Original Article





Development of a Questionnaire for the Assessment of Quality of Life in Korean Children With Allergic Rhinitis

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Purpose: Korean children have their own unique lifestyle based on their living environment and culture. This study aimed to develop a questionnaire to evaluate the quality of life in Korean children with allergic rhinitis. Methods: After a preliminary survey, an initial questionnaire was developed. Questions were modified to be easily understood by young children aged 6 to 7 years. The modified questionnaire was tested on children aged 6 to 12 years old. Item scores, defined as the proportion of children whose answer score was 1 point or higher was multiplied by the average answer score of each question, were used to identify questions that have practical application to the quality of life in Korean children with allergic rhinitis. Differences in answer scores between children with allergic rhinitis and those who were healthy were assessed by a Wilcoxon rank-sum test. The relationship between nasal index scores and quality of life scores was determined by a Spearman rank order test. Results: An initial questionnaire was composed of 21 items. We identified 19 questions with item scores above 0.5 in children with allergic rhinitis, many of which were related to nasal symptoms and 10 questions that were different between the allergic rhinitis group and the control group. The final questionnaire included the 10 questions that had both high item scores and a significant difference in the answer scores between the two groups. Conclusions: The developed questionnaire is essential and practical for assessing discomfort related to the symptoms felt by Korean children with allergic rhinitis.

Key Words: Allergic rhinitis; quality of Life; children; questionnaire

INTRODUCTION

Allergic rhinitis is a very common disease with the cardinal symptoms of nasal itching, sneezing, rhinorrhea, and nasal congestion. The prevalence rate of allergic rhinitis diagnosis in Korean elementary school students has been continuously increasing, from 15.5% in 1995 to 20.4% in 2000 and 28.5% in 2006.^{1,2} In addition, the age of onset is becoming increasingly younger.1 Chronic disease such as allergic rhinitis affects the quality of life (QOL) of children going through the process of growth and development by substantially interrupting their daily activities. The symptoms of allergic rhinitis can cause sleep disturbance, fatigue, poor concentration, and limitations in daily activities.3 However, the symptoms of allergic rhinitis appear to be milder than those of asthma or atopic dermatitis.⁴ Thus, they tend to be underestimated by parents and even by doctors. A standardized tool for evaluating allergic rhinitis specific QOL is necessary because the ultimate goal of treatment is for the improvement of patients' QOL.

Children with allergic rhinitis have a different living environment and culture. Thus, they may have a different proportion of subtypes of allergic rhinitis. They also may experience difficulties differently in their daily lives. The previously released QOL assessment tool for children with rhinitis may not properly reflect the discomfort of Korean children. Korean children have different living patterns, such as study hours and indoor activity time, and their environment than do children in other countries. More than 45% of Korean students spend up to 4 hours a week in after school lessons in mathematics. Therefore, it is necessary to have a QOL assessment tool for Korean children with allergic rhinitis that reflects their unique lifestyle, taking into account the domestic environment and daily activities.

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Also, a QOL assessment tool for children with allergic rhinitis developed previously in Korea did not have a process to choose essential questions for children with allergic rhinitis. Further, some questions contain words that are not suitable for children in the lower grades.⁸

Modern people are asked to respond to lots of surveys. Though there is a tool to evaluate a QOL precisely, the survey can be refused if it is impractical. Thus, a tool to assess the QOL in patients especially for the children should be practical with fewer essential questions. Therefore, the goal of this study was to develop a QOL assessment tool to evaluate the QOL of Korean children with allergic rhinitis in an easy and more accurate manner in order to properly manage Korean children with allergic rhinitis.

MATERIALS AND METHODS

The initial item development, revision of sentences, final item selection, validation of the tool QOL-KCAR (Quality of Life in Korean Children with Allergic Rhinitis), and response of the tool were conducted with different subjects. Written informed consent was obtained from each subject and their parents. The Institutional Review Board of Inha University Hospital approved this study.

Initial questionnaire

Item development

After comparison and analysis of previously reported questionnaires, ^{6,9,10} we surveyed children with allergic rhinitis, their parents, and professional specialists about disturbances in daily life related to allergic rhinitis. According to the results of the preliminary survey, a questionnaire was developed.

