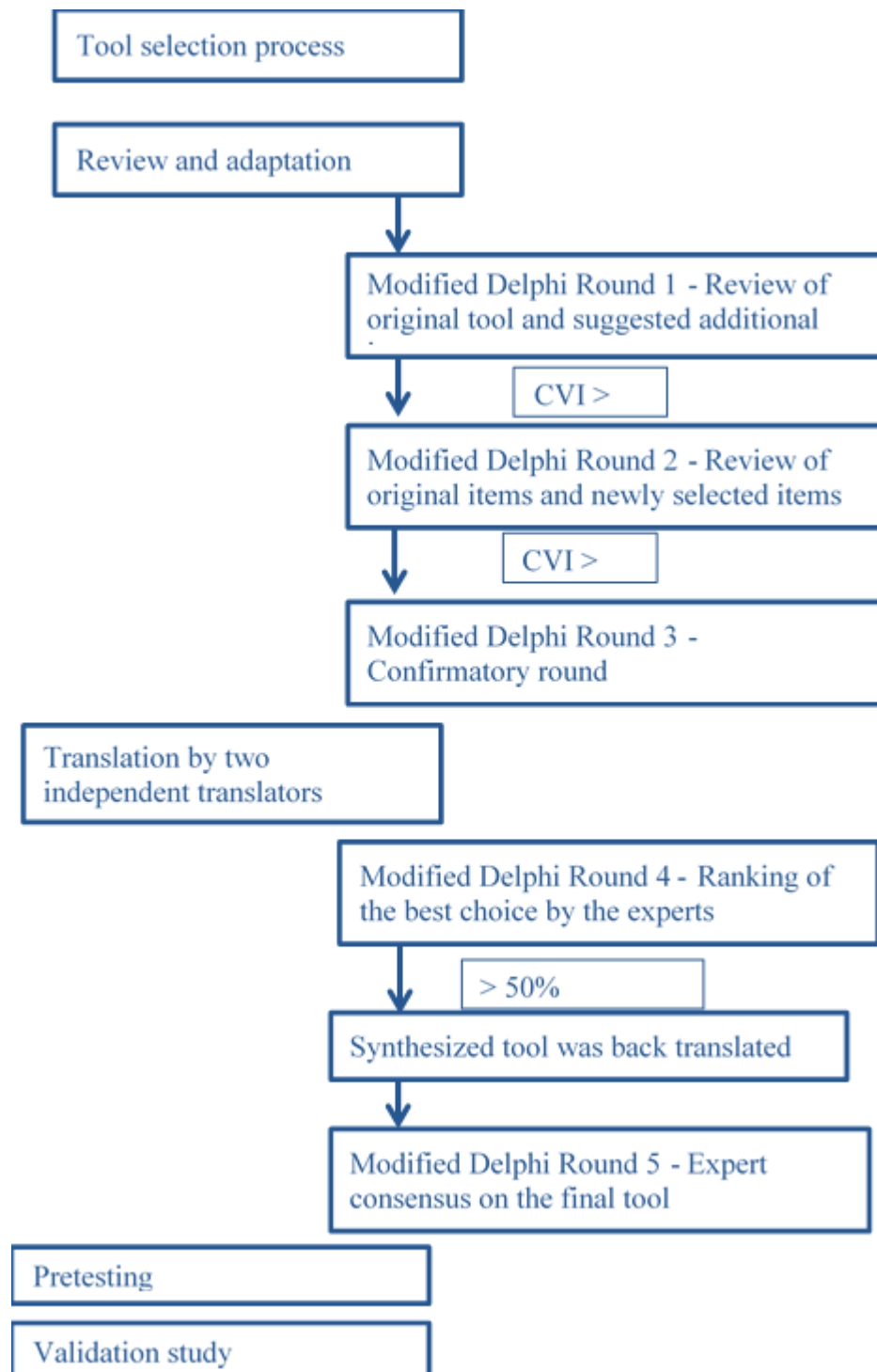


Figure 1: Diagrammatic presentation of the validation process

We used a modified Delphi technique to obtain expert consensus and suggestions for new items. Experts assessed each item for its relevance in describing the health-related quality of life of a child and appropriateness to the local setting and they marked their responses on a four-point ordinal scale. In addition, the experts suggested new items or split the existing items to obtain clarity. The new responses and suggestions were included in the subsequent rounds of consensus. At the end of each round, the principal investigator analyzed the responses using the content validity index (CVI). In calculating the content validity index, the responses for each item were added together and the average score for each item was calculated. Items with a CVI score of more than 0.5 were selected for the next round [10]. The principal investigator ensured that original conceptual constructs were maintained in the process [7]. Three modified Delphi rounds were required to conclude the items. New item inclusion and item-split resulted in 47 items in the final instrument.

