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Development of a Health-Related Quality of Life Questionnaire for Thai Patients with Rhinoconjunctivitis

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SUMMARY The objective of this study was to develop a disease-specific questionnaire for patients with rhinoconjunctivitis. All patients were recruited at the Out-Patient Clinic at Siriraj Hospital. Related topics were gathered from several sources, and a list of 63 items was produced. In phase I, the first version of the questionnaire was completed by 363 patients. Forty-eight items were identified by clinical impact analysis during the item removal process, two more questions were then added, giving a total of 50. Two hundred and forty-three patients completed the second version questionnaire in phase II. The average time taken to complete the questionnaire was 6.38 minutes. The item removal process in phase II was achieved by a multi-step process. There were 36 items in the third version questionnaire which consisted of six dimensions and two independent items as follows: symptoms (17 items), physical functioning (3 items), role limitations (3 items), sleep (3 items), social functioning (3 items), emotions (5 items), general health (1 item), and absenteeism (1 item). The scores of each item ranged from 1 to 5; a lower score indicating a better quality of life. Data from the selected 36 items was extracted to test the validity and reliability of the final version. The floor and ceiling effects of the scores for each dimension were low. Multitrait multi-item analysis was conducted to examine construct validity. The scaling success of convergent and divergent validity was 100% and 94%, respectively. Internal consistency determined by Cronbach's alpha coefficient, was satisfactory (0.79-0.87). The study indicates that the questionnaire is suitable for use in clinical settings. While the test results are encouraging, further work needs to be done on the test-retest reliability and on responsiveness.

In 1994, using the French version of the SF-36 questionnaire, Bousquet, *et al.*[1,2] concluded that allergic rhinoconjunctivitis (ARc) patients had a significantly impaired quality of life similar to those who have moderate to severe symptoms of asthma. This report and information from several other countries,[3,4] have interested us and other research groups worldwide. Thus we have conducted a study using the Thai version of the SF-36 questionnaire to evaluate the quality of life of Thai ARc patients as compared to healthy subjects. The results showed that the studied patients had a significantly impaired quality of life compared to healthy persons in all dimensions, except the social functioning dimension.[5] Nevertheless, the SF-36 questionnaire may have some drawbacks in evaluating the quality of life of ARc patients because it is a generic questionnaire which lacks depth of focus. It may not, therefore, be sufficiently responsive to detect small but, to the patients, important changes in their quality of life.[6]

We have also found that using questionnaires developed in other parts of the world, may not be accurate because they do not cater for the differences in race, culture, and socio-economic status of the people in each region. This study, therefore, was designed to develop a reliable and valid specific questionnaire for Thai ARc patients, which can be used for clinical studies

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and in clinical practice.

MATERIALS AND METHODS

Study design

The study protocol was approved by the Ethical Clearance Committee on Human Rights related to research involving human subjects, Faculty of Medicine, Siriraj Hospital, Mahidol University as part of the whole project entitled 'Quality of life in patients with allergic rhinoconjunctivitis'. The study was divided into two phases: phase I, questionnaire development, embracing item-generation and reduction processes and, phase II, the questionnaire testing process.

Phase I: questionnaire development

The steps for developing a questionnaire in this study were adapted from other studies.[7-9] The measurement goals of the questionnaire were to be used to assess the quality of life of patients aged over 13 years with rhinoconjunctivitis. The questionnaire should have both discriminative and evaluative properties and consist of 30-40 items which can be applied by self-administration.

Item generation

A list of topics likely to be important to patients' everyday life was prepared. Sources of these items included experts' opinions, information from existing questionnaires (both generic and specific instruments), and interviews with ten ARc patients (to obtain the patient's perception of the impact of ARc on their quality of life). A pool of 63 items was initially generated. These were grouped into five dimensions: symptoms (rhinitis, ear and throat, eye and other symptoms) (41 items), physical functioning (5 items), role limitations (4 items), sleep (3 items), social functioning (3 items) and emotions (7 items). The draft questionnaire was sent to six independent specialists (3 otorhinolaryngologists and 3 ophthalmologists) to check for missing information and redundancies. All specialists agreed with the content. This resulted in the first version of the questionnaire.

