

Measuring quality of life in children with rhinoconjunctivitis

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Objective: The objective of this study was to develop, pretest, and validate a questionnaire to measure quality of life in children with seasonal allergic rhinoconjunctivitis (SAR).

Methods (development study): Thirty-four children with SAR were enrolled from summer camps, notices in the media, and an allergy clinic (Southern Ontario). After generating a pool of 48 potentially important quality of life items, the children identified the ones that they experienced with their SAR and scored each for bother (1 = a little bothered to 4 = extremely bothered). Items identified most frequently and with the highest bother score were included in the Paediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ). The PRQLQ was pretested for ease of completion and accuracy of understanding.

Results (development study): The PRQLQ has 23 items in five domains (nose symptoms, eye symptoms, practical problems, other symptoms, and activities). Responses are given on a seven-point scale, and children are asked to score their experiences during the previous 7 days.

Methods (validation study): Seventy-five children with symptomatic SAR were enrolled from notices in the media and a pediatric allergy clinic (Austin, Tex.). A single cohort design was used, with children assessed at 0, 1, and 3 weeks. The PRQLQ was administered to the children by a trained interviewer at 1 and 3 weeks. A conventional nasal symptom diary was completed for 1 week before each of these clinic visits. Global ratings were completed at the final visit.

Results (validation study): In patients who were stable between clinic visits, the PRQLQ demonstrated good reliability (intraclass correlation coefficient = 0.93). The questionnaire was very responsive to change ($p < 0.001$) and was able to differentiate between patients who were in a stable clinical state and those whose clinical state changed between visits ($p = 0.005$). Correlations between the PRQLQ and diary scores were close to predicted and supported both the cross-sectional and longitudinal validity of the PRQLQ.

Conclusions: The PRQLQ measures the quality of life impairments important to children with SAR. Children provide reliable and accurate responses, the measurement properties

are strong, and the questionnaire can be used with confidence in clinical trials, clinical practice, and surveys. (*J Allergy Clin Immunol* 1998;101:163-70.)

Key words: *Quality of life, rhinoconjunctivitis, pediatrics*

Two of the aims of treating children with rhinoconjunctivitis must be to ensure that they feel better and that their enjoyment of everyday activities is improved. There is now strong evidence in both adults and adolescents with rhinoconjunctivitis^{1,2} and in adults and children with asthma^{3,4} that health-related quality of life (HRQL) correlates poorly with the conventional clinical indices of disease severity, and the same would therefore be expected in children with seasonal allergic rhinoconjunctivitis (SAR). Why should the correlation between symptom severity and HRQL be poor? In symptom diaries, patients record the *severity*, *frequency*, or both of nose symptoms (sneezing, stuffy, runny, and itchy) and eye symptoms (itchy, watery, sore, and red), whereas the symptom domain of a quality of life questionnaire asks patients how much they have been *bothered* by these symptoms. Because patients are very heterogeneous in their tolerance and acceptance of symptoms, a high correlation between severity and bother should not be expected. Quality of life questionnaires not only measure how much patients are bothered by their symptoms, they also measure the impact that the symptoms have on day-to-day functioning (physical, social, occupational, and emotional). With rhinoconjunctivitis patients leading a wide range of life styles, having very different personalities, and not having the same sleep abilities, it is to be expected that the correlation between symptom severity and other domains of HRQL will also not be high. Therefore if one is going to understand the burden of illness (impairment of HRQL) experienced by children with rhinoconjunctivitis and to have confidence that the children are benefiting from interventions, it is essential to measure HRQL directly. This information cannot be imputed from symptom diary data.

Originally, HRQL questionnaires were considered to be research tools, but recently clinicians have started to incorporate HRQL into routine clinical assessments. Disease-specific questionnaires provide a simple, quick, and standardized method for taking a brief medical history. They ask the questions that clinicians usually ask, such as: How much have you been bothered by your nose symptoms? Do they interfere with activities you like doing? Did the medication help? The advantages

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Supported by a grant from Hoechst Marion Roussel Inc.

Received for publication April 30, 1997; revised Sept. 22, 1997; accepted for publication Sept. 24, 1997.

