

# Development and validation of the Mini Rhinoconjunctivitis Quality of Life Questionnaire

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## Summary

**Background** The 28-item Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) has strong measurement properties but for large clinical trials, surveys and practice monitoring, where high efficiency is important, a shorter questionnaire is needed.

**Objective** To develop and validate an abbreviated version of the RQLQ.

**Methods** Using five RQLQ databases, items with high item–item correlations were combined and then the highest scoring items were selected for the MiniRQLQ (14 questions). There are five domains: activity limitations (standardized), practical problems and nose symptoms, eye symptoms and other symptoms. The MiniRQLQ, which is self-administered, was tested in a 5-week observational study in 100 adults with symptomatic rhinoconjunctivitis. Patients completed the MiniRQLQ, the RQLQ, and other measures of health status at baseline, 1 and 5 weeks.

**Results** In patients whose rhinoconjunctivitis was stable between clinic visits, reliability (reproducibility and ability to discriminate between patients of different impairment) was very acceptable for the MiniRQLQ (ICC = 0.93) but not quite as good as for the RQLQ (ICC = 0.97). Responsiveness to change in clinical status was better with the MiniRQLQ than the RQLQ ( $P = 0.044$ ). Construct validity (correlation with other indices of health status) was strong for both the MiniRQLQ and the RQLQ. Concordance between the two instruments was high (ICC = 0.87).

**Conclusions** The MiniRQLQ has strong measurement properties and measures the same construct as the original RQLQ. The choice of questionnaire should depend on the task at hand.

**Keywords:** conjunctivitis, health status, measurement, quality of life, questionnaires, rhinitis, rhinoconjunctivitis

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## Introduction

The Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) was developed to measure the problems that adults with rhinoconjunctivitis experience in their day-to-day lives [1]. It has 28 questions (items) in seven domains (activity limitations, sleep impairment, non-nasal/eye symptoms, practical problems, nasal symptoms, eye symptoms

and emotional problems), has strong measurement properties [1,2], has been translated into 16 languages and is used extensively throughout the world in both clinical studies and clinical practice. Although it usually takes about 7 min to complete at the initial visit and an even shorter time at follow-up visits, there is a need for an instrument with greater efficiency for clinical trials, group patient monitoring (managed care) and epidemiological surveys.

In this study, we have developed the Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) using recognized procedures for shortening quality of life questionnaires [3,4] and we have tested the measurement

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properties and validity of the new instrument. We have taken the original RQLQ to be the gold-standard and determined how well the MiniRQLQ agrees with the original RQLQ. In addition, we have compared the measurement properties of the two instruments.

### Development of the MiniRQLQ

The aim was to develop a version of the RQLQ, with approximately half the number of questions, which would measure the same construct as the RQLQ and meet the same specifications that were identified during the development of the RQLQ [1]. These were:

- 1 Both physical and emotional function should be included
- 2 Items must reflect areas of function which are most important to patients with rhinoconjunctivitis
- 3 Summary scores must be amenable to statistical analysis
- 4 The questionnaire should be reliable (reproducible) when the clinical state is stable
- 5 The questionnaire should be responsive to clinically important changes, even if those changes are small
- 6 The questionnaire should be valid (i.e. actually measures rhinoconjunctivitis-specific impairments to quality of life)

The original RQLQ has 28 questions in seven domains. To meet the third specification (amenable to statistical analysis), it was essential to ensure that each domain of the new questionnaire should have two or more items. We

had the option of selecting the top scoring two items in each of the current domains or reducing the number of domains. We decided on the latter option as having only two questions in each of the seven domains would have violated the second specification, namely ensuring that all items most important to patients were included.