Item reduction

The item reduction was intended to shorten the questionnaire by removing redundant items. The process was divided into two parts. In part 1, the first version containing 63 items, was applied to ARc patients to identify items that they considered an annoyance to them. Initially, the response options were graded in four-point scales, ranging from 1 (not at all) to 4 (extremely). The questions in the symptoms dimension asked if the patients had such symptoms and how bothersome they were. In addition, patients were asked to add items which were not on the list.

Clinical impact analysis, used also by other studies, was performed to identify important items.[7-9] For each item, a 'product score', the product of the proportion of patients identifying the item as a problem (frequency), and the mean importance attributed to that item, was calculated. This score was called 'product score'. The cut-point was identified by multiplying the least score (1) with the number of patients. Selected items that scored above the cut-point were used to produce the second version of the questionnaire for part 2.

Item-removal, using a multi-step process, was done in the part 2 study. The process included clinical impact analysis, missing data checking, highly endorsed response options verification, Cronbach's alpha coefficients, correlations between items, and reviewing by experts. The process was conducted as follows:

(1) Clinical impact analysis was done in the same way as part 1 but the cut-point was determined differently. Only items identified as 'slightly bothersome' and above were selected and, as a consequence, the cut-point was equal to 486 (243 x 2).

(2) The item descriptive statistics were used to examine missing and highly endorsed response options indicating problems with the wordings, response choices and understanding the questions. High missing data items or items where patients responded exceeded 70% at either end of the options were deleted.

(3) Cronbach's alpha coefficient if item deleted values indicated the reliability coefficient when such item was deleted. In general, a good questionnaire should have a reliability coefficient above 0.7.

(4) A high correlation coefficient ($r > 0.7$) was adopted to indicate if a pair of items followed the same trait. An item would be retained if it had a higher correlation coefficient compared to the other.

Phase II: testing the questionnaire

The psychometric properties, including construct validity and internal consistency, of the questionnaire, were analyzed. Note that:

- Validity is a property that the questionnaire measures what it is intended to measure. Construct validity, comprising convergent and discriminant validity, can be examined in the form of the relationship between the items and scales in the multitrait/multi-item correlation matrix. Convergent validity is the extent to which items, which are expected to measure the same construct, have a high correlation. Discriminant validity examines whether items or scales thought to measure different constructs, have a low correlation.

- Reliability: Internal consistency was a measure of the extent to which items within a scale correlate with each other to form a multi-item scale. To evaluate internal consistency, Cronbach's alpha coefficient was calculated. Alpha values of 0.70 or greater were considered satisfactory.

Subjects

Patients were recruited at the Allergy Out-Patient Clinic, Department of Otolaryngology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. These patients were older than 13 years of age, diagnosed allergic rhinoconjunctivitis after routine investigation (including allergy skin test to common aeroallergens). They were informed about the objective of the study and gave their written consent before being included. For patients aged less than 18 years, individual parental consents were obtained.

Patients were excluded if they had psychiatric or emotional problems, or language or cognitive difficulties which might prevent reliable completion of the questionnaire.

Analysis

All statistical analyses were performed using SPSS for Window version 9.0. In clinical impact analysis, a product score of an item was computed by multiplying the frequency of the patients' selection of an item by its mean importance. The scores were ranked from the highest to the lowest. Mean, standard deviation, and percentage of response and missing data of each item were calculated to present item-level descriptive statistics. Correlation coefficients between items, and between item and scales in this study were determined using the Pearson product – moment correlation coefficient.

After the item reduction step, data from the second version was analysed to check the construct validity and internal consistency properties of the final version. Construct validity is an evaluation of the correlations between items of the scales. Multitrait multi-item analysis was used for this purpose.[10] The correlation coefficients between an item and its own scale was corrected for overlap. Convergent validity was considered substantial and satisfactory if an item correlated with its hypothesized scale greater or equal to 0.4. Discriminant validity was confirmed when the correlation coefficients between an item and its hypothesized scales were significantly higher than the correlation between that item and other scales. A significant level of correlation was defined as two standard errors of a correlation coefficient. The standard error was approximately equal to the square root of (1 minus r^2, divided by number of samples minus 2). The results of the comparisons were presented in the form of percentages of scaling success as, the number of pairs of items, divided by the total number of comparisons, multiplied by 100. Cronbach's alpha coefficient was used in the reliability analysis.