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0091-6749/98 \$5.00 + 0 1/1/86354

Abbreviations used

HRQL:	Health-related quality of life
ICC:	Intraclass correlation coefficient
PRQLQ:	Paediatric Rhinoconjunctivitis Quality of Life Questionnaire
SAR:	Seasonal allergic rhinoconjunctivitis

are that the patient can complete the questionnaire in the waiting room, the clinician does not have to remember all the relevant questions, and a quick scan of the responses will reveal how much HRQL is impaired and may reveal problems not spontaneously volunteered by the patient. In addition, changes in HRQL scores between clinic visits provide a more accurate assessment of intervention effectiveness than does patient recall.

Studies in children with asthma⁵ and extremely low birth weight children⁶ have revealed that parents often have a poor perception of the problems that their child is experiencing. Therefore it is necessary to have valid HRQL questionnaires that can be completed reliably and accurately by the children themselves. In this study we have developed the Paediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ) for children 6 to 12 years old with SAR. We have evaluated whether children in this age range can provide reliable and accurate data, and we have tested the instrument for its measurement properties and validity.

METHODS

The development and testing of the PRQLQ required two separate studies, and these were conducted in different locations and used different subjects. The methods for the two studies are presented separately.

Study 1: Development

Subjects

Thirty-four children (6 to 12 years old) were enrolled in the development study conducted in Southern Ontario. All of the children had SAR and had experienced troublesome symptoms in the previous month. They were enrolled from children attending summer camps (sports, arts, and library), from responses to notices in the local media, and from children attending an allergy clinic. Children were selected to represent, as much as possible, the full range of the following criteria: rhinoconjunctivitis severity, age, sex, urban/rural environment, and socioeconomic and ethnic backgrounds. Children with asthma or other medical conditions that might affect HRQL were excluded.

Study design

Item generation phase. Initially we generated a list of all possible items of functional impairment that might be a problem to children with allergic rhinoconjunctivitis. The item pool was generated from the following sources: (1) item pools from the development of the Rhinoconjunctivitis Quality of Life Questionnaire,¹ the Adolescent Rhinoconjunctivitis Quality of Life Questionnaire,⁷ and the Paediatric Asthma Quality of Life

Questionnaire⁴; (2) discussion with children 6 to 12 years old with allergic rhinoconjunctivitis; (3) discussion with clinicians looking after children with rhinoconjunctivitis; and (4) a review of the pediatric HRQL literature.

We generated a list of 48 potential items that appeared to fall into eight domains (sleep problems; nose symptoms; eye symptoms; throat, mouth, and ear symptoms; other symptoms; practical problems; emotional function; and activity limitations).

Item reduction phase. The study was explained to the parent and the child; the parent was asked to sign an informed consent, which had been approved by the Ethics Committee of McMaster University Faculty of Health Sciences.

Each child was interviewed on one occasion. A brief allergic rhinoconjunctivitis history was taken, and medications used for rhinoconjunctivitis were recorded. The item reduction questionnaire was administered to each child by a trained interviewer. Each child was asked which of the 48 items in the item pool he or she experienced as a result of rhinoconjunctivitis. For each item that was positively identified, the child was asked to tell us the importance of that item: a little bothered (score = 1), somewhat bothered (score = 2), bothered a lot (score = 3), or extremely bothered (score = 4).

We calculated the proportion of children identifying each item positively (proportion), and for positively identified items, we calculated the mean importance score. We then calculated the overall impact score (proportion $\times$ importance). Items with the highest impact score were included in the PRQLQ.

Pretesting phase. The PRQLQ was pretested in 10 children with rhinoconjunctivitis who had not participated in either the item generation or item reduction phases. The purpose of the pretesting was to ensure that the wording in the questionnaire was easily understood by children as young as 6 years old, that they understood the concept of each question correctly, and that they understood the seven-point response options. The questionnaire was first administered to the child by a trained interviewer, and all places of possible poor understanding were noted. The interviewer then asked the child to tell her the meaning of each question. Wherever correct and easy understanding was considered even slightly questionable, alternative wording was found.

Study 2: Validation

Subjects

Eighty-three children (6 to 12 years old) participated in the validation study, which was conducted in Austin, Texas. Children were enrolled from those who responded to media notices and from patients attending a pediatric allergy clinic. Children were required to have troublesome allergic rhinoconjunctivitis that required additional medication. None had any other illness that might have had an impact on HRQL. Parents were asked to sign a consent and children to sign an assent that had been approved by an institutional review board (Research Consultants Review Committee, Austin, Tex.).