Regarding the scales for the responses, we considered 3- or 5-point scales. To make assessment easier for school-aged children, we created 2 types of answer sheets with either 3-point scales (Never-0, Often-1, Always-2) or 5-point scales (Never-0, A little-1, Sometimes-2, Often-3, Always-4). Five-point scales were determined after a correlation analysis. We developed the initial questionnaire items with 5-point scales for response options after conducting a pretest with children with allergic rhinitis. Patients with allergic rhinitis were asked to recall their experiences during the 7 days when they responded to the tool in the clinic. The questionnaire was administered by one of this study's researchers.

The tool's reliability was assessed by measuring Cronbach's $\boldsymbol{\alpha}$ of internal consistency.

Sentence Revision

When we interviewed children with allergic rhinitis with the initial questionnaire, we found that young children could not understand some of the questions because of their limited vocabularies. They also answered the same questions differently when the questions were worded slightly differently. We modi-

fied this tool by making the vocabulary and sentence structure easier for young children aged 6 to 7 years to understand. First, the researcher interviewed children with allergic rhinitis with the initial questionnaire tool and assessed their vocabulary. To determine which wording would correctly convey the meaning of each question to young children, we wrote three sentences for each item with slightly different wording. The three sentences with the same meaning were placed in the same tool. We compared the responses of 7 years old children to the questions after the children had read the questions by themselves with the responses of the same children after the researcher had read the questions to them. The modified questionnaire was composed of the sentences of each item with the highest concordance rate for the two answers.

Final questionnaire

Final item selection

To develop a tool composed of practical questions related to the discomfort experienced by children with allergic rhinitis, the modified QOL assessment tool was administered to an allergic rhinitis group and a healthy control group. The allergic rhinitis group comprised children aged 6 to 12 years with allergic rhinitis. Allergic rhinitis was defined on the basis of a history of 2 or more nasal symptoms including sneezing, nasal congestion, rhinorrhea, itching and a positive skin test. The healthy control group comprised children aged 6 to 12 years with neither past nor current allergic diseases. Each item score (= proportion X answer score) was calculated by multiplying the proportion of children who answered greater than a score of 1 on the question by the average answer score of the children. We selected the items for which the item score was greater than 0.5 in children with allergic rhinitis. We also chose items for which the answer score differed between the allergic rhinitis group and the healthy control group. Then, we ultimately selected the items that qualified for both criteria.

Validation of the tool

The nasal index score (NIS) and QOL assessment before treatment and after 2 to 4 weeks of treatment in patients with allergic rhinitis were compared to validate the questionnaire tool. The NIS was calculated by giving scores from 0 to 3 (for symptoms; none=0; mild, but weak=1; obvious, but tolerable=2; intolerable, affecting daily activities and sleep=3) for each of the 4 symptoms of nasal congestion, rhinorrhea, sneezing, and nasal itching felt by patients, with total scores ranging from 0 to 12.

Response of the tool

Children of 6-12 years with allergic rhinitis were asked to answer the question to indicate how easy or difficult it was to answer the final tool with 10 questions. Also response time from start to finish of the questionnaire was measured.

Statistics

Statistical analyses were performed by using SAS (ver. 9.4; SAS Institute Inc., Cary, NC, USA). The internal reliability of the initial questionnaire items was assessed with a Cronbach's α .

A correlation analysis was conducted between 3- and 5-point scales by a Spearman rank order test. A test for normality of the data was done with a Shapiro-Wilk test. A Wilcoxon rank sum test was applied to investigate differences in medians of answer score between the allergic rhinitis and health control. A Wilcoxon signed rank test was used to compare the median of the NIS and QOL scores before and after the treatment in children with allergic rhinitis. A Spearman rank order test was run to determine the relationship between NIS and QOL scores.

RESULTS

Initial questionnaire

Item development

We developed 5 groups of 21 questions regarding nasal symptoms (6), eye symptoms (4), other problems (3), medical management issues (4), and daily life (4) after a review of preexisting tools and the preliminary survey from pediatric patients, their parents, and professional specialists (Table 1).