The approach we took was almost identical to the one we used for the development of the MiniAQLQ [3]. We first ranked all 28 items in the RQLQ according to the scores made by patients participating in the original RQLQ development study [1] and four clinical trials [5–8]. We identified the top 14 items and then examined whether any could be combined. For this, we calculated item–item correlations. Items with Pearson correlation coefficients of 0.8 or greater were reviewed by four clinicians. If there was consensus that the items were measuring a similar concept, they were combined (e.g. fatigue/tiredness). After combining items, the next highest scoring items were added to the list to once more bring the total up to 14 and the process repeated until we had 14 items that either did not correlate closely with other items or which appeared to be measuring different concepts (Table 1).

These top scoring items were reviewed and placed in domains as similar in grouping as possible to the original RQLQ. The grouping of the items was based on clinical common sense (e.g. nose symptoms, eye symptoms, activity limitations) and on the specification that each domain

**Table 1.** Highest scoring items from the RQLQ included in the MiniRQLQ

Rank	Item	Inclusion
1	Need to rub nose/eyes	Included
2	Itchy eyes	Included
3	Patient-specific activity 1	Included as a generic activity
4	Need to blow nose repeatedly	Included
5	Patient-specific activity 2	Included as a generic activity
6	Sneezing	Included
7	Stuffy/blocked nose	Included
8	Patient-specific activity 3	Included as a generic activity
9	Tiredness	Included
10	Runny nose	Included
11	Fatigue	Included with 'tiredness' ( $r=0.93$ )
12	Thirst	Included
13	Worn out	Included with 'tiredness' ( $r=0.89$ )
14	Inconvenience of carrying tissues	Included with 'blow nose repeatedly' ( $r=0.80$ )
15	Sore eyes	Included
16	Reduced productivity	Included in generic activities
17	Watery eyes	Included
18	Lack of a good night's sleep	Included
19	Irritable	Included
20	Wake up during the night	Included with 'lack of a good night's sleep' ( $r=0.86$ )

should have no less than two questions. The three generic activities from the newly validated standardized version of the RQLQ, the RQLQ(S) [9], were combined into two activities and sleep problems were added to this domain as a single item. The MiniRQLQ (Appendix 1) has 14 items in five domains (activity limitations [ $n=3$ ], practical problems [ $n=2$ ], nose symptoms [ $n=3$ ], eye symptoms [ $n=3$ ] and other symptoms [ $n=3$ ]). The questionnaire is in self-administered format and is completed by patients without the assistance of an interviewer. Patients are asked to consider how they have been during the previous week and to respond to each question on a seven-point scale (0 = no impairment, 6 = severely impaired)

#### *Pre-testing of the MiniRQLQ*

To ensure that the wording is easily and accurately understood, the MiniRQLQ was administered to 10 patients. They were asked to identify any concerns they had about the meaning of the questions or instructions. After this, they were asked to tell us, in their own words, what they understood the meaning of each question to be. A few minor word changes were needed but not sufficient to necessitate any further testing.

#### **Validation study**

##### *Subjects*

One hundred adults (18–75 years) with current symptoms of rhinoconjunctivitis participated in the study. Patients were enrolled from participants in previous research studies and respondents to notices in the local media. Symptoms were required to be sufficiently troublesome to require additional medication and to score 0.5 or more on either the nasal or eye symptom domains of the RQLQ. Patients were not permitted to have nasal or sinus infections requiring treatment with antibiotics or to have any illness, other than rhinoconjunctivitis, that had an impact on health-related quality of life. They were required to understand the study instructions, the English version of the RQLQ and to be able to complete a daily symptom diary. All patients signed an informed consent. The study was approved by the McMaster University Faculty of Health Sciences Ethics Committee.

##### *Study design*

The study was a 5-week, unblinded, observational study with subjects assessed in the clinic at baseline and after 1, and 5 weeks. The MiniRQLQ, the self-administered version of the RQLQ, the Feeling Thermometer, the Standard Gamble and the SF-36 were completed at each visit. For 1 week before each follow-up visit, patients recorded

rhinoconjunctivitis symptoms and medication use in a diary. A global rating of change questionnaire was completed at 1 and 5 weeks. Patients always completed the MiniRQLQ at the very beginning of a clinic visit before any discussion with the study administrator. The RQLQ was always completed by patients at the very end of the visit. Thus the completion of the MiniRQLQ and the RQLQ were always separated by completion of the other instruments, review of the patient's diary, evaluation on current clinical status, discussion on current and future treatment needs, and the provision of medication and instruction on its use.

