Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ)의 한국어판 개발과 신뢰도, 타당도에 대한 연구

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Abstract

Korean Translation and Validation of the Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ)

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Objectives

In pediatrics of Korean Medicine, it is crucial to evaluate the overall symptoms of children, especially in the children who have serious troubles in their life. In the era when diagnosis in Korean Medicine is quite suitable to evaluate multiple allergic diseases, and when growing numbers are in needs, development of an objective measurement scale for diagnosis of allergic disease in Korean Medicine became essential. Therefore, in the study, pediatric Allergic Disease Quality of Life Questionnaire (PADQLQ) was translated into Korean version with validations on some aspects.

Methods

In this study, we translated and validated the PADQLQ and established psychometric evidence on its utility in Korean children with similar problems. 71 children, age of $6 \sim 18$ with allergic disease has participated.

Results

The internal consistency reliability of the PADQLQ by Cronbach's α was 0.94. In three domains (Practical, Physical, Emotional), the Cronbach's α was 0.77, 0.90 and 0.69. The Spearman's rank correlation coefficient between PADQLQ total score and VAS was 0.75 (p<0.001). And, Structural validity was evaluated by the ANOVA test. QoL differences of the four groups in the three domains (practical, physical, emotional) were significant. The item discriminative indices were ranged from 0.1651 to 0.8188.

Conclusions

Korean version PADQLQ is highly reliable and valid for children with allergic diseases. This is significant to assess the relative seriousness of the allergic diseases and to evaluate the efficacy of different treatments in Korean Medicine.

Key words: Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ), Translation, Validation, Reliability, Korean medicine

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I. Introduction

The prevalence of allergic diseases shows global variation. Some researches establish an increasing prevalence of allergic diseases 1,2). Other studies indicate a similar level or even a decrease in the prevalence^{3,4)}. The prevalence of allergic diseases of pediatrics was increased globally in these days. 5) The prevalence of asthma, atopic dermatitis, allergic rhinitis in Asia is changed in different localities, it is increasing generally in the developing countries 6,7). Under the recent study of Korean children with allergies, the prevalence of asthma, atopic dermatitis, allergic rhinitis increased from 1995 to 2000 as follows : "for atopic dermatitis, from 16.6% to 24.9% in elementary school students, and from 7.3% to 12.8% in middle school students for asthma, from 7.7% to 9.1%, and from 2.7% to 5.3%; and for allergic rhinitis, from 15.5% to 20.4%, and from 7.7% to 13.6% respectively"8).

The economic liability to treat allergic diseases in direct and indirect expenses are significant, and the developing countries even have a severe burden.⁹⁾

The interest for health-related quality of life (HRQoL) measurement for pediatrics is increasing for both study and clinic¹⁰⁾. There are lots of well-validated HRQoL measures in pediatrics¹¹⁾. Asthma, atopic dermatitis, allergic rhinitis can significantly lay a heavy burden for children's quality of life, with harmful effects on the child's body, mind and social life¹²⁾. One recent study indicated that the quality of life of allergic patients is affected to the same extent as that of patients suffering from conditions such as cardiovascular disease and diabetes¹³⁾.

Until today, various disease-specific Health-Related Quality of Life (HRQoL) instruments have been created for allergic diseases such as rhinitis, atopic dermatitis, asthma^{12,14}. But the patient who has a allergic disease frequently has multiple allergic reactions. Furthermore a patient with a prominent allergic disease has a strong chance to have a different allergic disease¹⁵⁾.

Therefore, a HRQoL questionnaire in different concept, 'Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ)' was made in UK. This assessment tool was developed to estimate the multisystem

symptoms of asthma, atopic dermatitis, allergic rhinitis on HRQoL and considered the aspects from body, mind and everyday social life. PADQLQ is made up of 26 items and it adopted a PRO (Patient-reported outcome) method. The PADQLQ is longitudinally valid as well, as it correlated with the VAS scores, other organ-specific instruments, clinical symptoms ¹⁶. By using this new instrument, the effect of allergic disease to different part of children can be evaluated numerically without using and combining of multiple organ-specific questionnaires. It is regarded as superior to both the PAQLQ and the PRQLQ, because it takes into account the effects of allergic diseases on other organs in addition to the organ of interest ¹⁷⁾.

The PADQLQ has been linguistically validated in Chinese and Swedish versions^{17,18)}. The cultural adaptation of a PRO (Patient-reported outcome) questionnaire to use in another country with different culture, ethnic and languistic barriers require a unique study process to have equivalence. It is applied equally between the UK and the Korean language¹⁹⁾.