Dimension scores were computed by summing all of the item responses in a dimension, whereby lower scores indicated a better quality of life. Minimum, maximum, mean, standard deviation, kurtosis, skewness, and ceiling/floor effects were analyzed.

RESULTS

Characteristics of study subjects

The total number of patients participating in phase I – part 1, was 363. Their ages ranged from 13 to 80 years with an average age ± S.D. of 34.5 ± 12.5. In phase I – part 2, 243 patients aged from 13 to 75 with an average age ± S.D. of 35.1 ± 13.3 participated. Most of the patients in both phases were female. About half of them were single and a number of patients had a graduate education level. Most patients in part 1 had a lower income than in part 2. The patients' characteristics are shown in Table 1.

Item reduction

In part 1 of phase I, the first version of the questionnaire,

comprising 63 items, was given to 363 ARc patients. The highest product score was 1,137 and the lowest was 168. Using the criteria mentioned earlier (cut-point = 363), 15 items in the symptom dimension were removed because 12 of the items had a lower score than the cut-point and three items were repetitive. As a result the total number of items was reduced to 48. All items in this intermediate version contained five-point scale (not at all = 1, slightly = 2, moderately = 3, a lot = 4 and extremely = 5) response options. All items were reviewed and a further two independent items were added. These were worded as follows: 'How would you rate your health in general, now?', and an open question, 'How many days were you absent from school or work per month because of the symptoms?'. The total number of items in the second version of the questionnaire was 50. The time specification in each item was 'two weeks ago' since it was anticipated that the effects of treatment should be felt after two weeks.

Table 1 Sample characteristics

	Part 1 Frequency	% (n = 363)	Part 2 Frequency	% (n = 243)
Gender				
Male	133	36.6	86	35.4
Female	228	62.8	157	64.6
(missing data)	2	0.6	-	-
Age (years)				
13 –34	200	55.1	124	51.0
35 – 54	131	36.1	96	39.5
≥ 55	27	7.4	23	9.5
(missing data)	5	1.4	-	-
Status				
Single	181	49.9	121	49.8
Married,	153	42.1	104	42.8
Divorced, Widowed, Separated	29	8.0	17	7.0
(missing data)	-	-	1	0.4
Education				
Primary school	76	20.9	55	22.7
High school	77	21.2	54	22.2
Graduate	209	57.6	131	53.9
(missing data)	1	0.3	3	1.2
Income (US $) per year				
< 2,724	190	52.3	82	33.7
2,724 – 13,632	108	29.8	139	57.2
> 13,632	9	2.5	15	6.2
(missing data)	56	15.4	7	2.9

The part 2 in phase I study was conducted using the second version of the questionnaire in a new group of ARc patients (n = 243). The average time ± S.D. in completing the questionnaire was 6.38 ± 4.36 minutes, ranging from 2 to 30 minutes. In this part, several steps were used to select items. Clinical impact analysis was the first step. The cut-point was 486. Product scores were ranked in order from 893 (annoyed with self) to 553 (taking a bath, dressing, brushing teeth) (Table 2). As can be seen, all items had a product score above 486, thus no item was removed.

The second step was to exclude items with too high an endorsement rate. Table 2 also shows the frequency of responses in each scale; the lowest and highest percentages of responses were 1.3 and 64.4 respectively. There were no items with a frequency ≥ 70% endorsement at either end of the response categories. Missing data ranged from 0.4% ("don't feel like going out") to 3.7% ("hoarse voice" and "circles around eyes"). The average missing rate was 2.1% per item. Since the percentage of responses and the missing data were acceptable, all items were retained.

