# Quality of Life of Patients with Perennial Allergic Rhinitis: Preliminary Validation of the Rhinoconjunctivitis Quality of Life Questionnaire in Singapore

Khai P. Leong<sup>1</sup>, Siew P. Chan<sup>2</sup>, Chwee Y. Tang<sup>1</sup>, Samuel C.L. Yeak<sup>3</sup>, Adrian S.M. Saurajen<sup>3</sup>, Paul K.H. Mok<sup>3</sup>, Jin K. Siow<sup>3</sup>, Nelson W.C. Chee<sup>3</sup>, Ravi Seshadri<sup>3</sup>, Seng B. Yeo<sup>3</sup>, Mark L.C. Khoo<sup>3</sup>, Julian C.Y. Lee<sup>3</sup> and Hiok H. Chng<sup>1</sup>

Though sufferers of perennial allergic rhinitis do not die from their ailment, they endure years of chronic nose disease that takes its toll on sleep, social functioning, productivity and other aspects of their lives. The economic and social burden of this disease is quite high as its prevalence is around 30% in our population.<sup>1</sup>

Health-related quality of life (HRQL) is the patient's perception of the effects of an illness and its treatment on him or her.<sup>2</sup> Besides the traditional measures of morbidi-ty and mortality, it is now recognized to be important for the assessment of the treatment of many chronic diseases, both in research and clinical practice.

The RQLQ was published in 1991<sup>3</sup> and validated in a prospective two-arm treatment-based study of seasonal allergic rhinitis.<sup>4</sup> The items in the questionnaire were reported by patients themselves to be important and to occur frequently. Using 28 questions or SUMMARY Though sufferers of perennial allergic rhinitis do not die from their ailment, they endure years of chronic nose disease that interferes with many important aspects of their lives. A rhinitis-specific instrument to gauge the quality of life of patients with this disease was published in 1991. Here, we validated the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) for use in English-speaking patients with perennial allergic rhinitis. We established that the RQLQ distinguishes between patients and control, demonstrates internal consistency and is sensitive to change. This study suggests that the RQLQ can be used to assess the quality of life of patients with perennial allergic rhinitis in Singapore.

items, the RQLQ measures seven areas, also known as domains or dimensions, in the patient's life that is thought to be affected by rhinitis, namely, sleep, non-rhinitis symptoms (eg. fatigue and thirst), practical problems (eg. the need to blow nose repeatedly), nasal symptoms, eye symptoms, activities and emotions. The questionnaire also requires the patients to name three activities in their own lives that they think are affected by their rhinitis. It has been translated into Dutch' and other languages (Prof EF Juniper, personal communication). An abridged version has recently been validated.<sup>6</sup>

Generic quality of life in-

struments, especially the SF-36, have also been used to assess the HRQL in perennial allergic rhinitics.<sup>7,8</sup> Occasionally, RQLQ and SF-36 have been used together to provide a more comprehensive view of the HRQL.<sup>9,10</sup>

We investigated if the RQLQ is relevant for local patients, if it differentiates between patients with controls and if it is sufficiently sensitive to detect improvement due to therapy and if it shows internal consistency.

From the <sup>1</sup>Department of Rheumatology and Immunology, <sup>2</sup>Clinical Epidemiology Unit and <sup>3</sup>Department of Otorhinolaryngology, Tan Tock Seng Hospital, Singapore. Correspondence: Khai P. Leong

## MATERIALS AND METHODS

Patients were recruited from the Department of Otorhinolaryngology and the Nose Clinic (a combined clinic run by Otorhinolaryngologists and Allergists), both at Tan Tock Seng Hospital.

Inclusion criteria for the present study are: 1) Subjects aged 18 years and above; 2) The presence of one or more of the features of allergic rhinitis (clear nasal discharge, nasal congestion or nose itch, plus ear itch, eye itch or sneezing) for at least a week in every month of the year; 3) Positive skin prick tests to at least one common aeroallergen, namely, D. pteronyssinus, D. farinae, cockroach, cat and dog (Greer Laboratories, Inc., Lenoir, North Carolina) and 4) Ability to understand written English.