The adapted tool was translated into the Sinhala language, which is the predominant language of the country, by two independent translators using standard guidelines [11]. The two translations for each item were ranked by a group of bilingual experts for appropriateness. Translated items with more than 50% agreement were selected. The synthesized version was back translated into English independently. The first adapted version and the back translated version were compared.

We pretested the translated tool among 20 mothers of children of 3 to 4 years to assess clarity, understandability and ability to make responses to the questions. Participants rephrased the items when there were difficulties [12]. Semantic equivalence was declared when each item was successfully understood and responded by 3 mothers from different educational backgrounds [12]. The instrument was used as an interviewer-administered questionnaire in the local setting. The original TAP QOL scoring was flexible to changes and this was applied to the adapted instrument as well.

Validation study: The validity of the Sinhala TAPQOL instrument was assessed using a descriptive cross-sectional study with an analytical component. It was conducted in the District of Colombo.

Children in the age group of 3 to 4 years without major acute illness at the time of data collection participated in the study. A study unit was an individual child. If the mother didn't accompany the child or didn't bring birth records of the child and the clinic details for the data collection, they were excluded from the study due to the possibility of incomplete data. We recruited both preterm and term born children to the study in order to calculate construct validity using the known group comparison method. Children were recruited to preterm and term groups based on the period of gestation at birth. Period of gestation was calculated using the best obstetric estimate (BOE) method using maternal health records [13]. A preterm child was defined as a child who was born before completion of 37 weeks of gestation.

Sample size and sampling method: The sample size was determined using the item to subject ratio for instrument validation by the principal component analysis method. The ratio considered was 1:10 [14]. A non-response rate of 5% was added. The required sample size was 492. We recruited an equal number of children into the preterm and term groups.

Children for the validation study were recruited using a two-stage cluster sampling method. Five Medical Officer of Health (MOH) areas were randomly selected from thirteen MOH areas in the Colombo district. A cluster consisted of children attending a growth monitoring center. From each MOH area, ten growth monitoring centers were randomly selected. All eligible children were enumerated at the center. They were categorized into preterm and term groups and recruited for the study. We continued the process until the required number of children was obtained from each MOH area.

Data collecting instrument: A pre-tested, interviewer administered questionnaire including the Sinhala version of the TAP QOL instrument and a few socio demographic variables was used to collect data from the children. The selected socio demographic variables were sex, birth weight, mother's educational status and occupational status. The final questionnaire for the validation study was pilot tested in a growth monitoring center among 10 children and mother pairs by the principal investigator.

Study implementation: Data was collected at growth monitoring centers. A letter of invitation was sent to all mothers of eligible children who were enrolled to the center indicating the data collection process and the documents they had to bring to the study. All mothers who attend the appointment were informed regarding the purpose of the study and the method of participation. Informed written consent was obtained from the mothers. The questionnaire was administered by the principal investigator and medical officers who were uniformly trained on the questionnaire. Inter-rater agreement between different data collectors was more than 0.7 [15].

We reached randomly selected 20 mother-child pairs from four data collecting centers and invited them for a second interview in two weeks. By comparing the initial and the second response, we calculated the test retest reliability of the questionnaire.

The study was conducted from September to December 2015. The Ethics Review Committee of the Faculty of Medicine, University of Colombo reviewed and approved the study (Protocol reference number EC-15-056).

Statistical analysis: Questionnaire items were scored according to the manual of the TAPQOL questionnaire [8]. The Sinhala version of the TAPQOL questionnaire was validated using exploratory factor analysis and principal component analysis [16]. Sampling adequacy with KMO statistic was assessed at 0.5. Bartlett's test for sphericity was performed and $p < 0.05$ was considered as adequate for further analysis. Five step factor extraction process was conducted using SPSS version 20.0 software [17]. Principal

component analysis was performed with varimax rotation and factors with Eigen value more than 1 were extracted.

The principal investigator and two experts examined the theoretical plausibility of the extracted factors and combined a few factors considering the theoretical constructs and explained variability [18]. Explanatory names were assigned to the factors (“subscales”) to describe different dimensions of the health of the child. Inter factor correlations were explored using the Spearman r correlation coefficient. Principal component analysis was performed for individual subscales to check for the unidimensionality of subscales.