Study design

The study was a 3-week, single-cohort study conducted during the fall pollen season of 1996. Children were seen at enrollment and after 1 and 3 weeks. At each visit, the children completed the PRQLQ. For 1 week before each follow-up visit (weeks 1 and 3), children completed a rhinoconjunctivitis symptom diary each morning and each evening. At the final follow-up visit (week 3), the child, the parent, and the clinician each completed a global rating of change questionnaire about

changes in the child's rhinoconjunctivitis since the previous visit.

At the second clinic visit (1 week), the clinician prescribed medication for the child's rhinoconjunctivitis symptoms. He or she prescribed the most appropriate treatment for the individual child. The medication was taken regularly until the final clinic visit.

Outcome measures

Paediatric Rhinoconjunctivitis Quality of Life Questionnaire (Appendix). The questionnaire has 23 questions in five domains (nose symptoms, eye symptoms, practical problems, other symptoms, and activity limitations). Responses are given by using two seven-point scales (a green card and a blue card, see Appendix), where 0 represents no impairment and 6 represents maximum impairment. The questionnaire was completed in the clinic at each clinic visit and the children were asked to recall their experiences during the previous 7 days. The questionnaire was administered by a trained interviewer. The parent, who accompanied the child to the clinic, was not present during the interview.

Symptom diary. Children were asked to complete a symptom diary each morning on rising and each evening on going to bed. On each occasion, they rated three nasal symptoms (stuffy nose, runny nose, and sneezing) and eye symptoms for both severity and duration of symptoms. Both severity and duration were scored on a four-point scale from 0 = none/none of the time to 3 = severe/all of the time. Children were asked to complete the diary on their own if possible. If parental help was required, parents were asked not to guide children in their responses or to challenge or interfere with responses chosen by the child.

*Global rating of change questionnaires.*⁸ Global rating of change questionnaires were completed independently by the child, the parent, and the clinician at the final clinic visit (week 3). The questionnaires asked about changes in the child's rhinoconjunctivitis since the previous clinic visit (week 1). If there had been an improvement or a deterioration, respondents were asked to rate the amount of improvement or deterioration by using a 15-point scale (+7 = a very great deal better to 0 = no change to -7 = a very great deal worse).

Testing the measurement properties

General approach. Health-related quality of life measurement instruments may have one or more purposes. An evaluative instrument is designed to measure longitudinal change in an individual or group. For instance, we may wish to determine whether HRQL in a group of children with rhinoconjunctivitis receiving an experimental intervention improves more than HRQL in a group of children receiving a control treatment. Responsiveness (the ability to detect important changes, even if they are small) and longitudinal construct validity (appropriate correlations between changes in the new questionnaire and changes in other measures) are the measurement properties required of an evaluative instrument.⁹

A discriminative instrument is designed to distinguish between persons at a single point in time. For instance, we may wish to discriminate between children experiencing mild impairment of quality of life and those experiencing more severe impairment so that the more severe can be enrolled into a clinical trial. Discriminative instruments require good reliability (high ratio of differences between patients to differences within patients) and cross-sectional construct validity (appropriate correlations between established rating scales and the instru-

TABLE I. Highest impact items (item reduction study)

Item	Number	Proportion	Importance	Impact*
Stuffy/blocked nose	32	.94	2.72	2.56
Itchy eyes	29	.85	2.80	2.39
Rub nose and eyes	28	.82	2.70	2.22
Sneezing	28	.82	2.60	2.14
Having to blow nose	24	.71	3.00	2.12
Running nose	29	.85	2.41	2.06
Having to carry kleenex	23	.68	2.22	1.50
Thirst	22	.65	2.00	1.29
Don't feel well	16	.47	2.60	1.22
Irritable	18	.53	2.11	1.12
Tired	21	.62	1.80	1.11
Having to take medications	28	.82	1.30	1.07
Hard to get to sleep	17	.50	2.10	1.05
Watery eyes	20	.59	1.75	1.03
Poor attention	15	.44	2.30	1.01
Playing outdoors	19	.56	1.80	1.01
Scratchy/itchy throat	13	.38	2.50	0.96
Headache	19	.56	1.70	0.95
Itchy nose	18	.53	1.80	0.95
Wake up during night	21	.62	1.50	0.93
Embarrassed	12	.35	2.60	0.92
Dry throat	16	.47	1.90	0.89
Swollen/puffy eyes	16	.47	1.90	0.89
Sore eyes	13	.38	2.30	0.88

*Impact = Proportion × Importance.

ment being tested).⁹ We have tested the PROLQ for both evaluative and discriminative properties.