Patients were excluded if they had chronic sinusitis, nasal polyposis, nasopharyngeal carcinoma, asthma uncontrolled with usual medications or recent life events that may interfere with HRQL evaluation.

Hospital staff and medical students who had no allergic airway disease or conditions that may influence their quality of life volunteered as controls.

Informed consent was obtained and the questionnaire was self-administered. The research nurse ensured that missing data was minimized. Patients were surveyed at presentation, and in four and eight weeks' time. To determine the reliability of the instrument, it was administered two times to patients one week apart. Controls filled up one set of the questionnaire only. In spite of the publication of a validated rhinitis symptom score,<sup>11</sup> there is still no widely accepted method of representing rhinitis symptoms. Our patients quantified their symptoms of runny nose, blocked nose and sneezing in the preceding two weeks utilizing a visual analogue scale. We found that this method is well-accepted by our patients and they typically take less than two minutes to fill it up.

All patients underwent skin prick tests and received appropriate allergen-avoidance counseling. The doctors treated their patients according to their own clinical judgement, and therapy might include topical nasal steroid, oral anti-histamine, ocular cromoglycate and <u>sympathomimetic</u> drugs.

The composite RQLQ score was taken to be the mean of the score of every individual item, as per Juniper *et al.*<sup>4</sup> which is different from the mean of the average score of each domain as used by De Graaf-in't Veld *et al.*<sup>5</sup> Since there are seven items in the dimension of non-rhinitis symptoms compared to three or four in the others, Juniper's method does increase the weight-age of that domain.

We analyzed the data with the SPSS Professional Statistics 8.0. We compared the RQLQ scores of patients and controls with the twotailed Mann-Whitney test as these scores were not normally distributed. The factors were extracted by principal axis factoring and rotated by the Varimax method. The change of symptom score with the change in the RQLQ score was correlated with Spearman's rho. All statistical tests were conducted at 5% level of significance.

## RESULTS

### Face and content validity

Face validity was built into the original design of the questionnaire.<sup>3</sup> Patient-reported symptoms that were deemed to occur frequently and to be important were included. Based on our experience, the items in the RQLQ adequately cover the areas of impairment in our patients' lives.<sup>12</sup>

## **Discriminant property**

Forty-four healthy controls and 40 patients completed the questionnaires with the symptom score using the visual assessment scale. These groups were comparable in terms of age (controls 27.47  $\pm 5.38$  years vs.  $28.55 \pm 9.73$  years) and sex distribution (20 female controls vs. 14 female patients). The comparison of the symptom scores and ROLO scores of the controls and the patients is shown in Table 1. Rhinitis patients score significantly higher in the RQLQ, in the individual items, the domain mean score as well as the summary mean RQLQ score.

## Reliability

We discovered that determining this property of the RQLQ using test-retest assessment was not possible with this cohort of patients. We originally planned to carry out the test-retest in the first few encounters with the patients. As most of them were new referrals to our clinic, and they started to improve soon after the correct treatment was instituted, even within one week. This was not a clinical trial, so there was no washout period in which the patients remained untreated. Therefore, the assess-

RQLQ scores	Controis	Perennial allergic rhinitics	Mann Whitney test (p-value)
Sleep	0.19	3.07	< 0.01
Non-rhinitis symptoms	0.28	3.29	< 0.01
Practical problems	0.41	4.22	< 0.01
Nasai symptoms	0.43	4.06	< 0.01
Eye symptoms	0.34	2.16	< 0.01
Activities	0.08	3.79	< 0.01
Emotion	0.21	3.58	< 0.01
Summary mean	0.28	3.41	< 0.01

Table 1 Comparison of the individual mean domain and summary RQLQ scores of controls and patients with perennial allergic rhinitis.

reliable.3

#### **Factor analysis**

Factor analysis suggested an optimal solution with five factors (Table 2). The overall Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy of 0.771 suggested that factor analysis was applicable in this study.<sup>13</sup> The cutoff point of factor loadings was chosen to be 0.5 and the total variance explained by the 5 factors was about 67%. We considered the magnitude of eigenvalues in determining the number of factors.