A Spearman rank order test was used to determine the rela-

Table 1. Items of the initial questionnaire

QOL-KCAR						
Group (number of items)	Item (21)	Question number				
Nasal symptoms (6)	Stuffy, blocked nose	Q21				
	Itchy nose	Q7				
	Sneezing	Q18				
	Runny nose	Q14				
	Rub nose	Q9				
	Blow nose	Q16				
Eye symptoms (4)	Watery eyes	Q11				
	Swollen eyes	Q 5				
	Itchy eyes	Q15				
	Rub eyes	Q17				
Other symptoms (3)	Mouth-breathing	Q1				
	Headache	02				
	Tiredness	Q4				
Daily life (4)	Playing outdoors	Q13				
	School activities	Q8				
	Study	Q20				
	Sleep disturbance	Q6				
Medical management (4)	Take medicine	Q10				
	Thirsty	Q12				
	Sleepy	Q19				
	Clinic visit	0.3				

KQOL-CR, Korean quality of life-children with rhinitis.

tionship between 3- and 5-point scales of the tool in 7 children with allergic rhinitis. There was a very strong, positive correlation between the 3-point and 5-point scales except for eye symptoms (Table 2). Therefore, we used 5-point scales for the tool considering the tool's sensitivity. The initial QOL tool was administered to 208 children with allergic rhinitis aged 6 years and older. The internal consistency of the tool was very high as measured by a Cronbach's α of 0.921 (Data were not shown).

Sentence revision

Children aged 6 to 8 years prefer certain words over others in certain sentences. We evaluated the responses of 60 children aged 6 to 8 years to the 63 questions for the 21 items and compared the answers they gave when they read the questionnaire by themselves with the answers they gave when the questions were explained to them by the researcher. We selected 21 sentences with the highest concordance score between the two responses.

Among the words uncomfortable, bothered, annoyed, and hard, the children preferred the word bothering for going to the hospital, the word hard for headache, and the word annoying for sleep disturbance. For nose symptoms, the children responded to the word uncomfortable instead of hard. In the sentences regarding medication, hard and bothered were understood with a similar frequency. For the words understood with a similar frequency, both words were used in the completed sentence, such as 'How hard was it or how much were you bothered...?' Note that in the sentences written in Korean we used both wordings in one sentence with the conjunction 'or'.

Final questionnaire

Final item selection

The allergic rhinitis group comprised 109 children (Table 3) and the healthy control group comprised 99 children. The mean age of the allergic rhinitis group was 10.1 ± 1.8 years and the mean age of the healthy control group was 10.1 ± 1.7 years. There was no significant difference in age between the two groups (P=0.98).

To select practical questions that addressed the discomfort due to the disease of children with allergic rhinitis, the score for each question (item score) was calculated. The results showed that the questions related to nasal symptoms, such as nasal

Table 2. Correlation coefficients between 3 scales and 5 scales of the tool

	Correlation coefficient, r	<i>P</i> value
Nasal symptoms	0.937	0.002
Eye symptoms	0.645	0.067
Other problems	0.939	0.006
Daily life	0.925	0.008
Medical management	0.852	0.031
Total	0.983	0.003

congestion, rhinorrhea, and nose blowing, had high scores (Table 4). From this analysis, 19 questions with an item score of 0.5 or higher were selected.

In addition, answers from the allergic rhinitis group were compared with the answers from the healthy control group. Ten questions with different answer scores between the two groups based on a significance level of 0.05 were selected (Table 5).

Ten questions (6 questions on nasal symptoms, 1 questions on eye symptoms, 2 questions on medical management, and 1 questions on other problems) that had an item score of 0.5 or higher and also had answer score differed significantly between the allergic rhinitis group and the healthy control group were

Table 3. Characteristics of subjects with allergic rhinitis (N=109)

Variable	n (%)	% of CRS
Age, years (Mean \pm SD)	10.11 ± 1.797	
Sex, male/female	67 (62.04)/41 (37.96)	
Classification of allergic rhinitis		
Mild intermittent	17 (15.97)	43.59
Mild persistent	24 (21.93)	56.25
Moderate to severe intermittent	8 (7.02)	61.54
Moderate to severe persistent	60 (55.26)	65.91