The third step: Cronbach's alpha coefficient if item deleted, for each item was determined. It represented Cronbach's alpha coefficient of a scale when an item was deleted. No items were rejected since alpha coefficients in each dimension were above the standard (> 0.70) ranging from 0.79 – 0.91. The correlation coefficients between items were then examined. Thirteen pairs had a high correlation coefficient. These were: three items from the symptoms dimension, two each from the physical functioning and role limitations dimension, one each from the sleep and social functioning dimensions,

Table 2 Descriptive statistics and frequency of responses of the questionnaire (50 items), N = 243

Items	Mean	S.D.	Product	Percentage of responses					Missing data
				None	Slightly	Moderately	A lot	Extremely	
RS1	3.62	1.11	865	1.7	15.1	32.2	21.8	29.3	1.7
RS2	3.31	1.10	779	2.1	23.4	34.5	20.9	19.1	3.3
RS3	3.61	1.12	871	2.5	15.8	27.0	27.4	27.4	0.8
RS4	3.45	1.08	821	2.9	16.4	34.5	25.2	21.0	2.1
RS5	2.79	1.13	655	6.4	45.1	24.7	11.1	12.8	3.3
RS6	2.78	1.08	657	5.5	45.8	22.9	16.5	9.3	2.9
ES1	2.78	1.05	665	6.7	39.3	31.8	13.4	8.8	1.7
ES2	2.73	1.00	645	5.9	43.2	28.4	16.5	5.9	2.9
ES3	2.64	0.94	629	5.9	45.8	31.1	12.6	4.6	2.1
ES4	2.68	0.97	629	6.0	45.1	29.8	13.6	5.5	3.3
ES5	2.73	1.01	647	5.9	44.7	24.9	19.4	5.1	2.5
ES6	2.62	1.05	613	6.4	53.8	19.2	12.4	8.1	3.7
ES7	2.57	0.98	609	6.8	51.9	25.3	9.7	6.3	2.5
OS1	2.75	0.98	654	5.0	42.9	29.8	16.8	5.5	2.1
OS2	2.68	0.97	630	6.4	43.8	29.8	15.3	4.7	3.3
OS3	2.98	1.09	714	5.0	32.5	35.4	14.2	12.9	1.2
OS4	2.58	0.88	603	5.6	47.9	34.2	8.1	4.3	3.7
OS5	3.12	1.04	733	4.3	25.5	34.5	25.5	10.2	3.3
OS6	2.87	1.07	681	5.5	37.6	31.6	14.8	10.5	2.5
OS7	3.63	1.11	871	2.5	13.8	30.0	25.8	27.9	1.2
OS8	3.14	1.10	747	4.6	26.9	32.4	22.3	13.9	2.1
OS9	3.31	1.01	780	1.7	21.6	34.3	29.2	13.1	2.9
OS10	3.33	1.08	797	2.5	21.8	33.5	24.3	18.0	1.7
OS11	3.35	1.07	797	2.5	21.4	31.5	27.7	16.8	2.1
OS12	3.25	1.05	776	3.3	22.2	34.3	26.8	13.4	1.7
OS13	3.12	1.11	742	3.4	31.9	28.6	21.8	14.3	2.1
PF1	2.93	1.02	706	2.9	37.3	33.2	17.0	9.5	0.8
PF2	2.68	0.92	644	4.6	45.0	32.5	13.3	4.6	1.2
PF3	2.60	0.99	621	7.1	49.4	25.9	11.7	5.9	1.7
PF4	2.40	0.89	573	8.4	59.4	19.7	9.2	3.3	1.7
PF5	2.31	0.90	553	10.0	64.4	13.0	9.2	3.3	1.7
RL1	2.38	0.90	563	8.0	62.9	16.5	8.9	3.8	2.5
RL2	2.66	0.97	632	5.5	47.9	28.2	12.6	5.9	2.1
RL3	2.96	1.10	707	3.8	40.2	23.0	22.6	10.5	1.7
RL4	2.99	1.07	711	4.2	34.9	29.0	21.8	10.1	2.1
SP1	3.20	1.15	767	4.6	27.9	28.3	22.1	17.1	1.2
SP2	3.16	1.18	752	4.2	31.9	26.1	19.3	18.5	2.1
SP3	3.17	1.13	757	3.8	28.9	30.5	20.5	16.3	1.7
SF1	2.93	1.10	705	4.6	37.8	31.1	13.7	12.9	0.8
SF2	2.73	1.01	654	4.2	48.8	25.0	14.6	7.5	1.2
SF3	3.05	1.15	739	3.3	37.2	26.4	16.9	16.1	0.4
E1	3.72	1.13	893	1.3	15.0	29.2	19.6	35.0	1.2
E2	3.35	1.12	793	2.5	22.8	32.9	21.1	20.7	2.5
E3	3.35	1.17	797	2.5	26.9	26.5	21.4	22.7	2.1
E4	2.98	1.13	710	3.8	39.1	26.1	17.2	13.9	2.1
E5	2.69	1.08	634	7.6	47.5	21.6	15.3	8.1	2.9
E6	3.16	1.11	750	2.5	30.0	32.9	17.7	16.9	2.5
E7	3.21	1.23	764	3.8	31.5	28.6	12.2	23.9	2.1
OH	3.13	0.76	744	-	19.3	52.9	23.5	4.2	2.1