The first factor included all the items in the domains of practical problems and nasal symptoms. The second factor included mainly eye symptoms. The third included items in the domains of sleep and non-rhinitis symptoms. The fourth covered the emotional items and the fifth the activity domain.

The second factor indicated that the questions on 'fatigue',

ment of the reliability of the RQLQ 'reduced productivity', 'tiredness' must await further recruitment of and 'worn out' are internally correpatients who have stable disease. lated and would be candidates for We expect the RQLQ to be fairly elimination in scale-shortening,<sup>14</sup> which was indeed the case in the miniROLO.6

## Sensitivity to change

Fifteen patients completed three sets of questionnaires and their data was analyzed to investigate the responsiveness of the instrument. We calculated the mean of the two comparisons made between the second and first interviews and the third and the second interviews. The correlation of the change of mean symptom score with the change of RQLQ score was 0.91, with that of sleep was 0.48, non-rhinitis symptoms 0.79, practical problems 0.84, nasal symptoms 0.88, eye symptoms 0.57, activities 0.71 and emotions 0.69.

#### DISCUSSION

In this work, we showed that the RQLO: 1) Distinguishes well between perennial allergic rhinitics and healthy controls; 2)

Items loaded into five factors; and 3) Is sensitive to changes in the patients' rhinitis symptoms.

Rhinitis patients consistently rate all the items in the RQLQ significantly higher than the controls, indicating poorer HRQL. Meltzer and his colleagues<sup>9</sup> reported that only ten out of the 28 items reached statistical significance when they compared rhinitis patients and controls. Their study is different from ours because the questionnaire was sent by post and presence of rhinitis was subjectreported.

The ROLO was developed with the 'Impact Method' and the chosen items were assigned to seven domains based on the researchers' intuition and experience.<sup>15</sup> Using factor analysis and data from our own patients, we showed that these items loaded into five factors. Therefore, while the division to seven domains is reasonable, there is strong correlation between items in the domains of practical problems and nasal symptoms and in the domains of sleep and non-rhinitis symptoms.

Table 2

Factor analysis: Principal Axis Factoring followed by Varimax rotation with Kaiser Normalization, ignoring items with loadings less than 0.5. See text for discussion.

Factor	1	2	3	4	5
Sleep (a)			.510		
Sieep (b)		.531			
Sleep (c)			.648		
Non-rhinitis symptom (a)			.602		
Non-rhinitis symptom (b)					
Non-rhinitis symptom (c)			.718		
Non-rhinitis symptom (d)			.538		
Non-rhinitis symptom (e)					
Non-rhinitis symptom (f)					
Non-rhinitis symptom (g)			.683		
Practical problems (a)	.541				
Practical problems (b)	.605				
Practical problems (c)	.730				
Nasal symptoms (a)	.566				
Nasal symptoms (b)	.840				
Nasal symptoms (c)	.815				
Nasal symptoms (d)	.601				
Eye symptoms (a)		.757			
Eye symptoms (b)		.823			
Eye symptoms (c)		.827			
Eye symptoms (d)		.762			
Activities (a)					.510
Activities (b)					.731
Activities (c)					
Emotional (a)				.733	
Emotional (b)				.833	
Emotional (c)				.649	
Emotional (d)					
Variance (%)	36.5	11.3	7.3	6.2	5.5
Cumulative variance	36.5	47.8	55.1	61.3	66.8

mean ROLO score and the mean scores of the individual domains varied in the same direction as the reliability of the RQLQ using change in the symptom ratings. We test-retest assessment in this cohort found that the correlation of change of patients. Most of these patients in quality of life scores with the are newly referred to our clinic, severity of symptoms is generally and their RQLQ scores improved higher than those reported in other with treatment within one week. studies,<sup>3,9</sup> with practical problems Bousquet et al.<sup>8</sup> also noted that the and nasal symptoms showing the SF-36 scores could change within a

The change in the summary highest correlation presently.