In the clinic of pediatrics of Korean Medicine, many children receive a traditional treatment (eg. acupuncture, moxibustion, herb medicine). It is necessary to assess the symptoms of the allergic disease. The evaluation is needed in research, as well as in the treatment. The purpose of this study is to translate the original version or PADQLQ into Korean and to examine the psychometric properties of a Korean version.

II. Materials and methods

1. Subjects

This study was carried out in accordance with the ethical standards. The approval of Institutional Review Board of $\bigcirc\bigcirc$ Hospital at $\bigcirc\bigcirc$ was obtained. A total of 71 patients (31 females and 40 males) aged 4-17 were enrolled in this study and all of them completed the questionnaire. All parents signed the informed consent to allow their child to participate in this study. Their data was summarized in Table 1.

Table 1. General Characteristics of the Subjects (N = 71)

Variables	n (%) or mean ± SD
Age (years)	10.2 ± 2.9
Gender, Male / Female	40 (56.3%) / 31 (43.7%)
Type of Allergic Diseases	
Rhinitis	56 (78.8%)
Atopic Dermatitis	3 (4.2%)
Asthma	1 (1.4%)
Rhinitis, Atopic Dermatitis	8 (11.3%)
Rhinitis, Asthma	1 (1.4%)
Rhinitis, Atopic Dermatitis, Asthma	2 (2.8%)

2. HRQoL Instrument

PADQLQ is made up of three domains: practical (8 items), physical (15 items), emotional (3 items). The questions were also designed to be answered without parental help. All the questions were answered by a 7-point Likert scale which 0 means 'not troubled at all' and 6 means 'extremely troubled'. The total score of the PADQLQ was 156, summation of the scores for all 26 questions. The lower the score of PADQLQ is, the better the QoL of children with allergic diseases. Before the study begins, the written permission from Dr. Graham Roberts (developer of the original UK version of PADQLQ) was obtained for the Korean translation and validation. The patients completed Korean version of PADQLQ once. Parents and one of the authors from the clinic were allowed to assist during its completion. Concurrently, the participants were tested by a visual analogue scale (VAS) as well.

3. Translation Process

According to the international guideline for questionnaire translation (forward and backward translation) two independent Korean versions were made by a doctor of Korean medicine fluent in English and an English bilingual translator (two forward translators). The translation was carried out under the guidelines of ISPOR (International Society for Pharmacoeconomics and Outcomes Research) Translation and Cultural Adaptation group³⁶⁾. With these two forward translation versions are combined by authors. After reconciliation, the Korean version had backward-translation process into English by a bilingual native speaker of UK who is different from

forward translators.

After the revision process to make it easy for understanding, a cognitive debriefing was performed by a focus group meeting with six patients. With the focus group meeting result, some linguistic changes were made.

The product of translation process was examined thoroughly and approved by the author of original UK PADQLQ version (Dr. Graham Roberts). Minor revision was made in accordance with Dr Graham's advice. Korean version has no serious discrepancies compared to the original UK version.

4. Statistical Analysis

To measure the internal consistency of the PADQLQ, the Cronbach's a coefficients were calculated for collectively for the items in each of the three domains as well as for total PADQLQ items. To show the cross-sectional validity between the PADQLQ scores (total and domain) and the VAS score, we calculated Spearman's rank correlation coefficient. The statistical test was carried out in SPSS (Ver. 18.0 Professional Pack). A p-value below 0.05 was considered to be statistically significant. In order to perform cross-sectional validity, 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. VAS was employed in allergic diseases for both evaluation of symptoms and using in the clinic. It is recommended in the World Allergy Organization (WAO) guidelines^{37,38)}. The patients who enrolled on this study were asked to check an "X" along a 10-cm line between two ends indicating no impact (VAS = 0) to maximum impact

Table 2. Focus Group Meeting Participant's Character

	Age	Gender	Disease	Time
Subject 1	7	M	AR*, AD*	5.00
Subject 2	7	F	AR, AD, Asthma	7.33
Subject 3	8	F	AR	7.05
Subject 4	6	M	AR	~**
Subject 5	6	M	AR, AD	4.56

^{*} AR : Allergic Rhinitis, AD : Atopic Dermatitis

(VAS = 10). The VAS score was determined with administration of the PADQLQ.