Rhinitis symptoms (RS), Eye symptoms (ES), Other symptoms (OS), Physical functioning (PF), Role limitations (RL), Sleep (SP), Social functioning (SF), Emotions (E), Overall health (OH)

Table 3 Correlations[a] between the items and hypothesized scales of the Rhinoconjunctivitis Quality of Life Questionnaire (36 items), N = 243

	RS	ES	OS	PF	RL	SP	SF	E	OH
RS1	**0.67**	0.38	0.37	0.26	0.41	0.29	0.33	0.41	0.24
RS2	**0.59**	0.40	0.29	0.12	0.38	0.20	0.19	0.38	0.21
RS3	**0.52**	0.36	0.42	0.29	0.38	0.30	0.35	0.44	0.20
RS4	**0.62**	0.38	0.35	0.21	0.34	0.23	0.25	0.37	0.26
ES1	0.44	**0.76**	0.48	0.28	0.37	0.28	0.26	0.31	0.16
ES2	0.45	**0.83**	0.53	0.25	0.35	0.25	0.28	0.33	0.19
ES3	0.46	**0.65**	0.42	0.37	0.36	0.26	0.31	0.30	0.25
ES4	0.36	**0.70**	0.51	0.20	0.34	0.35	0.32	0.38	0.23
OS1	0.27	0.25	**0.41**	0.30	0.27	0.33	0.34	0.37	0.18
OS2	0.36	0.40	**0.53**	0.32	0.41	0.31	0.27	0.35	0.20
OS3	0.24	0.25	**0.54**	0.36	0.36	0.35	0.38	0.45	0.21
OS4	0.45	0.58	**0.71**	0.38	0.55	0.50	0.41	0.57	0.31
OS5	0.34	0.44	**0.75**	0.45	0.54	0.37	0.39	0.47	0.35
OS6	0.32	0.43	**0.75**	0.53	0.52	0.39	0.39	0.49	0.40
OS7	0.31	0.36	**0.68**	0.45	0.41	0.37	0.28	0.35	0.20
OS8	0.38	0.40	**0.63**	0.46	0.42	0.34	0.30	0.42	0.28
OS9	0.36	0.51	**0.58**	0.41	0.54	0.24	0.41	0.46	0.27
PF1	0.22	0.27	0.51	**0.75**	0.52	0.35	0.53	0.51	0.40
PF2	0.28	0.33	0.55	**0.80**	0.52	0.35	0.52	0.51	0.36
PF3	0.22	0.26	0.47	**0.64**	0.37	0.29	0.41	0.35	0.29
RL1	0.39	0.31	0.47	0.41	**0.55**	0.41	0.44	0.39	0.34
RL2	0.46	0.40	0.63	0.50	**0.74**	0.44	0.52	0.63	0.38
RL3	0.41	0.38	0.55	0.50	**0.73**	0.45	0.59	0.62	0.38
SP1	0.33	0.35	0.46	0.43	0.44	**0.70**	0.48	0.49	0.28
SP2	0.25	0.27	0.42	0.32	0.39	**0.72**	0.39	0.42	0.21
SP3	0.30	0.31	0.45	0.33	0.48	**0.76**	0.45	0.50	0.27
SF1	0.35	0.33	0.46	0.48	0.54	0.43	**0.77**	0.69	0.34
SF2	0.38	0.40	0.49	0.56	0.55	0.45	**0.80**	0.65	0.39
SF3	0.29	0.29	0.42	0.46	0.53	0.45	**0.71**	0.62	0.41
E1	0.43	0.30	0.46	0.35	0.53	0.37	0.54	**0.74**	0.42
E2	0.40	0.37	0.58	0.47	0.51	0.47	0.62	**0.77**	0.43
E3	0.44	0.38	0.58	0.42	0.55	0.46	0.59	**0.81**	0.47
E4	0.43	0.39	0.59	0.48	0.61	0.50	0.66	**0.73**	0.43
E5	0.50	0.29	0.35	0.28	0.49	0.34	0.45	**0.51**	0.35