CRS, chronic rhinosinusitis,

 Table 5. Item and answer scores between allergic rhinitis and control group

	Allergic rhinitis group (n=108)			Healthy control group (n=53)					
_	Item	A	Answer score		Item	Answer score			<i>P</i> value
	score	Median	Mean	SD	score	Median	Mean	SD	_
Q1. Mouth-breathing	1.26	1	1.94	1.03	0.64	0	1.89	1.02	0.001
Q2. Headache	0.99	1	1.81	1.01	1.23	1	1.86	0.94	0.158
Q3. Clinic visit	1.15	1	1.92	1.15	0.98	1	1.86	1.11	0.405
Q4. Tiredness	1.37	1	1.95	0.99	1.36	1	2.00	1.04	0.883
Q5. Swollen eyes	0.65	0	2.00	0.97	1.36	0	1.73	1.01	0.097
Q6. Sleep disturbance	1.14	1	2.05	1.06	0.83	0	2.00	0.87	0.126
Q7. Itchy nose	1.34	1	1.99	0.97	0.62	0	1.5	0.80	< 0.001
Q8. School activities	1.21	1	2.09	1.09	1.17	1	2.00	1.15	0.663
Q9. Rub nose	1.26	1	2.00	1.07	0.60	0	2.13	0.99	< 0.001
Q10. Take medicine	1.19	1	2.22	1.11	0.60	0	1.78	0.81	0.009
Q11. Watery eyes	0.39	0	1.50	0.88	0.42	0	1.47	0.74	0.764
Q12. Thirsty	0.72	0	1.86	1.09	0.38	0	1.82	0.87	0.030
Q13. Playing outdoors	0.48	0	2.17	1.31	0.38	0	1.67	0.89	0.940
Q14. Runny nose	1.59	1	2.18	1.17	1.00	0	2.04	1.11	0.006
Q15. Itchy eyes	1.19	1	2.21	1.17	0.79	0	1.83	0.94	0.119
Q16. Blow nose	1.47	1	2.18	1.06	0.85	0	1.96	1.19	0.002
Q17. Rub eyes	1.13	1	2.07	1.1	0.72	0	2.00	1.11	0.033
Q18. Sneezing	1.26	1	2.00	1.05	0.66	0	1.67	0.73	0.003
Q19. Sleepy	0.68	0	1.74	1.04	0.47	0	1.47	0.8	0.324
Q20. Study	1.08	1	2.11	1.12	0.87	0	2.19	1.21	0.210
Q21. Stuffy, blocked nose	1.88	2	2.42	1.17	1.04	0	1.77	1.09	< 0.001

Table 4. Item scores in children with allergic rhinitis

	Proportion	Answer score, Mean	Item score
Q21. Stuffy, blocked nose	0.78	2.42	1.88
Q14. Runny nose	0.73	2.18	1.59
Q4. Tiredness	0.70	1.95	1.47
Q16. Blow nose	0.68	2.18	1.37
Q1. Mouth-breathing	0.65	1.94	1.34
Q3. Clinic visit	0.60	1.92	1.26
Q10. Take medicine	0.54	2.22	1.26
Q7. Itchy nose	0.67	1.99	1.26
Q8. School activities	0.58	2.09	1.21
Q9. Rub nose	0.63	2.00	1.19
Q2. Headache	0.55	1.81	1.19
Q18. Sneezing	0.63	2.00	1.15
Q6. Sleep disturbance	0.56	2.05	1.14
Q20. Study	0.51	2.11	1.13
Q15. Itchy eyes	0.54	2.21	1.08
Q17. Rub eyes	0.54	2.09	0.99
Q12. Thirsty	0.39	1.86	0.72
Q19. Sleepy	0.39	1.74	0.68
Q5. Swollen eyes	0.32	2.00	0.65
Q13. Playing outdoors	0.22	2.17	0.48
Q11. Watery eyes	0.26	1.50	0.39

Table 6. Final questionnaire for assessment of QOL

Items related with rhinitis	None (Never)	A little	Sometimes	Often	Always
1. How hard was it for you because you had to breathe in and out through your mouth?	0	1	2	3	4
2. How uncomfortable was your itchy nose?	0	1	2	3	4
3. How uncomfortable was it rubbing your nose?	0	1	2	3	4
4. How hard or annoying was taking medication or using nose spray for your allergies?	0	1	2	3	4
5. How hard was it for you to get thirsty after taking medication or spraying it into your nose?	0	1	2	3	4
6. How uncomfortable was your runny nose?	0	1	2	3	4
7. How uncomfortable was it to blow your nose?	0	1	2	3	4
8. How uncomfortable was it to rub your eyes?	0	1	2	3	4
9. How hard was it to have a sneezing?	0	1	2	3	4
10. How uncomfortable was it to have a stuffy nose?	0	1	2	3	4

QOL, quality of life.