We determined construct validity using the known group comparison method. According to the published literature, the quality of life of preterm children is low in comparison to the term born children [19, 20]. Comparison of the quality of life between preterm and term born children is a widely used method to establish construct validity in quality of life scales for children [21, 22]. Thus, we compared the quality of life of preterm born children with term born children using the Sinhala questionnaire. Each subscale score was compared using independent samples t-test at 95% significance level [8]. Reliability of the scale was measured by test retest method and by assessing internal consistency with Cronbach’s α [23]. Alpha value magnitude of 0.7 or greater was considered satisfactory [24]. For test retest reliability, two responses given two weeks apart were compared using the Spearman r correlation coefficient. Correlation coefficient of more than 0.7 was considered adequate [25].

Acceptability of the instrument was assessed by proportion of missing responses in each subscale. Floor and ceiling effects of measurements were presented with percentage achieved by both groups. Ceiling effect was defined when more than 70% responses in each subscale were placed at the maximum possible value [26].

Results

The total sample was 467 children with a response rate of 94.9%. Out of the sample, 242 (51.7%) children were preterm born and 225 (48.2%) were term born.

Description of the study participants: The study population consisted of children in the age range of 36 to 48 completed months. Mean age of participant children was 38.72 (SD \pm 3.69) months. Majority of preterm born children were born with low birth weight (n=169, 69.8%; 95%CI, 64-75.6%). However, there was 26 (11.6%) term born children who belonged to the low birth weight category as well.

All respondents for the questionnaire were mothers of the children (100%). Among mothers, 92.7% had schooled up to grade 6 or beyond (n=433). The majority (86.3%, n=404) of them were not employed.

Properties of the Sinhala version of TAP QOL: KMO measure for sampling adequacy was 0.691. Normality of item scores was not tested due to ordinal categories in each item. Correlation between all items was more than 0.5. Barlett’s test statistic was 7325.9

(df=1081) and the finding was significant ($p=0.001$) at 95% significance level. Thus, all items were included in the factor analysis. Factor structure of the instrument was explored using exploratory factor analysis with principal component analysis. Principal component analysis extracted 16 factors with Eigen values >1 . Items with a loading of less than 0.4 were excluded from the factor structure. A total of 44 items were extracted from this method. Four factors were amalgamated to related factors. The extracted factors were classified according to the dimensions of health (eg: physical, emotional, cognitive and behavioural). Twelve factors were assigned to descriptive names (subscales).

The physical wellbeing domain had seven subscales, namely subscales on sleep wellbeing, general wellbeing, eating behaviour, respiratory symptoms, abdominal symptoms, skin symptoms and motor functions. Anxiety and positive emotions constituted emotional wellbeing. The cognitive domain was measured in the communication subscale and behavioral /social wellbeing had two subscales, namely social interaction and aggressive behaviour.

Acceptability: All subscales had a missing values percentage of less than 2% (Table 1). More than 75% of children obtained the maximum score in the subscales of skin symptoms, motor functioning and positive emotions (ceiling effect). Only the subscale on aggressive behaviour had 17.9% of children receiving the minimal score ($n=83$).

Table 1: Proportion of missing values, proportion of responses with the minimum and maximum score of the individual subscale (N=467)

Subscale	No of items	Alpha	r coefficient	Number of missing responses	Responses with the minimum score	Responses with the maximum score	Total responses
				N(%)	N(%)	N(%)	
Sleep wellbeing	3	0.886	0.983	5 (1.0)	4 (0.8)	253(54.6)	462
General wellbeing	4	0.893	0.522	1(0.2)	3(0.6)	169(36.5)	466
Eating behaviour	2	0.722	1.000	2(0.4)	25(5.3)	144(30.9)	465
Respiratory symptoms	3	0.843	0.864	1(0.2)	3(0.6)	169(36.1)	466
Abdominal symptoms	4	0.851	0.791	0(0.0)	4(0.8)	163(34.8)	467
Skin symptoms	2	0.947	1.000	0(0.0)	12(2.5)	407(86.9)	467
Motor functions	5	0.990	0.837	0(0.0)	5(1.0)	431(92.1)	467
Communication functions	6	0.949	0.764	(1.5)	3(0.6)	334(72.4)	460
Social Interaction	4	0.746	0.997	6(1.3)	2(0.4)	84(18.2)	461
Aggressive behaviour	2	0.477	0.834	5(1.1)	83(17.9)	40(8.6)	462
Anxiety subscale	5	0.742	0.838	9(2.0)	3(0.6)	31(6.8)	459
Positive emotions	4	0.976	1.000	0(0.0)	9(1.9)	414(88.5)	467
Total	44	0.699					

Reliability: All subscales had a Cronbach's alpha of more than 0.7 except for the subscale on aggressive behaviour (0.477). All subscales showed significant and high correlations with two weeks prior and after values in the assessment of test retest reliability.