[a] Pearson item-scale correlation coefficients corrected for overlapping. S.E. = 0.06.

Values in boxes are correlation coefficients between an item and its hypothesized scale. The underlined values are correlation coefficients that are significantly greater than the correlation coefficients between an item and its hypothesized scales.

Rhinitis symptoms (RS), Eye symptoms (ES), Other symptoms (OS), Physical functioning (PF), Role limitations (RL), Sleep (SP), Social functioning (SF), Emotions (E), Overall health (OH).

Table 4 Item convergent and discriminant validity of the Rhinoconjunctivitis Quality of Life Questionnaire (36 items)

Dimensions	No. of items	Correlations of items with own scale [a]	Correlations of items with other scales [b]	Convergent validity [c]	Discriminant validity [d]
Rhinitis symptoms	4	0.52 – 0.67	0.12 – 0.44	4/4 (100%)	30/32 (94%)
Eye symptoms	4	0.65 – 0.83	0.16 – 0.53	4/4 (100%)	32/32 (100%)
Other symptoms	9	0.41 – 0.75	0.18 – 0.57	9/9 (100%)	66/72 (92%)
Physical functioning	3	0.55 – 0.74	0.31 – 0.63	3/3 (100%)	24/24 (100%)
Role limitations	3	0.64 – 0.80	0.22 – 0.55	3/3 (100%)	19/24 (79%)
Sleep	3	0.70 – 0.76	0.21 – 0.50	3/3 (100%)	24/24 (100%)
Social functioning	3	0.71 – 0.80	0.29 – 0.68	3/3 (100%)	22/24 (92%)
Emotions	5	0.51 – 0.81	0.30 – 0.66	5/5 (100%)	37/40 (93%)

a = Correlations of items with own scale, corrected for overlap (range)

b = Correlations of items with other scales (range)

c = Scaling success = number of item-scale correlations ≥ 0.40 / total number of correlations (corrected for overlap).

d = Scaling success = number of correlations of items with own scales (corrected for overlap) significantly higher (≥ 2 S.E.) than correlations with other scales / total number of correlations.

and four from the emotions dimension. Thus, 13 items having a lower correlation with their own scale were deleted.

On completion of the item reduction step, all deleted items were reviewed again. Items considered by specialists as being important to the patients were then retrieved and positioned into identified dimensions. Finally, because a large proportion of the remaining items were in the symptom dimension compared to others, it was decided that some of these should be deleted. This was achieved by selecting those items in the symptom dimension which had high product scores. Eight items were removed by this process leaving a total of 36 items for inclusion into the final version of the questionnaire (Fig. 1).

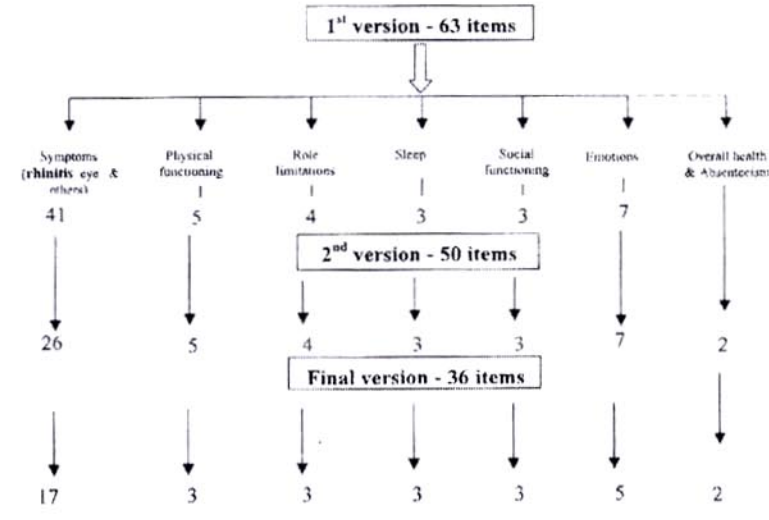

Fig. 1 Item reduction and replacement process in phase I

Testing (the final version)

