ORIGINAL ARTICLE

Development of the Chinese version of the Paediatric Allergic Disease Quality of Life Questionnaire: reliability and validity

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Objective Paediatric Allergic Disease Quality of Life Questionnaire is a health-related assessment tool designed for children with allergic diseases. This study aimed to translate the original English version of the Questionnaire to Chinese and to provide psychometric evidence on the validity and reliability of the translated version.

Design Cross-sectional study.

Setting Out-patient clinic of a non-teaching hospital in Hong Kong.

Participants The Paediatric Allergic Disease Quality of Life Questionnaire was translated to Chinese and then completed by a group of 115 Hong Kong Chinese children (66 male and 49 female; mean age, 11 years) with allergic disease(s). All subjects were asked to respond using visual analogue scales dealing with issues related to the perceived morbidity of allergic diseases. To assess test-retest reliability, 2 weeks later a subgroup of 16 individuals was retested with the same Questionnaire.

Results The internal consistency of the Chinese Paediatric Allergic Disease Quality of Life Questionnaire was satisfactory (Cronbach alpha=0.92). The correlation between the total Questionnaire score and the visual analogue scale score was moderately significant (Spearman's rho=0.49; 95% confidence interval, 0.34-0.62). Structural validity as studied by confirmatory factor analysis found that the structure of subscales was remarkably similar to the original English version. The intra-class correlation between the Questionnaire score from the first and the second test in the subgroup of 16 subjects was 0.75, indicating adequate repeatability.

Conclusion The validity and reliability of the Chinese version of the Paediatric Allergic Disease Quality of Life Questionnaire was established for clinical use.

New knowledge added by this study

- In Chinese children, rhinitis symptoms had a greater impact on health-related quality of life compared to asthmatic symptoms.
- The Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ) was valid for patients with perennial allergic diseases.
- The validity and reliability of the Chinese version of the PADQLQ was similar to the original English version.

Implications for clinical practice or policy

- The quality of life of local children with allergic diseases could and should be assessed as part of standard assessment of children with allergic diseases using the validated Chinese version of the PADQLQ.

Key words
Asthma; Child; Eczema; Quality of life; Rhinitis, allergic, perennial

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Introduction

Allergic diseases are commonly encountered in children. The prevalence of asthma, allergic rhinitis, and eczema are 7.9%, 33.9%, and 30.7%, respectively in Hong Kong children.[1] Allergic diseases are reported to affect health-related quality of life (HRQoL) of children significantly.[2] Measurement of HRQoL is often used as a means of assessing

treatment effectiveness in international clinical trials, including those dealing with allergic diseases.[2,3] However, most of the HRQoL assessment tools are only available in English, which renders them less useful in non–English-speaking populations.[4] Organ-specific HRQoL assessment tools such as Paediatric Asthma Quality of Life Questionnaire (PAQLQ[5]) and the Paediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ[6]) were employed in some paediatric clinical trials. In patients with allergic diseases, PAQLQ and PRQLQ are more sensitive and specific than generic HRQoL assessment tools.[7]

A recently introduced Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ[8]) is a HRQoL assessment tool designed for children with allergic diseases. It is regarded as superior to both the PAQLQ and the PRQLQ, because it takes into account the effects allergic diseases on other organs in addition to the organ of interest. Roberts et al[9] showed that the PADQLQ score was associated with airway inflammation as measured by exhaled nitric oxide levels in a group of children with various allergic diseases. Although Chinese is the native language of one-fifth of the world population, PADQLQ was not yet translated into Chinese. The purpose of this study was to establish psychometric evidence for the Chinese version of the PADQLQ after translation from the original English version, and to evaluate the translated version's structural validity and item quality, as well as its test-retest reliability and internal consistency.

兒童敏感病生活質量問卷中文版的發展：信度及效度

目的 兒童敏感病生活質量問卷（PADQLQ）是一項專為研究兒童過敏性疾病而設計的一個與健康有關的評估工具。本研究旨在把PADQLQ原來的英文版翻譯成中文，繼而為中文版的信度及效度提供心理測量證據。

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參與者 把PADQLQ原來的英文版翻譯成中文，並邀請患有過敏性疾病的115名兒童填寫此中文問卷。參與者包括66男49女，平均年齡11歲。參與者會利用視覺模擬量表為過敏性疾病所帶來的疾患進行評分。兩星期後，再邀請其中16名參與者重覆填寫相同的問卷，以找出問卷的重測信度。