We could not determine

week of treatment with cetirizine. It is suggestive that the RQLQ is so sensitive to change that it could detect improvement in HRQL within a week.

In conclusions, this preliminary study suggests that the RQLQ can be used to assess the quality of life of English-speaking patients in Singapore with perennial allergic rhinitis. Our patients reported significant impairment in all the HRQL domains in the questionnaire.

# **ACKNOWLEDGEMENTS**

We thank Professor Elizabeth Juniper, McMaster University Medical Centre, Hamilton, Ontario, for allowing us to use the Rhinoconjunctivitis Quality of Life Questionnaire in this study, and Ms Rosie Chow, for assistance with data collection. We are grateful to all the volunteer controls. This study is supported by grants from the Tan Tock Seng Hospital and the Academy of Medicine, Singapore.

#### REFERENCES

- 1. Chia SE, Lim WK, Koh D. A prevalence study of chronic rhinitis among residents in Telok Blangah Town, Singapore. Ann Acad Med Singapore 1994; 23: 358-62.
- 2 Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. Ann Intern Med 1993; 118: 622-9.
- 3. 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.
- 4. Juniper EF, Guyatt GH, Andersson B, Ferrie PJ. Comparison of powder and aerosolized budesonide in perennial rhinitis: validation of rhinitis quality of life questionnaire. Ann Allergy 1993; 70: 225-30.
- 5. De Graaf-in't Veld T, Koenders S, Garrelds IM, van Wijk RG. The relationships between nasal hyperactivity,

quality of life, and nasal symptoms in patients with perennial allergic rhinitis. J Allergy Clin Immunol 1996; 98: 508-13.

- Juniper EF, Thompson AK, Ferrie PJ, Roberts J. Development and validation of the Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ) (abstract). J Allergy Clin Immunol 1999; 103: S170.
- Bousquet J, Bullinger M, Fayol C, Marquis P, Valentin B, Burtin B. Assessment of quality of life in patients with perennial allergic rhinitis with the French version of the SF-36 Health Status Questionnaire. J Allergy Clin Immunol 1994; 94: 182-8.
- Bousquet J, Duchateau J, Pignat JC, Fayol C, Marquis P, Mariz S, Ware JE, Valentin B, Burtin B. Improvement of

quality of life by treatment with cetirizine in patients with perennial allergic rhinitis as determined by a French version of the SF-36 questionnaire. J Allergy Clin Immunol 1996; 98: 309-16.

- Meltzer EO, Nathan RA, Selner JC, Storms W. Quality of life and rhinitic symptoms: Results of a nationwide survey with the SF-36 and RQLQ questionnaires. J Allergy Clin Immunol 1997; 99: S815-9.
- Mackowiak JI. Fluticasone propionate aqueous nasal spray (FP) improves rhinitis quality of life and reduces lost labor costs (abstract). Ann Allergy 1994; 72: 99.
- 11. Wasserfallen J-B, Gold K, Schulman KA, Baraniuk JN. Development and validation of a rhinoconjunctivits and asthma symptom score for use as an

outcome measure in clinical trials. J Allergy Clin Immunol 1997; 100: 16-22.

- Yeak S, John AB, Chee N, Chng HH. Rhinitis in Singapore. Allergy 1996; 51: 757-8.
- Subhash S: Applied multivariate technique. John Wiley & Sons, USA, 1996.
- Coste J, Guillemin F, Pouchot J, Fermanian J. Methodological approaches to shortening composite measurement scales. J Clin Epidemiol 1997; 50: 247-52.
- Juniper FJ, GH Guyatt, DL Streiner, DR King. Clinical impact versus factor analysis for quality of life questionnaire construction. J Clin Epidemiol 1997; 50: 233-8.