##### *Treatment*

At enrolment, patients were asked to tolerate 1 week without any additional medications so that we could make an estimate of the reliability (reproducibility) of the instruments while the patients were in a stable clinical state. Those who refused were permitted to increase their usual rhinoconjunctivitis medication. After 1 week, all patients were advised to increase their rhinoconjunctivitis medications in the manner recommended by their clinician. Those who did not have a treatment plan were offered fexofenadine (Allegra) 60 mg and up to 120 mg daily when needed. Those who did not like using a non-sedating antihistamine and preferred a nasal steroid were offered fluticasone propionate nasal spray (Flonase) two puffs in each nostril twice daily. Patients who refused additional rhinoconjunctivitis medication continued on their previously established medications throughout the study.

##### *Additional outcome measures*

###### *The Feeling Thermometer*

This preference rating scale explores how patients feel about their own health state and the value that they place upon it [10]. The instrument looks like a thermometer with clearly defined end points: 0 = least preferred health state (death) and 100 = most preferred health state (perfect health). In this study, patients first read aloud a description of three hypothetical health states:

*Mild rhinoconjunctivitis* 'You have rhinoconjunctivitis (nose and eye allergies/hay fever) but it bothers you very little. You have mild to moderate nose and eye symptoms but they rarely interfere with your day-to-day activities. Occasionally they prevent you from getting a good night's sleep and you may feel a bit tired during the day. Your symptoms hardly ever make you feel frustrated or irritable.'

*Moderate rhinoconjunctivitis* 'You have rhinoconjunctivitis and it bothers you quite a bit. You have fairly troublesome nose and eye symptoms quite a lot of the time

and these sometimes cause you to have a headache. Your symptoms frequently interfere with your day-to-day activities. Often they prevent you from getting a good night's sleep. You sometimes feel tired and have difficulty concentrating. You get frustrated and feel irritable because of your symptoms.'

*Severe rhinconjunctivitis* 'You have severe rhinconjunctivitis and it is very troublesome. Your nose and eye symptoms are extremely bothersome and you often have a bad headache. Your day-to-day activities are very restricted and it is always difficult to sleep at night. You feel very tired during the day and it is very difficult to concentrate. This makes you feel very frustrated and you are very irritable.'

Patients were asked to place three markers on the thermometer to reflect their feelings about each state. We then asked patients to think about how their own rhinconjunctivitis had been during the previous week and to place a marker on the thermometer to reflect their feelings about this.

#### *The Standard Gamble*

This utility instrument also measures the value that patients place on their health state [10]. Initially, patients are asked to think about a particular health state and then to consider whether they would prefer to remain in that health state for the next 10 years or take a chance with a new (imaginary) treatment. They are told that the new treatment has the ability to return them to perfect health immediately with no side-effects but also has the ability to cause instant death. Initially, the probability of returning to perfect health if they took the new treatment is set at 100% with absolutely no chance of death. Usually, all those who understand the concept choose to take the new treatment rather than stay in their present health state. The probability of returning to perfect health on taking the new treatment is then gradually reduced (and the chance of death increased) until the patient decides to remain in their current health state rather than take a chance on the new treatment. The indifference point represents the value that the patient places on that health state. In this study, patients first completed the Standard Gamble with each of the three hypothetical rhinconjunctivitis states used for the Feeling Thermometer and then it was administered for how their own rhinconjunctivitis had been during the previous week.

#### *Global Rating of Change Questionnaire*

The global rating of change questionnaire asks patients about change in their rhinconjunctivitis quality of life since their previous clinic visit [11]. The questionnaire has a 15 point scale (+7 = very much better, 0 = no change and -7 = very much worse).