Statistical analysis

Categorizing children. Conceptually, testing of the PROLQ's measurement properties required definition of a population of children with rhinoconjunctivitis who remained stable between the second and third clinic visits (week 1 to week 3) and another population who experienced changes in their rhinoconjunctivitis over the same time period. We categorized children either as having stayed the same (group A) or changed (group B) by using the global rating of change questionnaires. If respondents scored -1, 0, or +1 on the global rating, they were considered to have stayed the same, and if they scored between -7 and -2 or between +2 and +7, they were considered to have changed.⁸

When we test the measurement properties of quality of life questionnaires in adults, we use the patient global ratings to categorize them into groups A and B.³ When we validated the Paediatric Asthma Quality of Life Questionnaire,⁴ we found that the youngest children were unable to complete the global ratings reliably, probably because they could not remember how they were 4 weeks previously, and so we used the clinician's global rating. In this study we used a weighted kappa¹⁰ to look at the agreement in global rating scores between the children (<10 years and >10 years), the clinicians, and the parents. We decided a priori that if the kappa values between the younger children and the adults were worse than the kappa values between the older children and the adults that this would be a strong indication that the

TABLE II. Concordance (kappas*) for global ratings of change questionnaires

	Child and parent	Child and clinician	Parent and clinician
All children (<i>n</i> = 74)	0.50	0.38	0.61
Children 10-12 years (<i>n</i> = 39)	0.66	0.61	0.64
Children 6-9 years (<i>n</i> = 35)	0.35	0.15	0.56

*Weighted kappa: range 0 to 1, where 0 = no concordance and 1 = full concordance.¹⁰

These data were used to determine whether the child's, the parent's, or the clinician's global rating of change should be used to categorize into groups A and B (see text).

younger children did not fully understand the global ratings and that the clinicians' scores should be used to categorize the children.

Scoring the PRQLQ. Individual items within the PRQLQ are equally weighted. The questionnaire is analyzed directly from the scores recorded and the results are expressed as the mean score per item for each of the domains, as well as for overall quality of life (i.e., both the domain and overall scores range from 0 to 6). The overall score is estimated from the mean score of all items (thus ensuring that greater weight is given to the domains with the larger number of items).

Evaluative properties. We examined the responsiveness of the PRQLQ in two ways. First, using a paired *t* test, we assessed the ability of the instrument to detect within-subject changes in patients who changed (group B). Second, using an unpaired *t* test of the differences, we examined the ability of the instrument to distinguish between groups A and B in terms of change in quality of life between the beginning and end of the study period. For both of these estimations, symmetry of the data from those who improved and those who deteriorated justified our changing the sign in those who deteriorated.

We assessed longitudinal construct validity by correlating within-subject changes in quality of life scores with within-subject changes in diary symptom scores. We also examined the correlation of changes in quality of life scores with global rating of change. We made a priori predictions that if the PRQLQ was truly measuring rhinoconjunctivitis-specific quality of life in these children, the correlations should be similar to those observed in adults with rhinoconjunctivitis.¹⁻³

Discriminative properties. We used data from children who were stable between consecutive clinic visits (group A) to determine the reliability of the PRQLQ. We determined the signal (the variability between subjects) and the noise (the variability within subjects) and expressed the results as an intraclass correlation coefficient (ICC) (ratio of signal to signal plus noise). We examined cross-sectional construct validity by correlating quality of life scores at the second clinic visit (week 1) with scores from the daily symptom diary during the previous week. Once again, we made a priori predictions that the correlations should be close to those observed in adults.¹⁻³

RESULTS

Item reduction phase

All 34 children enrolled in the study completed the questionnaire and provided complete data sets. There were 16 females and 18 males, with a mean age of 9.7

TABLE III. Reliability of the PRQLQ in children with stable rhinoconjunctivitis (*n* = 13)

	Within-subject SD	Between-subject SD	ICC
Overall quality of life	0.35	1.29	0.93
Nose symptoms	0.83	0.96	0.57
Eye symptoms	0.54	1.74	0.91
Practical problems	0.78	1.50	0.79
Other symptoms	0.56	1.48	0.88
Activity limitations	0.52	1.33	0.87

years (SD = 1.8 years). Fifteen children were currently taking an antihistamine for their rhinoconjunctivitis, two were using an inhaled nasal steroid, four were using a nonsteroidal nasal spray, one was taking eye drops, and four were using a combination of medications. Eight children were not currently taking any medications but had required medications during the previous month.