Table 7. The comparison between the nasal index score (NIS) and the Quality of Life (QOL) before and after treatment

Item	Before treatment (n=14)			After treatment (n=14)			Dualua	
item	Median	Mean	SD	Median	Mean	SD	<i>P</i> value	
Q1	1	1.5	1.5	0	8.0	1.1	0.148	
Q7	1	1.4	1.0	1	1.1	0.9	1.000	
Q9	1	1.2	1.1	1	0.9	0.9	0.672	
Q10	1	1.2	1.2	1	0.9	1.1	0.556	
Q12	0	0.9	1.2	0	0.3	0.8	0.234	
Q14	1.5	1.7	1.3	1	1.1	1.1	0.191	
Q16	1	1.6	1.2	0	0.6	8.0	0.043	
Q17	0.5	0.9	1.3	0	0.4	0.6	0.266	
Q18	1	1.1	1.0	0	0.5	0.7	0.172	
Q21	1	1.7	1.3	0.5	1.2	1.5	0.361	
QOL median	1	1.3	0.9	0.5	0.7	0.8	0.072	
QOL total	10.5	13.1	8.1	5	7.9	6.6	0.094	
NIS total	4	4.4	2.8	2	2.7	2.6	0.103	
Sneezing	1	1.1	0.5	0.5	0.6	8.0	0.109	
Rhinorrhea	1	0.9	1.0	0.5	0.6	0.6	0.391	
Itching	1	1.3	1.1	0	0.4	0.8	0.037	
Obstruction	1	1.1	0.9	1	1.1	1.0	0.852	

ultimately selected. With eye symptoms placed in the group of other problems, the final questionnaire was composed of three groups of questions (6 nasal symptoms, 2 other problems, and 2 medical management issues: Q1, 7, 9, 10, 12, 14, 16, 17, 18, and 21). Each question had a 5-point scale; thus, the final QOL assessment tool had a score distribution of 0 to 40 (Table 6).

Validation of the tool

The validity of the final tool with 10 questions was verified in allergic rhinitis patients. The NIS and QOL were assessed in 18 patients diagnosed with allergic rhinitis (mean age, 10.05 ± 1.88 years) before and 2 to 4 weeks after treatment. Although there were no statistically significant difference, the NIS decreased

from 4.4 ± 2.8 before treatment to 2.7 ± 2.6 after treatment (P=0.103), and QOL improved from 13.1 ± 8.1 to 7.9 ± 6.6 . The answer scores differed per question before and after the treatment (Table 7).

The correlation coefficient between NIS and QOL was 0.25 (P=0.0125) in allergic rhinitis patients.

Response of the tool

After validation of the tool, 32 children completed the final questionnaire. The average age was 9.6 ± 2.8 years (range 6.8-14, male 20, female 12). The mean time to finish the questionnaire was 102.8 ± 43.2 seconds. Among them, 18 (56.2%) found that it was very ease to answer the questionnaire, 11 (37.5%) somewhat ease, 1 (3%) somewhat difficult, and 1 (3%) very difficult.

DISCUSSION

Allergic rhinitis is not only limited to the physical symptoms of the nose and eyes but also provokes disturbances in the general well-being of the affected subjects. This study aimed to develop a questionnaire to measure the disease related QOL of Korean children with allergic rhinitis. Allergic rhinitis is not just a mild disease, because it can lead to or aggravate other diseases such as sinusitis, otitis media, and asthma when not properly controlled. Also, considering that its prevalence is continuously increasing compared with the prevalence of asthma, it is very important to manage it effectively.

Because Korean children have a living environment and lifestyle that differ from those of children in other countries, the types and symptoms of allergic rhinitis in Korean children might differ as well. Therefore, this study was aimed at developing the QOL-KCAR, which can properly reflect Korean children's actual difficulties in daily activities due to their allergic rhinitis. For this tool to be practically used for the management of children with allergic rhinitis, assessment of QOL should be easy and disease-specific. Thus, this study tried to develop a questionnaire comprised of essential disease-specific items.