#### *The Medical Outcomes Study Short Form 36 (SF-36)*

This is a self-administered generic health profile which provides summary scores in two domains, physical health and mental health [12]. Internal consistency and cross-sectional validity have been demonstrated for patients with rhinconjunctivitis [13].

#### *Clinical Measures of Rhinconjunctivitis*

For 1 week before each follow-up clinic visit, patients completed a diary of their symptoms and medication requirements. Each morning and each evening they scored the severity (0 = nil, 1 = mild, 2 = moderate, 3 = severe) and frequency (0 = nil, 1 = a few short episodes, 2 = frequent episodes, 3 = continuous) of: sneezing; stuffy nose; runny nose; itchy nose; and eye symptoms. Results are expressed as mean scores for nose and eye symptoms (0 = asymptomatic, 3 = very symptomatic). In addition, each evening patients recorded the amount of rhinconjunctivitis medication used during the previous 24 h.

#### *Statistical analysis*

The first objective was to compare the data from the MiniRQLQ with those obtained from the original RQLQ (criterion validity). We calculated the mean and standard deviation for overall quality of life and each domain of the two instruments at the second clinic visit. We examined concordance between the MiniRQLQ and the RQLQ using an intraclass correlation coefficient and evaluated bias with a paired *t*-test. In addition, we examined the closeness of the association between the two instruments using a Pearson correlation coefficient. Internal consistency was estimated using Cronbach's alpha.

The second part of the analysis was to examine the measurement properties (reliability, responsiveness, both cross-sectional and longitudinal construct validity [14] and the minimal important difference [11]) of the MiniRQLQ and the RQLQ.

The estimate of reliability required defining a group of patients whose rhinconjunctivitis did not change between consecutive clinic visits (0-1 and 1-5 weeks). Patients were included in the reliability analysis if they scored -1, 0 or +1 on the global rating of change questionnaire completed at weeks 1 and 5. If a patient's clinical state was stable during both time periods (0-1 and 1-5 weeks) and thus the patient contributed two data points, a single point was blindly selected by our statistician using a random number generator. Test-retest reliability has been estimated as the within-subject standard deviation and related to the overall standard deviation as an intraclass correlation coefficient. This statistic also provides evidence of the

instrument's ability to discriminate between patients of different levels of impairment.

Responsiveness of the two instruments was determined in three ways. First, in the patients who experienced a change in their rhinoconjunctivitis between weeks 1 and 5, we examined whether the instruments could detect change using a paired *t*-test. Patients who either improved or deteriorated by a score of 2 or greater on the global rating completed at week 5 were included. Second, we determined whether the instruments could detect a difference between these patients who changed during this time period and those patients who remained stable using an unpaired *t*-test. Third, we calculated a responsiveness index ( $\Delta/\Delta_{SD}$ ) for each instrument [15]. Difference in responsiveness indices between instruments was tested using a paired *t*-test.

The minimal important difference (MID) for the two instruments has been determined from patients who experienced a global rating of change of +3, +2, -2 or -3 during the 1-5-week period [11].

Both cross-sectional and longitudinal construct validity have been evaluated by correlating the two instruments (RQLQ and MiniRQLQ) with other measures of rhinoconjunctivitis severity (diary symptoms), generic health status (SF-36), patient preference rating (Feeling Thermometer) and utility (Standard Gamble). Our hypothesis was that if the MiniRQLQ measures the same construct as the original RQLQ, it should correlate with other measures of health status in the same manner as the original RQLQ.

## Results

All 100 patients completed the study. There were 47 males and 53 females and their mean age was 39.0 years ( $SD=11.95$ ).

### Comparison of instruments

Summary data (mean  $\pm$  SD) from the RQLQ and the MiniRQLQ at each visit are shown in Table 2. At visit 2, the overall scores for the MiniRQLQ (mean = 2.79;  $SD=1.18$ ) were significantly higher than for the RQLQ (mean = 2.43;  $SD=1.23$ ) ( $P<0.001$ ). Nevertheless, the correlation between the two instruments was high ( $r=0.91$ ) and thus yielded a high level of concordance (ICC = 0.87). Internal consistency was similar for both instruments (Cronbach's alpha: MiniRQLQ = 0.90; RQLQ = 0.92).