Dimensionality of the instrument: Multidimensionality of the subscales was established by calculating the Spearman correlation coefficient between subscale scores. All subscale correlations were less than 0.4 except for the relationship between sleep wellbeing and abdominal symptoms. All individual subscale scores were subjected to separate principal component analysis to confirm the unidimensionality of subscales. All subscales except the subscales on motor functions and anxiety subscale extracted one factor in the analysis.

Construct validity: In Table 2, subscale scores were compared between the groups of preterm and term born children. In ten subscales, the mean scores obtained by preterm children were less than the mean scores of the term born group. In six subscales, the observed mean differences were statistically significant ($p < 0.05$).

Table 2: Scores obtained for individual subscale and the comparison of scores between term and preterm groups

Subscale	Preterm			Term			Total	Significance
	No	Mean	SD	No	Mean	SD		
Sleep wellbeing	237	88.2	19.5	225	89.5	15.0	463	0.410
General wellbeing	242	87.1	15.2	225	90.8	10.3	462	0.029
Eating behaviour	242	65.7	32.2	223	72.6	23.2	466	0.001
Respiratory symptoms	242	82.1	25.7	225	86.0	19.1	467	0.050
Abdominal symptoms	242	83.4	19.1	225	86.6	14.9	467	0.048
Skin symptoms	242	94.8	15.6	225	94.6	15.0	467	0.906
Motor functions	242	99.1	4.05	225	99.0	4.08	467	0.771
Communication	242	93.6	13.5	225	96.7	7.8	461	0.003
Social Interaction	239	74.2	18.5	222	74.7	21.7	462	0.789
Aggressive behavior	239	44.9	30.9	223	49.7	25.8	463	0.042
Anxiety subscale	239	71.7	15.1	225	75.4	12.5	458	0.024
Positive emotions	242	96.7	9.5	225	97.6	8.8	467	0.310

Discussion

The Sinhala version of the health-related quality of life questionnaire for preschool aged children has 44 items arranged in twelve subscales. The subscales look at different dimensions of the health of a child and all items are unique. The instrument was reliable and likely to provide the same result when applied to the same child while on the same health status. The questionnaire was well accepted by mothers. Further, it was capable of identifying differences in HRQOL among subgroups of children although subtle differences in quality of life in a healthy population may be overlooked. Further, the Sinhala version of TAP QOL had comparable psychometric properties to the original version of the questionnaire [7]. The questionnaire was built on constructs which have

been successfully used in many countries and by many researchers for the past decade [7]. The validation and adaptation process in the local setting included both qualitative and quantitative techniques. We used extensive scientific methods to extract factors and to identify subscales. Thus, the scientific value of the validated instrument is high.

Health related quality of life looks at the dimensions of a person's life which can be changed by the health care system [27]. Despite having many focused interventions to improve the quality of life of preschool aged children in Sri Lanka we did not have an effective outcome assessment measure. The newly validated instrument fills that gap. In addition, the items on physical wellbeing and communication have a second part that describes the impact on life due to the symptom [21]. They provide a useful tool to assess the burden of health problems of the child at the field or clinic level.

In establishing construct validity using the known group comparison method, preterm born children obtained low scores in 10 subscales. However, a statistically significant difference was observed in only in six subscales. Thus, the ability of the instrument to classify preterm from term children was restricted only to six subscales. However, a similar issue was observed in the validation of the tool in other countries whenever they had tried to establish discriminant validity using preterm and term born children [7,28]. This problem was explained by lack of variability of the measured health outcome in the said population. It was suggested to revalidate the instrument in a large sample with varying health outcomes to confirm the findings.

The items in the instrument and its subscales showed good acceptance with a non-response rate below 2% for all subscales. We observed a high ceiling effect with > 70% of respondents obtaining the maximum score in four subscales. Again, the reason could be the lack of variability of the specific health outcome. Ceiling and floor effects are measures of responsiveness in an instrument [29]. Trivial differences in a healthy population may not be demonstrated by the validated instrument. However, this limitation is seen in many translated versions of TAP QOL[30].

The Sinhala TAP QOL questionnaire provides a practical and feasible method to assess the health-related quality of life of preschool aged children. It has only 44 questions and could be applied with minimal training. The Sinhala HRQOL questionnaire for preschool aged is recommended for use in the community, in research and in the clinical setting for health evaluation and epidemiological assessments.

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