Data from the second version of the questionnaire (n = 243) were tested for validity and reliability. Construct validity in the form of multitrait/multi-item correlation matrix is shown in Table 3. The correlation coefficients between items and their own scales are in the boxes. The underlined values are the coefficients which were higher than 2 S.E. of the correlation coefficients. As presented in Table 4, convergent validity of the questionnaire was satisfactory, yielding 100%. The eye symptoms, physical functioning, and sleep dimensions had 100% scaling success on

discriminant validity. The average scaling success of discriminant validity was 94%. Items in the dimensions with low scaling success rate were highly correlated with other dimensions. For instance, items in the role limitations dimension correlated with other dimensions i.e. other symptoms, social functioning and emotions, greater than 2 S.E. as shown (underlined) in Table 3. These had the lowest scaling success rates (79%). The other four dimensions (rhinitis symptoms, other symptoms, social functioning and emotions) had scaling success rates over 90%.

Correlation coefficients between dimensions are shown in Table 5. The Cronbach's alpha coefficients are presented in diagonal form showing the correlation within each scale. All dimensions met the minimum reliability standard (> 0.70). The correlation coefficients between dimensions were demonstrated. Each dimension should correlate with its own scale higher than with other scales (discriminant validity). As hypothesized, all dimensions were found to have higher correlation coefficients with their own scales than with others, thus measuring a distinct health construct.

Mean scores of the questionnaire items ranged from 2.73 to 3.50. The lower scores indicated less impairment on quality of life. The least impairments were with eye symptoms and role limitations whereas the highest impairment was with rhinitis symptoms (Table 6). Not all dimensions had minimum and maximum scores of 1 and 5, with the exception of rhinitis symptom dimension, for example where the minimum score was 1.25. Floor and ceiling effects were low in all dimensions. Frequency responses to general health questions are shown in Fig. 2. The mean general health score was 3.13 (± 0.76). Mean absence from work or school was 1.70 (± 2.56) days per month with minimum 0 and maximum 15 days. Following completion of testing, the final version was

Table 5 Reliability coefficients and inter-scale correlations of Rhinoconjunctivitis Quality of Life Questionnaire (36 items). Cronbach's alpha coefficients of each dimension are in boxes.

Dimensions	RS	ES	OS	PF	RL	SP	SF	E
Rhinitis symptoms	0.79							
Eye symptoms	0.53	0.87						
Other symptoms	0.52	0.61	0.87					
Physical functioning	0.49	0.44	0.64	0.81				
Role limitations	0.33	0.36	0.59	0.55	0.85			
Sleep	0.33	0.36	0.51	0.41	0.51	0.85		
Social functioning	0.38	0.38	0.51	0.56	0.60	0.50	0.87	
Emotions	0.53	0.42	0.63	0.50	0.64	0.52	0.72	0.87
Overall health	0.30	0.27	0.37	0.37	0.44	0.28	0.42	0.51

Table 6 Descriptive statistics of the Rhinoconjunctivitis Quality of Life Questionnaire (36 items), N = 243

Dimensions	Mean	SD	Minimum	Maximum	% Floor	% Ceiling	Skewness	Kurtosis
Rhinitis symptoms	3.50	0.87	1.25	5.00	0	5.8	-0.13	-0.60
Eye symptoms	2.73	0.86	1.00	5.00	2.5	0.8	0.43	-0.41
Other symptoms	3.25	0.77	1.00	5.00	0.8	0.8	-0.20	-0.37
Physical functioning	2.78	0.87	1.00	5.00	2.5	1.3	0.39	-0.40
Role limitations	2.73	0.86	1.00	5.00	2.9	1.7	0.62	-0.04
Sleep	3.19	1.02	1.00	5.00	2.5	9.1	0.15	-0.80
Social functioning	2.90	0.97	1.00	5.00	1.2	5.0	0.59	-0.50
Emotions	3.36	0.94	1.00	5.00	0.4	5.8	0.10	-0.97

approved for recommendation as the Rhinoconjunctivitis Quality of Life Questionnaire (Rcq-36) as shown in the Appendix.