### Measurement properties

#### Reliability

Forty-four patients remained stable between clinic visits and contributed data to the reliability analysis. The within-subject standard deviations and intraclass correlation coefficients for each of the instruments for overall scores and

**Table 2.** MiniRQLQ and RQLQ ( $n=100$ ; range 0 = no impairment, 6 = maximum impairment)

	Summary data (mean $\pm$ SD)		
	Visit 1	Visit 2	Visit 3
<i>MiniRQLQ</i>			
Overall	2.98 $\pm$ 1.12	2.79 $\pm$ 1.18	1.73 $\pm$ 1.29
Activities	2.82 $\pm$ 1.23	2.70 $\pm$ 1.21	1.71 $\pm$ 1.41
Practical problems	3.89 $\pm$ 1.28	3.57 $\pm$ 1.49	2.20 $\pm$ 1.59
Nose symptoms	3.44 $\pm$ 1.39	3.22 $\pm$ 1.33	2.06 $\pm$ 1.50
Eye symptoms	2.66 $\pm$ 1.49	2.49 $\pm$ 1.53	1.39 $\pm$ 1.33
Other symptoms	2.42 $\pm$ 1.46	2.24 $\pm$ 1.47	1.43 $\pm$ 1.24
<i>RQLQ</i>			
Overall	2.58 $\pm$ 1.16	2.43 $\pm$ 1.23	1.49 $\pm$ 1.22
Activities	3.47 $\pm$ 1.38	3.17 $\pm$ 1.51	1.88 $\pm$ 1.57
Sleep	1.97 $\pm$ 1.51	1.95 $\pm$ 1.48	1.31 $\pm$ 1.45
Non-hay fever symptoms	2.16 $\pm$ 1.27	2.05 $\pm$ 1.30	1.29 $\pm$ 1.30
Practical problems	3.29 $\pm$ 1.50	3.07 $\pm$ 1.63	1.94 $\pm$ 1.49
Nose symptoms	3.17 $\pm$ 1.42	2.96 $\pm$ 1.46	1.89 $\pm$ 1.44
Eye symptoms	2.62 $\pm$ 1.56	2.46 $\pm$ 1.65	1.36 $\pm$ 1.35
Emotions	1.99 $\pm$ 1.38	1.88 $\pm$ 1.40	1.08 $\pm$ 1.20

**Table 3.** Reliability ( $n=44$ )

Instrument and domain	Within-subject SD	Between-subject SD	ICC
<i>MiniRQLQ</i>			
Overall	0.32	1.14	0.93
Activities	0.37	1.23	0.92
Practical problems	0.52	1.42	0.88
Nasal symptoms	0.45	1.27	0.89
Eye symptoms	0.49	1.39	0.89
Other symptoms	0.41	1.39	0.92
<i>RQLQ</i>			
Overall	0.22	1.24	0.97
Activities	0.60	1.56	0.87
Sleep	0.28	1.55	0.97
Non-hay fever symptoms	0.33	1.27	0.94
Practical problems	0.43	1.62	0.93
Nose symptoms	0.44	1.47	0.92
Eye symptoms	0.40	1.51	0.93
Emotions	0.30	1.30	0.95