Ⅲ. Results

1. Translation

Two independent translators for Forward Translation evaluated the difficulty of each sentence, items, choices of PADQLQ. They had significantly different ratings on 7 items. They were 'Think about how much of a problem your allergies have caused you in the past week', 'How much have you been troubled by the following as a result of your allergies in the past week?', 'Being unable to get to sleep or have a good night sleep?', 'Not hearing well', 'Coughing or wheezing?', 'Needing to rub your eyes', 'Being tired or worn out'. Except for these sentences, the difficulty of each questionnaire items has a good concordance (84.4%).

2. Focus Group Meeting

For linguistic validation, focus group meeting which is made up of 5 children with allergic diseases was held. Participants' mean age was 6.8 yrs, and two females and three males. Their average time to complete questionnaire was 6 min (Subject 4 was excluded) (Table 2).

3. Reliability and Validity

The internal consistency reliability of the PADQLQ by Cronbach's α was 0.94. For the three domains (Practical, Physical, Emotional), the Cronbach's α was 0.77, 0.90 and 0.69.

Cross-sectional validity was examined by comparing

the PADQLQ score and the VAS score. The PADQLQ and the VAS score correlated significantly for both in the score of total and domains. The Spearman's rank correlation coefficient between PADQLQ total score and VAS was 0.75 (p < 0.001).

The special property was examined by grouping children into four groups by their VAS score: Group 1 VAS 0-1 (G1), Group 2 VAS 1-3 (G2), Group 3 VAS 3-5 (G3) and Group 4 VAS 5-10 (G4). The distinction between 4 groups was evaluated by the Kruskal-Wallis test, the outcome data was significantly different between them (p < 0.001).

Structural validity was evaluated by the ANOVA test. QoL differences of the four group in the three domain (practical, physical, emotional) were significant. In the practical and emotional domains, (G1, G2), (G1, G3), (G1, G4), (G2, G4) were significantly different. In the physical domain, all the group (G1, G2), (G1, G3), (G1, G4), (G2, G3), (G2, G4), (G3, G4) were significantly different.

The item discriminative indices ranged from 0.1651 to 0.8188. Item discriminative indices are presented in Table 3. The four least discriminative items were Q26 ('feeling frighten by the thought of an asthma attack'), Q18 ('rashes on your skin'), Q5 ('needing to carry or use medicines, inhalers or creams'), Q4 ('Not hearing well') (Table 3).

IV. Discussion

The diagnosis of Korean Medicine is based on the four examinations (inspection, listening and smelling examination, inquiry, palpation) and eight principles (yin-yang,

^{**} Subject 4 could not completed the questionnaire

Table 3. Results of Item Analysis: the Discriminative Indices

Items	Item discriminative index
Q1	0.7251
Q2	0.4858
Q3	0.6584
Q4	0.3408
Q5	0.2999
Q6	0.7690
Q7	0.6273
Q8	0.7237
Q9	0.6396
Q10	0.6386
Q11	0.5925
Q12	0.4168
Q13	0.4631
Q14	0.6714
Q15	0.8188
Q16	0.5069
Q17	0.6094
Q18	0.2571
Q19	0.4136
Q20	0.6340
Q21	0.6471
Q22	0.7456
Q23	0.5966
Q24	0.6960
Q25	0.5304
Q26	0.1651

exterior-interior, cold-heat, deficiency-excess). Through the pattern identification with evidences obtained from the above process, doctors of Korean Medicine could make a diagnosis. In the cases of pediatrics, however, most of diagnosis depends not on the children's own report but parents' report on symptoms and the doctors' inspection. Accordingly, the need of PROs (Patient-Reported Outcomes) instruments is growing. Recently, in Korean Medicine of Pediatrics, studies about allergic diseases in pediatrics used the health-related quality of life (HRQoL) assessment ^{20,21)}. Prior to this study, the assessment of doctor's inspection is the mainstream of evaluation method in most studies²²⁾. Until now, organ-specific HRQoL questionnaires are mainly used, however, allergic diseases affect on multisystem. Among many instruments, the Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ) was selected, because the original English version of PADQLQ was developed to evaluate HRQoL in children / adolescents with multisystem allergic diseases. It has been out of existence, it was important to develop the Korean version of PADQLQ. Therefore, we translated

and validated the PADQLQ to meet the demands of Korean children with allergic diseases. In this study, we translated the questionnaire and established psychometric evidence for its utility in Korean children with similar problems.