The analysis of the item reduction questionnaire is shown in Table I. The table presents the number and proportion of children who reported experiencing each item, the mean importance score for each positively identified item (importance), and the overall impact of the item (proportion $\times$ importance). We constructed the PRQLQ (Appendix) by selecting the items with the highest impact scores.

The final questionnaire has 23 items in five domains. When we reviewed the top scoring items, they grouped together very easily into the five well-balanced domains. The first and second domains record the problems that children experience with their nose and eye symptoms, respectively. The third domain consists predominantly of practical problems and things that are a nuisance to children with rhinoconjunctivitis. We have included the only emotional function item that scored highly (embarrassed) in this domain because it seemed that this domain is most representative of how children feel about their rhinoconjunctivitis. The fourth domain consists of symptoms, other than nose and eye symptoms, that are bothersome to children with SAR. The final domain we have entitled "activities," and this includes two questions concerning sleep. Scores for "scratchy/itchy throat" and "dry throat" showed high item-item correlation and appeared to be measuring a very similar problem. To ensure that the "other symptom" domain was not over-weighted by throat symptoms, both of which had scored fairly low (Table I), we decided not to include "dry throat" in the final questionnaire.

Pretesting

We found that one "lead-in" and two questions required modification. Originally, we had used "hayfever" as a common term for SAR. This was not easily understood by all children and was changed to "your nose and eye allergies." Not all the children understood the term "irritable," so we added two nongrammatical but popular words that are used to express this feeling (cranky/

TABLE IV. Correlations between the PRQLQ and diary symptoms at week 1

PRQLQ	Symptom diary				
	Stuffy nose	Runny nose	Sneezing	Mean nose symptoms	Eye symptoms
Overall quality of life	0.22†	0.44†	0.39†	0.41†	0.41†
Nose symptoms	0.33†	0.47*	0.46*	0.52*	0.25‡
Eye symptoms	0.12‡	0.19‡	0.27‡	0.23‡	0.59*
Practical problems	0.16†	0.36†	0.31†	0.34†	0.31†
Other symptoms	0.06‡	0.23‡	0.20‡	0.20‡	0.16‡
Activities	0.25†	0.40†	0.35†	0.41†	0.32†

Before the analysis, the following predications were made concerning the correlations we should expect to see between diary symptoms and the PRQLQ. If most of these predications were met, it would be a strong indication of the validity of the PRQLQ. The a priori predications were based on the results from previous studies in which nasal symptoms were correlated with validated rhinoconjunctivitis quality of life questionnaires¹⁻³. Asterisks indicate a priori predictions. * $r = 0.6 - 0.45$, † $r = 0.45 - 0.25$, ‡ $r < 0.25$.

grouchy). We have retained the original grammatically correct word for when the instrument is translated into other languages. Originally, we had used the term “generally don’t feel well,” but the expression commonly used by children is “don’t feel well all over.”

Validation study

Of the 83 children enrolled, eight dropped out and provided insufficient data for inclusion in the analysis. One child missed the second clinic visit but has been included in the analysis. The 75 children included in the analysis had a mean age of 9.8 years (SD: 1.9 years), and 40% were female. Seventy-six percent were Caucasian, 11% were African-American, and the remaining 13% were of other ethnic origin. The severity of their rhinoconjunctivitis during the first week, as measured by the average scores from their symptom diaries, ranged between 0.12 and 2.41 (mean: 0.98, SD: 0.50), where 0 = none and 3 = severe. For inadequately controlled symptoms, children were prescribed either a systemic antihistamine, a topical nasal steroid, antihistamine/decongestant eye drops, or a combination of all three medications.

Categorizing children

It was apparent from the weighted kappa values that the younger children experienced difficulty completing the global rating of change questionnaire (Table II) and therefore the clinicians’ ratings have been used to categorize the children into groups A and B.