**Table 4.** Responsiveness – mean change in score between visits 2 and 3

Instrument and domain	Patients who were stable between visits: mean $\pm$ SD ( $n = 17$ )	Patients who changed between visits: mean $\pm$ SD ( $n = 83$ )	Difference ( $P$ -value)
<i>MiniRQLQ</i>			
Overall	– 0.09 $\pm$ 0.49	1.30 $\pm$ 1.56**	<0.001
Activities	– 0.12 $\pm$ 0.66	1.21 $\pm$ 1.71**	0.002
Practical problems	– 0.21 $\pm$ 0.81	1.69 $\pm$ 1.97**	<0.001
Nose symptoms	0.00 $\pm$ 0.57	1.40 $\pm$ 1.78**	0.002
Eye symptoms	– 0.12 $\pm$ 0.54	1.35 $\pm$ 1.71**	<0.001
Other symptoms	– 0.06 $\pm$ 0.56	0.99 $\pm$ 1.57**	0.008
<i>RQLQ</i>			
Overall	0.00 $\pm$ 0.36	1.13 $\pm$ 1.50**	0.003
Activities	0.00 $\pm$ 0.74	1.53 $\pm$ 1.91**	0.002
Sleep	– 0.10 $\pm$ 0.61	0.80 $\pm$ 1.68**	0.032
Non-hay fever symptoms	0.09 $\pm$ 0.49	0.90 $\pm$ 1.42**	0.024
Practical problems	– 0.25 $\pm$ 0.57	1.41 $\pm$ 1.87**	<0.001
Nose symptoms	0.07 $\pm$ 0.50	1.28 $\pm$ 1.83**	0.009
Eye symptoms	– 0.09 $\pm$ 0.50	1.32 $\pm$ 1.72**	0.001
Emotions	0.13 $\pm$ 0.24*	0.94 $\pm$ 1.47**	0.027

\* $P < 0.05$ , \*\* $P < 0.001$

individual domains are shown in Table 3. In summary, reliability of the MiniRQLQ was good but not quite so good as that of the RQLQ.

#### Responsiveness and MID

Eighty-three patients experienced changes of 2 or greater on the global rating of change completed at visit 5 and thus contributed data to the responsiveness analysis. Table 4 shows that responsiveness was very good in both instruments. Both were able to detect the within-subject changes with a high degree of significance in all domains ( $P < 0.001$ ). The mean change in overall score was greater for the MiniRQLQ (1.30) than for the RQLQ (1.13),

**Table 5.** Minimal Important Difference (MID). Mean change in overall scores (Visits 2–3) vs global rating of change (Visit 3)

Instrument	Global Rating of Change			
	0–1 ( $n = 17$ )	2–3 ( $n = 26$ ) MID	4–5 ( $n = 35$ )	6–7 ( $n = 22$ )
<i>MiniRQLQ</i>				
$\Delta$ Overall	– 0.09 (0.49)	0.70 (1.15)	0.94 (1.65)	2.59 (1.04)
<i>RQLQ</i>				
$\Delta$ Overall	0.002 (0.36)	0.49 (0.96)	0.80 (1.51)	2.42 (1.24)

suggesting that the MID is greater for the MiniRQLQ than the RQLQ. This observation is supported by the data in Table 5 which show that the MID (global rating of change category 2–3) was 0.70 for the MiniRQLQ whereas it is

**Table 6.** Cross-sectional validity (Pearson correlation coefficients)

Instrument and domain	Nasal diary	Eye diary	SF-36 physical	SF-36 mental	FT	SG
<i>MiniRQLQ</i>						
Overall	0.73	0.62	–0.29	–0.39	–0.53	–0.16
Activities	0.71	0.52	–0.26	–0.31	–0.45	–0.09
Practical problems	0.71	0.47	–0.24	–0.24	–0.43	–0.20
Nose symptoms	0.78	0.31	–0.12	–0.23	–0.37	–0.17
Eye symptoms	0.44	0.80	–0.25	–0.32	–0.47	–0.15
Other symptoms	0.51	0.47	–0.36	–0.52	–0.53	–0.09
<i>RQLQ</i>						
Overall	0.69	0.61	–0.35	–0.45	–0.60	–0.13
Activities	0.66	0.49	–0.25	–0.25	–0.49	–0.14
Sleep	0.50	0.33	–0.22	–0.30	–0.50	0.02
Non-hay fever symptoms	0.58	0.52	–0.44	–0.52	–0.58	–0.11
Practical problems	0.63	0.42	–0.27	–0.27	–0.47	–0.14
Nose symptoms	0.70	0.36	–0.19	–0.28	–0.48	–0.13
Eye symptoms	0.45	0.84	–0.29	–0.32	–0.49	–0.14
Emotions	0.57	0.48	–0.28	–0.58	–0.49	–0.09