To develop such a QOL assessment tool, questions were selected after review the previously developed questionnaires. The preexisting QOL tools are the QOL assessment tool for children^{6,11,12} with rhinitis and the QOL assessment tool for adult⁹ with rhinoconjunctivitis. Additional questions were developed after interviews of allergic rhinitis patients and their parents and after having multiple discussions with allergists who treated children with allergic rhinitis.

The initial questionnaire comprised 21 questions that covered the areas of nasal symptoms, eye symptoms, other problems, daily life, and medical management. Each question had a quantitative scale that addressed the subjective difficulties of symptoms or activities related to symptoms instead of the intensity or frequency of the symptoms themselves. Score scales were considered to prevent concentration toward the center. Because 7-point scales can be unsuitable for school children, 3and 5-point scales were compared. Five-point scales were chosen by taking into account the sensitivity of the tool. The vocabulary and sentence structure of the selected questions were then modified. Children with allergic rhinitis and second graders at an elementary school were interviewed with the initial questionnaire. We investigated the wording they preferred in sentences. For example, when the question asked, "How hard was it for you to go to a doctor?" some children simply answered "I did not have a hard time but it was bothersome." Thus, they used the word bothersome to describe the action of going to a doctor. They used the words hard and annoying with similar frequency when discussing medication. In those cases, both words were used to compose the question in Korean. In addition to modify sentences with the best word, we noted on the questionnaire that words such as uncomfortable, hard, annoying, and bothering should be understood to have the same meaning to prevent the children from having difficulty in giving accurate answers owing to words.

Each question's item score was calculated to analyze how much each question reflected the difficulty experienced by children with allergic rhinitis. The mean answer score of the 21 questions was 1.50-2.42. The score for nasal obstruction was the highest and that for watery eyes was the lowest. Two questions with an item score at or lower than 0.5 (Q13 playing outdoors, and Q11 watery eyes) were excluded from the final questionnaire. Items that did not differ significantly between the allergic rhinitis patient group and the healthy control group (Q2 headache, Q3 clinic visit, Q4 tiredness, Q5 swollen eyes, Q6 sleep disturbance, Q8 school activities, Q11 watery eyes, Q19 sleepiness, and Q20 study) were additionally excluded. Therefore, the final questionnaire comprised 10 questions.

Concerning the excluded questions, headache did not reflect a disease-specific discomfort, because the healthy children had a higher item score than that in the allergic rhinitis patients. Considering that the subjects were physically active schoolchildren, we expected difficulties in playing outside, school activities, and study compared to healthy children. However, the comparative analysis showed that the difficulties in such activities were not that great, because the item scores were similar between the patient group and the healthy control group in Korean children. These findings are consistent with the results of other studies. ^{6,13}

To validate the final questionnaire, the NIS and QOL were assessed before and after treatment. As the NIS decreased after treatment, QOL showed improvement. Each item score decreased after the treatment, thus showing that the questionnaire is reliable. The correlation coefficient between NIS and QOL was about 0.25. The poor correlation between QOL and NIS reflects that the degree of objective symptoms and the discomfort felt by an individual do not match. About 94% of children responded that it was "very easy" or "somewhat easy" to answer the question. Response time of the Questionnaire was less than 3 minutes. Thus, the final QOL-KCAR was found to be easy to answer.

This instrument was developed for the evaluation of the quality of life in Korean children with allergic rhinitis. However, this tool was not evaluated to have capacity to distinguish between patients with allergic rhinitis and different groups of patients such as patients with chronic rhinosinusitis. The quality of life by using this tool may not be different between allergic rhinitis and chronic rhinosinusitis since nasal diseases share many symptoms and 20%-75% of patients with allergic rhinitis have chronic rhinosinusitis. In this study about 56% of this study's subjects with allergic rhinitis also had chronic sinusitis. Further studies are needed so that this tool can distinguish the QOL of patients with AR from that in patients with other nasal diseases.

In conclusion, the QOL-KCAR assessment tool comprising 10 questions was developed to assess the practical difficulties experienced in daily activities of Korean children with allergic rhinitis. To effectively manage allergic rhinitis, not only the patient's objective symptoms but also the subjective QOL reflecting discomfort due to the disease should be assessed. The QOL-KCAR is expected to be useful as a suitable tool for assessing QOL in Korean children with allergic rhinitis.

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