Discriminative properties. In 13 children, rhinoconjunctivitis remained stable between clinic visits at weeks 1 and 3 (group A). The reliability of the questionnaire in these children is shown in Table III. For overall quality of life and for each of the domains, within-subject variance was very consistent and yielded high ICCs for all except the nose symptom domain. The lower ICC in this domain was primarily the result of a low between-subject variance. These results provide evidence of excellent reliability. Actual and predicated cross-sectional correlations between quality of life and diary symptom scores are shown in Table IV. These correlations are for

all children at the week 1 visit. The correlations are very similar to those observed for adults and adolescents with rhinoconjunctivitis,¹⁻³ thus providing support for the cross-sectional validity of the instrument. It is noteworthy that the highest correlations were between the nasal domain of the PRQLQ and diary nasal symptoms and between the eye domain of the PRQLQ and eye symptom scores in the diary. In addition, the poorest correlations were between the other symptom domain of the PRQLQ and the diary nose and eye symptoms scores. Each of these observations provides further evidence of validity.

Evaluative properties. Sixty-one children experienced a change in their rhinoconjunctivitis between weeks 1 and 3 (group B). The results of the responsiveness analysis are shown in Table V. In brief, the instrument picked up no change in quality of life in those children with stable rhinoconjunctivitis but was easily able to detect a change in overall quality of life and in each domain in those children whose rhinoconjunctivitis changed between visits. In addition, the instrument was able to detect the difference between those who remained stable and those who changed. However, this only reached conventional statistical significance ($p < 0.05$) for the overall score. In each of the domains, the probability value was less than 0.09.

Actual and predicated correlations between change in quality of life scores and change in diary symptom scores are shown in Table VI. As with the cross-sectional actual correlations, the longitudinal correlations were close to predicted. A similar pattern was also observed between the various domains of the PRQLQ and the different symptoms of the diary (i.e., nose symptoms correlated highest with the nasal domain and eye symptoms correlated closest with the eye domain).

DISCUSSION

In the questionnaire development study, the children (6 to 12 years old) were very consistent in their responses to the item reduction questionnaire. This consistency allowed us to construct the PRQLQ with confidence. We found that many children are very bothered by nasal,

TABLE V. Responsiveness of the PRQLQ

Domain	Change in PRQLQ scores*		
	Children with stable rhinoconjunctivitis (n = 13)	Children in whom rhinoconjunctivitis changed (n = 61)	Difference (p value)
Overall quality of life	-0.07	0.57‡	0.005
Nose symptoms	-0.04	0.80§	0.087
Eye symptoms	-0.04	0.55†	0.061
Practical problems	-0.22	0.53‡	0.075
Other symptoms	-0.15	0.37	0.087
Activities	0.12	0.62‡	0.084

*Scores are expressed as the change in mean score per item.

† $p < 0.05$, ‡ $p < 0.01$, § $p < 0.001$.

TABLE VI. Correlations between change in PRQLQ and change in diary symptoms

Change in PRQLQ	Change in symptom diary					
	Stuffy nose	Runny nose	Sneezing	Mean nose symptoms	Eye symptoms	Physician global rating
Overall quality of life	0.52†	0.50†	0.54†	0.59†	0.51†	0.45†
Nose symptoms	0.58*	0.58*	0.63*	0.67*	0.47‡	0.42†
Eye symptoms	0.42‡	0.38‡	0.43‡	0.46‡	0.53*	0.30†
Practical problems	0.41†	0.41†	0.46†	0.48†	0.36†	0.35†
Other symptoms	0.26‡	0.25‡	0.20‡	0.27‡	0.23‡	0.49‡
Activities	0.45†	0.43†	0.48†	0.51†	0.48†	0.32†

Before the analysis, the following predications were made concerning the correlations we should expect to see between diary symptoms and the PRQLQ. If most predications were met, it would be a strong indication of the validity of the PRQLQ. The a priori predications were based on the results from previous studies in which nasal symptoms were correlated with validated rhinoconjunctivitis quality of life questionnaires¹⁻³.

Asterisks indicate a priori predictions. * $r = 0.7 - 0.55$, † $r = 0.55 - 0.35$, ‡ $r < 0.35$.

ocular, and systemic symptoms and the practical nuisance of having symptoms. In these domains, they were very similar to adults and adolescents with rhinoconjunctivitis.^{1,7} However, the item reduction data showed that these children are much less bothered by activity limitations and emotional problems than adults and adolescents.^{1,7} A limitation of the development study was that it took place in Southern Ontario, and our sample may not have been fully representative of all children between the ages of 6 and 12 years with SAR. We tried to ensure that our sample represented a wide range of disease severity and that the subjects came from both urban and rural environments. We enrolled children from a variety of sources and tried to ensure that all ethnic and socioeconomic groups were included. Subsequently, like the Paediatric Asthma Quality of Life Questionnaire,⁴ which has been translated into 18 languages, testing of the Dutch and Spanish for North American versions of the PRQLQ has revealed good content validity in these cultures (unpublished data). Nevertheless, further studies will be required to confirm the content validity of the instrument for all cultural groups.