Translation of PADQLQ into Korean version was good. There were not any remarkable discrepancies in the translation and cultural adaptations of the PADQLQ. It was easily grasped, and easy to complete by the Korean children. The Korean version of PADQLQ had a excellent internal consistency reliability for total PADQLQ (Cronbach α = 0.94) and moderate to high for three domains (Cronbach α in practical = 0.77, physical = 0.90, emotional = 0.69). In addition, good validity was proved. The cross-sectional validity tested by Spearman's rank correlation coefficient (0.75, p < 0.001) between total PADQLQ score and Visual Analogue Scale (VAS). Without four least discriminative items, result of item analysis was fine.

In the translation process, reconciliation of two sets of translations from two different forward translators was very important and delicate. As a result, the harmonization of the Korean version was good. Backward translation was in concordance with original meaning. Original developer of PADQLQ (Dr. Graham) suggested only minor revision. His main suggestion was to focus on the symptoms by allergic disease. What it means children could be misled by the repeated questions 'how much have you been troubled by the following as a result of your allergies in the past week?' to have other problems in addition to their allergies. When the revised Korean version of PADQLQ was tested in the focus group meeting, children pointed out some difficulties that could not be understood or easily passed unobserved. For example, for them the word 'rash', in Korean '발진' was difficult to understand. To clarify the meaning we included its explanation 'allergic symptoms on your skin which is splashed with red.' It turned out extra explanation was useful as a final Korean version of PADQLQ. During the field study, none failed to complete nor asked for its meaning of the Korean PADQLQ. It demonstrates that the this new version is easy to use in children and adolescents.

The Korean version of PADQLQ's internal consistency reliability is high and very comparable to the original English version of PADQLQ as well as other language versions. Cronbach α in each study was 0.92 in Chinese, 0.96 in Swedish, 0.95 in original English, respectively.

About the validity of this study, cross-sectional validity and the item discriminative indices were mostly high (ranged from 0.2999 to 0.8188). We considered that the least discriminative items Q26 ('feeling frighten by the thought of an asthma attack'), Q5 ('needing to carry or use medicines, inhalers or creams') were related to asthma. In this research, the total number of patients with asthma was only 4 (5.6%). The patients without asthma may not be able to understand these items completely. About Q18 ('rashes on your skin') item, children may not be able to understand the meaning of 'rash' completely. Without these problems, the rest of items

were structurally validated.

This is the first try to translate and validate different aspects and examine psychometric properties of the original English PADQLQ into Korean version in children with allergic diseases. Before this study, there are only disease-specific Quality of Life (QoL) questionnaires that only evaluate allergic rhinitis or asthma symptoms could have some risks of missing to catch the whole burden of disease. And all subjects in the validation phase of the original study had seasonal allergic diseases only, whereas in our study, patients with perennial allergic diseases were also included. Therefore, the validity of the Korean PADQLQ was extended to include patients with perennial allergic diseases. But a limitation of this research is that test-retest reliability was not tested. We will additionally carry out the test-retest process in the future.

The Korean version of PADQLQ can be used in the clinic of Korean Medicine of pediatrics. It will be useful to evaluate the symptoms of children with allergic diseases as well as to assess the HRQoL. PADQLQ will make the four examination process of Korean Medicine enriched with the children patients' own expression about their symptoms. This objective assessment by the PADQLQ could used in the international research settings. It also can help to maximize the Korean Medicine's curative value in children who have allergic diseases.

V. Conclusion

This study is to translate original UK version of PADQLQ into Korean and to suggest cultural adaptation for Korean children with both seasonal and perennial allergic diseases. Korean version PADQLQ is highly reliable and valid for children with allergic diseases. This could be used to evaluate the severity of the allergic diseases and for assessing the efficacy of diverse therapies in children, such as Korean Medicine's treatment including acupuncture, moxibustion, and herb medicine.

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【별첨 1】

소아청소년의 알레르기 질환 삶의 질 설문지

알레르기 질환이란? 비염, 아토피, 천식 등의 과민성 질병들이에요

삶의 질이란? 삶에 대한 만족의 정도를 의미해요

소아청소년의 알레르기 질환 삶의 질 설문지

지난 일주일 동안, 알레르기 때문에 불편했던 정도를 생각해 보아요.

숨쉴 때 증상과 눈, 코, 피부에 나타난 증상들을 모두 떠올려 보아요.

지난 일주일 동안, 알레르기 때문에 불편했던 정도에 대해 가장 잘 설명하고 있는 번호에 동그라미 쳐가면서 답해 보세요. 여기에는 맞는 답도, 틀린 답도 없어요. 이건 시험이 아니에요.