Instrument and domain	$\Delta$ Nasal diary	$\Delta$ Eye diary	$\Delta$ SF-36 physical	$\Delta$ SF-36 mental	$\Delta$ FT	$\Delta$ SG
<i>MiniRQLQ</i>						
$\Delta$ Overall	0.71	0.68	-0.13	-0.27	-0.68	-0.15
$\Delta$ Activities	0.68	0.59	-0.12	-0.21	-0.62	-0.17
$\Delta$ Practical problems	0.75	0.61	-0.19	-0.22	-0.65	-0.15
$\Delta$ Nose symptoms	0.74	0.49	-0.12	-0.27	-0.61	-0.08
$\Delta$ Eye symptoms	0.52	0.79	-0.09	-0.22	-0.59	-0.17
$\Delta$ Other symptoms	0.52	0.60	-0.12	-0.32	-0.65	-0.13
<i>RQLQ</i>						
$\Delta$ Overall	0.65	0.67	-0.16	-0.31	-0.73	-0.21
$\Delta$ Activities	0.72	0.62	-0.18	-0.27	-0.68	-0.14
$\Delta$ Sleep	0.51	0.50	-0.06	-0.18	-0.60	-0.15
$\Delta$ Non-hay fever symptoms	0.54	0.63	-0.20	-0.33	-0.68	-0.18
$\Delta$ Practical problems	0.69	0.58	-0.15	-0.26	-0.67	-0.18
$\Delta$ Nose symptoms	0.67	0.54	-0.13	-0.29	-0.70	-0.17
$\Delta$ Eye symptoms	0.49	0.79	-0.11	-0.29	-0.65	-0.25
$\Delta$ Emotions	0.57	0.54	-0.17	-0.28	-0.63	-0.24

**Table 7.** Longitudinal validity (Pearson correlation coefficients)

0.49 for the RQLQ. Both instruments, both overall and for each domain, were able to detect differences between the patients who remained stable between weeks 1–5 and those who changed. The MiniRQLQ was slightly more responsive (responsiveness index = 0.83) than the RQLQ (responsiveness index = 0.76) and this difference reached statistical significance ( $P = 0.044$ ).

#### Construct validity

If one makes the assumption that the RQLQ measures rhinoconjunctivitis-specific quality of life, then one would expect the MiniRQLQ not only to correlate well with the original RQLQ, but also to correlate with other measures of health status in a similar manner to which the RQLQ correlates with them (Tables 6 and 7). Correlations for the RQLQ and the MiniRQLQ are very similar and sufficiently close to one and other for us to have confidence that the MiniRQLQ is measuring the same construct as the RQLQ, namely, rhinoconjunctivitis-specific quality of life.

#### Discussion

The results from this study provide evidence that the MiniRQLQ has strong discriminative and evaluative measurement properties [14] and can be used with confidence in both cross-sectional (epidemiological) surveys and longitudinal studies (e.g. clinical trials, practice monitoring).

At each clinic visit, the MiniRQLQ gave higher overall and domain scores (except activity limitation) than the

RQLQ. Although the individual domains cannot be statistically compared with each other because they are not measuring identical constructs, the difference in overall scores between the MiniRQLQ and the RQLQ was significant. This difference is not surprising since the items that are most troublesome to patients were selected for the MiniRQLQ and thus the less troublesome (lower scoring) items have been omitted. This finding is important because it indicates that the results from cross-sectional studies (including baseline assessments in clinical trials), cannot be compared directly. The lower scores for the activity domain of the MiniRQLQ are also not surprising since patients select their most troublesome activities for the RQLQ and these may not all be covered by the three generic activities of the MiniRQLQ. In addition, one of the activities included in the MiniRQLQ concerns sleep. This tends to be a moderately low scoring item (Table 1) and may not be troublesome for all patients.