The results from the validation study provide strong evidence of the validity of the PRQLQ. The instrument

was tested in a wide range of children between 6 and 12 years old. Evidence that the children understood both the questions and their task in giving responses from the seven-point scale is provided by the reliability statistic and cross-sectional correlations. The good reliability shows that the children were consistent in their responses and thus fully understood the seven-point response options. The good cross-sectional validity shows that the children understood the questions accurately. These results are consistent with those found in studies of the Paediatric Asthma Quality of Life Questionnaire, in which the ability of young children to use seven-point response scales has been explored in greater depth.^{4,11}

Responsiveness and longitudinal validity were also good. The questionnaire picked up changes in overall quality of life and in each domain in children whose rhinoconjunctivitis changed between weeks 1 and 3. It was also able to detect a difference between those children who remained stable and those who changed for overall quality of life ($p < 0.005$). Although none of the domains reached conventional significance, all of them showed probability values less than 0.09. With only 13 children in the "stable" group, this lack of conventional significance probably is a result of a lack of power.

The only problem that we encountered was with the

time specification. Some of the younger children had difficulty understanding the concept of "during the last week." In these children we asked the parent to identify an event that had happened a week previously and then asked the children to answer each question, thinking about how they had been since that event.

In conclusion, the PRQLQ can be completed reliably by children 6 to 12 years old. The instrument has demonstrated good measurement properties and can be used with confidence in clinical studies.

REFERENCES

1. Juniper EF, Guyatt GH. Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis. *Clin Exp Allergy* 1991;21:77-83.
2. De Graaf-in 't Veld T, Koenders S, Garrelds IM, Gerth van Wijk R. Relationship between nasal hyperreactivity, quality of life, and nasal symptoms in perennial rhinitis. *J Allergy Clin Immunol* 1996;98:508-13.
3. Juniper EF, Guyatt GH, Dolovich J. Assessment of quality of life in adolescents with allergic rhinoconjunctivitis: development and testing of a questionnaire for clinical trials. *J Allergy Clin Immunol* 1994;93:413-23.
4. Juniper EF, Guyatt GH, Ferrie PJ, Griffith LE. Measuring quality of life in asthma. *Am Rev Respir Dis* 1993;147:832-8.
5. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in children with asthma. *Qual Life Res* 1996;5:35-46.
6. Guyatt GH, Juniper EF, Feeny DH, Griffith LE. Children and adult perceptions of childhood asthma. *Pediatrics* 1997;99:165-8.
7. Rosenbaum PL, Saigal S. Measuring health-related quality of life in pediatric populations: conceptual issues. In: Spilker B, editor. *Quality of life and pharmaco-economics in clinical trials*. 2nd ed. Philadelphia: Lippincott-Raven Publishers; 1996. p. 785-91.
8. Juniper EF, Guyatt GH, Willan A, Griffith LE. Determining a minimal important change in a disease-specific quality of life questionnaire. *J Clin Epidemiol* 1994;47:81-7.
9. Guyatt GH, Kirshner B, Jaeschke R. Measuring health status: what are the necessary measurement properties? *J Clin Epidemiol* 1992; 45:1341-5.
10. Fleiss LJ. *Statistical methods for rates and proportions*. 2nd ed. New York: John Wiley & Sons; 1981. p. 222-5.
11. Juniper EF, Guyatt GH, Feeny DH, Griffith LE, Ferrie PJ. Minimum skills required by children to complete health-related quality of life instruments: comparison of instruments for measuring asthma-specific quality of life. *Eur Respir J* 1997;10:2285-94.

APPENDIX

Paediatric Rhinoconjunctivitis Quality of Life Questionnaire: A quality of life questionnaire for 6- to 12-year-olds with allergic rhinoconjunctivitis

The Paediatric Rhinoconjunctivitis Quality of Life Questionnaire has been tested and validated using the wording and format that follows. It is important that interviewers adhere to the exact wording when addressing the patient (regular type) and follow the instructions (italics). Deviation from both wording and instructions may impair the reliability and validity of the questionnaire.