結果 PADQLQ中文版有滿意的內部一致性（Cronbach α=0.92）。問卷總得分與視覺模擬量表評分有頗為重要的相關性（Spearman's rho=0.49；95%置信區間0.34-0.62）。結構驗證性因素分析顯示PADQLQ中文版與原本英文版的結構效度極為相似。第一次填寫問卷和第二次由16名參與者填寫問卷的組內相關系數為0.75，顯示有足夠的可重覆性。

結論 兒童敏感病生活質量問卷中文版的信度及效度足以作臨床使用。

Methods

The original English version of this questionnaire was previously validated in a group of children 7 to 16 years of age; for the validation phase the children were aged 8.5 to 16.5 years, and for the development phase they were aged 6 to 16 years.[8] It had satisfactory longitudinal and cross-sectional validity. The PADQLQ consists of 26 questions grouped into three domains: activities (8 questions), symptoms (15 questions), and emotions (3 questions). The questions were also designed to be answered without parental help. For each question, the subjects were asked for the perceived bother due to their allergic diseases. For each question, a 6-point scale from "not bothered" (score=0) to "extremely bothered" (score=6) was used to recording the perceived degree of bother. The total score of the PADQLQ was derived by summation of the scores for all 26 questions. The score for each of the domains was also calculated by summation of the relevant scores.

The PADQLQ was translated by one of the authors who was bilingual, and the translated version was then back-translated by another author, who was also bilingual. The discrepancies arising from the translation and back-translation were resolved by the third author, who was also bilingual and a paediatric pulmonologist (Appendix). All eligible patients who attended the Paediatric Respiratory Clinic of Kwong Wah Hospital from November 2006 to May 2007 were recruited and informed consent was obtained. They were deemed eligible if diagnosed with one or more of the following diseases: asthma, allergic rhinitis, eczema, and allergic conjunctivitis. Each patient was asked to complete the self-administered PADQLQ. Parents and an assistant from our clinic were allowed to assist during its completion. A visual analogue scale (VAS) with a maximum score of 10 was also employed to record how much the patients were generally bothered by their allergic diseases. The subjects were asked to put an "X" along a 10-cm line between two ends indicating no impact to maximum impact. The VAS score was determined before administration of the PADQLQ. The person administering the questionnaire was blinded with respect to the diagnosis of each subject.

Statistical analysis and internal consistency

The aim of the statistical analysis was to show that the Chinese version had similar properties to the original English version. The procedures of psychometric analysis were based on the principles of Classical Test Theory. Internal consistency (ie the

degree of agreement between individual items in the questionnaire) was measured by the Cronbach α coefficient, which was calculated for each item individually as well as collectively for the items in each of the three domains.

Cross-sectional validity

Similar to the original version, the Chinese PADQLQ score needed to distinguish between subjects with different degrees of impaired HRQoL; the total score was therefore expected to correlate with the VAS score using Spearman's correlation. Moreover, we expected at least a moderate degree of association between the PADQLQ and VAS scores (0.4<rho<0.6).

Test-retest reliability

An arbitrarily selected subgroup of 16 subjects were invited to submit a second PADQLQ response by mail 2 weeks after completing the first one. The intra-class correlation for the two PADQLQ scores was used as a measure of repeatability.

Structural validity

Confirmatory factor analysis was performed to assess whether the structure of the Chinese PADQLQ was similar to that of the original English version. A structural equation model was specified and estimated by maximum likelihood testing using the so-called Sem package of R.[10] Each item was to be loaded into the latent factor (Activity, Emotion, and Symptom) it belonged to. The Satorra-Bentler scaled Chi squared was used to assess the fit of the structural equation model (ie how well the data fitted the proposed structural equation model). The closer the factor loadings are to 1 (range, 0-1), the more appropriate it was for questions in one particular domain to be grouped together. This could also mean that the structure of the Chinese version was close to the original English version.

Item analysis was also conducted to obtain the discriminative indices for each question. The discriminative index describes item to total score correlation. It ranges from 0 to 1; for any particular question, higher values indicate greater latent variability (ie HRQoL for the current study).

This study was approved by the institutional review board of research (Clinical Research Ethics Committee, Kowloon West Cluster, Hospital Authority).