The high correlation ( $r = 0.91$ ) between the RQLQ and the MiniRQLQ suggests that the two instruments are measuring the same construct (quality of life in patients with rhinoconjunctivitis) and therefore the only difference is that the MiniRQLQ consistently yields higher scores. Further evidence that the MiniRQLQ is measuring the same construct as the RQLQ is provided by the consistent cross-sectional and longitudinal correlations with other measures of health status.

Although the RQLQ tended to have slightly better reliability than the MiniRQLQ and is thus better able to discriminate between patients of different levels of

impairment, the MiniRQLQ was significantly more responsive to change than the RQLQ.

It is important to note that the minimal important difference for the MiniRQLQ is around 0.7 whereas for the RQLQ, it is about 0.5. The reason for this difference may lie in the fact that rhinoconjunctivitis interventions are usually directed at the problems that are most troublesome to patients. Since the least troublesome items were removed from the RQLQ when developing the MiniRQLQ, it is likely that the MiniRQLQ contains the items that are most responsive to the changes brought about by interventions. This difference in the MID between the two instruments will be important to remember when interpreting the results of clinical trials.

Patients completed the MiniRQLQ and the RQLQ at the same clinic visit and completion of the MiniRQLQ at the beginning of the visit may have influenced responses to the RQLQ at the end of the visit. However, to compare the measurement properties of the two instruments, it was necessary for patients to complete the questionnaires on the same day. To minimize confounding, we separated completion of the two instruments as much as possible, each visit usually taking about 1 hour. Since the MiniRQLQ was the primary instrument of interest, patients always completed this questionnaire as soon as they arrived in the clinic and before any discussions with the research assistant.

Disease-specific quality of life questionnaires are designed to measure the problems that are most important to the majority of patients with that condition but patients are heterogenous in their experiences and priorities and no questionnaire is ever going to cover all the problems experienced by all patients. The more one reduces the number of items in a questionnaire, the more likely it is that individual patient problems will be omitted and the instrument will lose content validity. The three patient-specific activity items of the RQLQ are particularly well suited for helping clinicians identify the activities that are most important to individual patients and the wider range of questions is more likely to highlight specific patient problems. Therefore, while the MiniRQLQ can certainly be used with confidence in group studies such as clinical trials and cross-sectional surveys, it is likely that the longer and more patient-specific original RQLQ will be more useful in clinical practice. However, further studies are needed to compare the usefulness of the MiniRQLQ and the RQLQ in the management of individual patients.

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**Appendix 1** Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ)©

Please complete all questions by circling the number that best describes how troubled you have been during the last week as a result of your nose/eye symptoms.

	Not troubled	Hardly troubled at all	Somewhat troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
<i>Activities</i>							
1. Regular activities at home and at work (your occupation or tasks that you have to do regularly around your home and/or garden)	0	1	2	3	4	5	6
2. Recreational activities (indoor and outdoor activities with friends and family, sports, social activities, hobbies)	0	1	2	3	4	5	6
3. Sleep (difficulties getting a good night's sleep and/or getting to sleep at night)	0	1	2	3	4	5	6
<i>Practical problems</i>							
4. Need to rub nose/eyes	0	1	2	3	4	5	6
5. Need to blow nose repeatedly	0	1	2	3	4	5	6
<i>Nose symptoms</i>							
6. Sneezing	0	1	2	3	4	5	6
7. Stuffy blocked nose	0	1	2	3	4	5	6
8. Runny nose	0	1	2	3	4	5	6
<i>Eye symptoms</i>							
9. Itchy eyes	0	1	2	3	4	5	6
10. Sore eyes	0	1	2	3	4	5	6
11. Watery eyes	0	1	2	3	4	5	6
<i>Other symptoms</i>							
12. Tiredness and/or fatigue	0	1	2	3	4	5	6
13. Thirst	0	1	2	3	4	5	6
14. Feeling irritable	0	1	2	3	4	5	6

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