Parents should not be present during the interview. It is the child's own experiences that you want to evaluate. Some parents may want to influence this evaluation and some children may want to look to the parent for guidance.

Reassure the child that there are no right or wrong answers. Do not interpret questions for children. If they have difficulty, just ask them to do the best they can.

Make sure that the child understands the time frame of "during the last week." If in doubt, ask the parent to identify an event that occurred a week previously (e.g., a football match) and then ask the child to think about how he/she has been since that event.

Show the blue and green response cards to the child and explain the options. For children who can read, we suggest that you ask them to read aloud each of the response options. For younger children, read through each of the responses with them. Make sure that the child understands the concept of the grading from 0 (not bothered/none of the time) to 6 (extremely bothered/all of the time).

I want you to tell me how much you have been bothered by your nose and eye allergies during the past week. I will tell you which card to use. Pick the number that best describes how much you were bothered by your allergies during the past week. Make sure that when you ask about "allergies" that the child understands that you mean their nose and eye symptoms.

1. How much were you bothered by a STUFFY, BLOCKED NOSE during the past week? [BLUE CARD]
2. How much were you bothered by SNEEZING during the past week? [BLUE CARD]
3. How much were you bothered by a RUNNY NOSE during the past week? [BLUE CARD]
4. How much were you bothered by an ITCHY NOSE during the past week? [BLUE CARD]
5. How much were you bothered by ITCHY EYES during the past week? [BLUE CARD]
6. How much were you bothered by WATERY EYES during the past week? [BLUE CARD]
7. How much were you bothered by SWOLLEN/PUFFY EYES during the past week? [BLUE CARD]
8. How much were you bothered by SORE EYES during the past week? [BLUE CARD]
9. How much were you bothered by HAVING TO RUB YOUR EYES AND NOSE during the past week? [BLUE CARD]
10. How much were you bothered by HAVING TO BLOW YOUR NOSE during the past week? [BLUE CARD]
11. How much were you bothered by HAVING TO CARRY KLEENEX during the past week? [BLUE CARD]
12. How much were you bothered by HAVING TO TAKE MEDICATIONS FOR YOUR ALLERGIES during the past week? [BLUE CARD]
13. How much were you bothered by THIRST during the past week? [BLUE CARD]
14. How much were you bothered by a SCRATCHY/ITCHY THROAT during the past week? [BLUE CARD]
15. How much were you bothered by having a HEADACHE during the past week? [BLUE CARD]
16. How much were you bothered by your allergies PLAYING OUTDOORS during the past week? [BLUE CARD]

Change to the GREEN card

17. How often did your allergies make you feel TIRED during the past week? [GREEN CARD]
18. How often did your allergies make you feel NOT WELL ALL OVER during the past week? [GREEN CARD]
19. How often did your allergies make you feel IRRITABLE (cranky/grouchy) during the past week? [GREEN CARD]
20. How often did your allergies make you feel

EMBARRASSED during the past week?
[GREEN CARD]

21. How often did your allergies make it HARD TO GET TO SLEEP during the past week? [GREEN CARD]
22. How often did your allergies WAKE YOU UP DURING THE NIGHT during the past week? [GREEN CARD]
23. How often did your allergies MAKE IT HARD TO PAY ATTENTION during the past week? [GREEN CARD]

RESPONSE OPTIONS**GREEN CARD**

6. All of the time
5. Most of the time
4. Quite often
3. Some of the time
2. Once in a while
1. Hardly any of the time
0. None of the time

BLUE CARD

6. Extremely bothered
5. Very bothered
4. Quite bothered
3. Somewhat bothered
2. Bothered a bit
1. Hardly bothered at all
0. Not bothered

DOMAINS

Nose Symptoms:
Stuffy/blocked nose
Sneezing
Runny nose
Itchy nose

Eye Symptoms:
Itchy eyes
Watery eyes
Swollen/puffy eyes
Sore eyes

Practical Problems:
Rub nose and eyes
Blow nose
Carry kleenex
Take medications
Feel embarrassed

Other Symptoms:
Thirst
Don't feel well all over
Irritable
Tired
Headache
Scratchy/itchy throat

Activities:
Playing outdoors
Hard to get to sleep at night
Hard to pay attention
Wake up during the night

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Languages: The PRQLQ is available in several languages. For current information, contact Professor Juniper.