TABLE 1. Characteristics of subjects

Characteristic	Single-test group (n=115)	Test-retest group (n=16)
Male gender	66 (57%)	9 (56%)
Mean (standard deviation) age (years)	11 (3)	11 (3)

TABLE 2. Factor loadings from confirmatory factor analysis of the Chinese version of the Paediatric Allergic Disease Quality of Life Questionnaire

Item	Activities subscale	Symptoms subscale	Emotions subscale
Q1	0.990*	-	-
Q2	0.460*	-	-
Q3	0.865*	-	-
Q4	0.464*	-	-
Q5	1.000*	-	-
Q6	0.829*	-	-
Q7	0.440*	-	-
Q8	-	0.459*	-
Q9	-	0.535*	-
Q10	-	0.683*	-
Q11	-	0.566*	-
Q12	-	0.526*	-
Q13	-	0.782*	-
Q14	-	1.000*	-
Q15	-	0.847*	-
Q16	-	0.809*	-
Q17	-	0.685*	-
Q18	-	0.600*	-
Q19	-	1.000*	-
Q20	-	0.720*	-
Q21	-	0.780*	-
Q22	-	0.349*	-
Q23	-	-	0.872*
Q24	-	-	0.784*
Q25	-	-	0.552*
Q26	0.996*	-	-

* Statistically significant, P<0.05

Results

All parents approached agreed to allow their child to participate in this study, giving a 100% response rate. A total of 115 patients (66 male and 49 female) with allergic disease(s) were recruited, with a mean age of 11 (standard deviation, 3) years. Their demographic data are summarised in Table 1. The internal consistency of the Chinese version of the PADQLQ was satisfactory, as evidenced by a high Cronbach α coefficient of 0.92. The respective Cronbach α coefficients for the activities, symptoms, and emotions domains were 0.68, 0.89, and 0.66, indicating satisfactory internal consistency within each domain. The total PADQLQ score was correlated moderately well with the perceived morbidity VAS score (rho=0.49; 95% confidence interval [CI], 0.34-0.62).

TABLE 3. Results of item analysis: the discriminative indices

Items	Item discriminative index
Q1	0.742
Q2	0.505
Q3	0.620
Q4	0.499
Q5	0.740
Q6	0.625
Q7	0.436
Q8	0.433
Q9	0.536
Q10	0.580
Q11	0.488
Q12	0.496
Q13	0.563
Q14	0.705
Q15	0.604
Q16	0.536
Q17	0.525
Q18	0.490
Q19	0.723
Q20	0.593
Q21	0.618
Q22	0.353
Q23	0.616
Q24	0.607
Q25	0.465
Q26	0.720

The three-factor model of the PADQLQ was in keeping with the data we obtained. The Satorra-Bentler scaled Chi squared was 724.61, degrees of freedom being 296 (P<0.001). This suggested that the Chinese version of the PADQLQ consisted of three unidimensional subscales, similar to the original English version. Table 2 shows the standardised factor loadings. All factor loadings were statistically significant, although those for Q2, Q4, Q7, Q8, and Q22 were below 0.5.

The item discriminative indices ranged from 0.353 to 0.742 (Table 3). The three least discriminative items were Q22 ('having a headache'), Q8 ('coughing and/or wheezing at night'), and Q7 ('unable to play sports outside').

Test-retest reliability

The differences in age and gender between the single-test group and test-retest group were not statistically significant (Table 1). All of the subjects returned the completed second PADQLQ questionnaire by mail 2 weeks after completing the first one. The intra-class correlation between the two scores was moderate (intra-class correlation=0.75; 95% CI, 0.435-0.905). This showed that the questionnaire had adequate repeatability.

Discussion

The original PADQLQ was developed to evaluate HRQoL in children/adolescents with multisystem allergic diseases. It was validated and found to have good cross-sectional and longitudinal validity. In our study, we translated the questionnaire and established psychometric evidence for its utility in Chinese children with similar problems. Notably, we had a larger sample compared to that used in the validation phase of the original study[8] (n=115 vs 36) and the mean age of our subjects was slightly lower (11 vs 12 years). All our subjects were ethnically Chinese, whereas children of different ethnic origins were included in the original study. All subjects in the validation phase of the original study had seasonal allergic diseases only, whereas in ours patients with perennial allergic diseases were also included. In other words, the validity of the Chinese PADQLQ was extended to include patients with perennial allergic diseases.