지난 일주일 동안, <u>알레르기 때문에</u> 아래 내용(불편한 점)들을 얼마나 겪었나요?										
	전혀	거의	약간	어느 정도	많이	심하게	대단히 심하게			
집중하기 어려워서 불편했다	0	1	2	3	4	5	6			
학교에서 배운 내용을 기억하기 어려워서 불편했다	0	1	2	3	4	5	6			
잠이 들기 어렵거나 밤에 푹 잠들기 어려워서 불편했나요?	0	1	2	3	4	5	6			
소리를 잘 듣기가 어려워서 불편했다.	0	1	2	3	4	5	6			
약이나 흡입기나 크림을 가지고 다니거나 <u>또는</u> 사용해야만해서 불편했나요?	0	1	2	3	4	5	6			

지난 일주일 동안, <u>알레르기 때문에</u> 아래 내용(불편한 점)들을 얼마나 겪었나요?											
전혀 거의 약간 어느 많이 심하게 대단히 심하게											
뛰거나 놀 때, 기침이 나거나 숨쉴 때 쌕쌕 소리가 나서 불편했나요?	0	1	2	3	4	5	6				
밖에서 운동을 하기 힘들어서 불편했나요?	0	1	2	3	4	5	6				

지난 일주일 동안 했던 모든 활동들을 생각해 보세요.										
전혀 거의 약간 어느 정도 많이 심하게 대단히 심하게										
그 활동들을 하는 동안, 알레르기 때문에 얼마나 불편했나요?	0	1	2	3	4	5	6			

지난 일주일 동안, <u>알레르기 때문에</u> 아래 내용(불편한 점)들을 얼마나 겪었나요?											
전혀 거의 약간 어느 장도 많이 심하게 대단히 심하게											
밤에 기침을 해서 불편했나요?	0	1	2	3	4	5	6				
기침이 나거나 숨쉴 때 쌕쌕 소리가 나서 불편했나요?	0	1	2	3	4	5	6				
숨이 차거나 가슴이 답답해서 불편했나요?	0	1	2	3	4	5	6				

지난 일주일 동안, <u>알레르기 때문에</u> 아래 내용(불편한 점)들을 얼마나 겪었나요?											
	전혀	거의	약간	어느 정도	많이	심하게	대단히 심하게				
눈을 비벼야 해서 불편했어요	0	1	2	3	4	5	6				
눈이 부어서 불편했어요	0	1	2	3	4	5	6				
코가 간질간질해서 불편했어요	0	1	2	3	4	5	6				
코가 막혀서 불편했어요	0	1	2	3	4	5	6				
코를 문질러야 해서 불편했어요	0	1	2	3	4	5	6				
코를 풀어야 해서 불편했어요	0	1	2	3	4	5	6				

지난 일주일 동안, <u>알레르기 때문에</u> 아래 내용(불편한 점)들을 얼마나 겪었나요?											
	전혀	거의	약간	어느 정도	많이	심하게	대단히 심하게				
피부에 발진(발긋발긋한 피부의 알레르기 증상)이 생겨서 불편했어요	0	1	2	3	4	5	6				
피부에 문제가 있어 보여서 불편했나요?	0	1	2	3	4	5	6				
피곤하거나 지쳐서 불편했어요	0	1	2	3	4	5	6				
목이 말라서 불편했어요	0	1	2	3	4	5	6				
목이 건조하거나, 간질간질하거나 아파서 불편했어요	0	1	2	3	4	5	6				
머리가 아팠어요	0	1	2	3	4	5	6				

지난 일주일 동안, <u>알레르기 때문에</u> 아래 내용(불편한 점)들을 얼마나 겪었나요?										
전혀 거의 약간 어느 정도 많이 심하게 대단히 심하게										
짜증이 나거나 불만스러워서 불편했어요	0	1	2	3	4	5	6			
다른 친구들과 다르다고 느껴져서 불편했어요	0	1	2	3	4	5	6			
천식 발작이 일어날 것이라는 생각에 두려워서 불편했어요	0	1	2	3	4	5	6			

알레르기 질환(비염, 아토피, 천식 등) 때문에 얼마나 많이 불편했나요? 그 정도를 아래의 표 위에 엑스(X)자로 표시해 보세요. (10점은 가장 많이 불편했던 것이고, 0점은 불편하지 않았던 것입니다)

0	1	2	3	4	5	6	7	8	9	10