The translated version had high internal consistency overall as well as within each domain and the level of internal consistency was comparable to that of the original version. There was a moderate degree of correlation between scores obtained for the Chinese PADQLQ and our VAS, the latter being taken as the gold standard. The degree of correlation observed seemed to be slightly less than that noted in the original study, though the original VAS consisted only of a scale of seven faces (from smiling to crying) while ours had a scale of 10 (0 denoting "not troubled" and 10 denoting "extremely troubled"). The Chinese version was also found to have adequate test-retest reliability. The questionnaire was administered by only one member of our staff and hence inter-administrator variability was eliminated, though slight intra-administrator variability was possible despite a conscious effort to minimise the same.

Our questionnaire consisted of three unidimensional subscales, and was structurally very similar to the original version. Notwithstanding the three underlying subscales, we believed that the total score, as opposed to three subscale scores, would be adequate to accurately assess HRQoL and how it changed with symptom severity and treatment. Interestingly, the item pertaining to difficulty indices generally yielded quite low scores. The three highest were all related to allergic rhinitis symptoms, which appeared to reflect a much greater impact on HRQoL from rhinitis symptoms than those from asthma. This

was in keeping with both the original PADQLQ study[8] and others.[11,12] The low discriminative indices for items 7 and 8 also indicate that asthmatic symptoms cause less impairment of HRQoL than those of allergic rhinitis.

A commonly encountered problem when translating questionnaires is that questions may have to be modified to incorporate specific cultural aspects of the targeted ethnic group.[13,14] All items of the original PADQLQ are not so culture-specific, and we believe no special modifications were required when translating them directly from English to Chinese. Another limitation of this study was that our subjects were all recruited from one hospital, so the representativeness of this sample remains to be established. Some performance indicators had wide CIs (especially cross-sectional validity and test-retest validity), which could be attributable to the random variations due to insufficient sample size or the actual biological variation. Notably, test-retest reliability was only tested in a subgroup of 16 subjects. This subgroup of subjects might not have been a representative sample of the original sample, though they did not differ significantly in terms of age and gender. It is therefore important to conduct further studies to confirm cross-sectional validity and test-retest reliability in Hong Kong and other Chinese communities.

Conclusion

We have translated the English PADQLQ into Chinese and validated its use in Hong Kong Chinese children with both seasonal and perennial allergic diseases. The Chinese version had good internal and cross-sectional validity, as well as satisfactory reliability. It consisted of three unidimensional subscales, with a structure remarkably similar to that of the original version. We expect this questionnaire to be a useful tool in assessing HRQoL and its changes in relation to treatment. This questionnaire appears more useful than disease- or organ-specific HRQoL questionnaires, as the different allergic diseases often coexist in children with atopy. Further work is warranted to validate this Chinese version in other parts of China.

Appendix

Additional material related to this article can be found on the HKMJ website. Please go to <http://www.hkmj.org>, search for the appropriate article, and click on Full Article in PDF following the title.

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APPENDIX. Questionnaire

兒童敏感病生活質素問卷(PADQLQ)

想一下過去一星期，敏感對你的影響。想一下所有關於呼吸、眼、鼻和皮膚的病徵。請選出每條問題的最適合形容你的困難之答案。這不是測驗，所以沒有正確答案。

請問敏感在過去一星期對你的以下問題有幾大影響？

		沒有影響	差不多沒有影響	有些少影響	有中度影響	有頗大影響	有非常大影響	有極大影響
1	不能集中精神							
2	不能記憶學校學到的東西							
3	不能入睡，或令你不能睡得好							
4	聽覺不佳							
5	需要帶備，或者服用藥物、使用吸入器或擦藥膏							
6	跑步或遊玩時出現咳嗽或喘鳴							
7	不能外出玩體育運動							
8	晚上出現咳嗽或喘鳴							
9	任何時間出現咳嗽或喘鳴							
10	感覺呼吸不順，或者胸口崩緊							
11	需要擦眼							
12	眼腫、眼漲							
13	鼻癢							
14	鼻塞或有很多鼻涕							
15	需要擦鼻							
16	需要噴鼻涕 / 抹鼻涕							
17	皮膚出疹							
18	皮膚的樣子							
19	感到疲倦或勞累							
20	感到口渴							
21	喉嚨乾、喉嚨癢或喉嚨痛							
22	有頭痛							
23	感到易怒或挫折							
24	感到和你的朋友有不同							
25	因為怕哮喘發作，而感到驚慌							
26	回想過去一星期進行的活動。在進行這些活動時，敏感對你的影響是							