DISCUSSION

Although there is growing concern about the impact of rhinoconjunctivitis symptoms on patients' quality of life, there is no disease-specific questionnaire available for Thai patients. Instruments developed in Western countries may not be suitable for Thai patients because of different cultures. In addition, some instruments have too many levels of response options so that our patients cannot clearly distinguish the differences between adjacent choices. This study aimed to develop a disease-specific questionnaire for use in routine allergy clinics.

A disease-specific questionnaire was developed through several stages to confirm that items important to patients, but not redundant, were included. Clinical impact analysis allows items that are important to patients, to be selected. Although factor analysis is one of the methods recommended for item selection,[8] it was not used in this study. Juniper *et al.*[11] compared factor analysis and clinical impact analysis and concluded that the two methods give different results. Clinical impact analysis was used in this study because it was believed that items of functional impairment should be included in the questionnaire. Although this method could identify important items, some items were synonyms or referring to similar symptoms. Deletion of items with high correlation coefficients could prevent the inclusion of redundant items.[12]

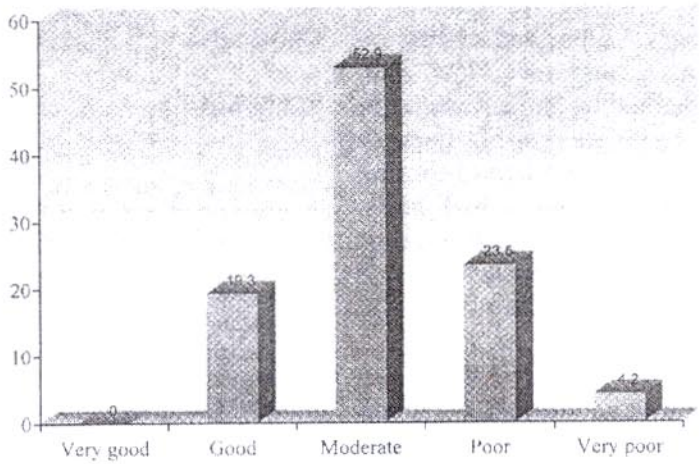

Fig. 2 Frequency of ARc patients responding to general health question (How would you rate your health in general, presently?), N = 243.

The Rcq-36 was used in a busy clinic setting in order to test its applicability. The time to complete the questionnaire was relatively short. Missing data of the intermediate version (50 items) was found to be low. The distribution of answers indicated by the frequency of each response option was acceptable since most of the answers distributed among 'slightly', 'moderately' and 'a lot'. A seven-point scale was recommended in some studies [13], however experience showed that it is difficult for patients to distinguish the difference between many response options. Thus a five-point scale was used for our questionnaire. The final version consisted of 36 items as closed-ended questions, in a grid format, to assess symptoms, physical functioning, sleep, social functioning and emotions. Items in the symptom dimension are almost identical to Juniper's rhino-conjunctivitis quality of life questionnaire[7] and the rhino-conjunctivitis symptom score developed by Wasserfallen, *et al.*[14] They consider symptoms, which are identical and have significant impact on patients in various areas. The intermediate version could be completed in a relatively short time and the majority of the patients completed the questionnaire without assistance. The final version should take less time and be practical for use in routine clinic settings. The time specification in some instruments is a four-week period[10] while other questionnaires refer to a one-week period.[7,15,16] The questionnaire at this stage uses a two-week period because we assumed that the recall and detection changes after treatment could be concluded in that time.

Following item reduction, the analysis of validity and reliability was conducted on the selected 36 items. It was evident that both convergent and divergent validity was satisfactory although the divergent validity was low on the role limitations dimension. Therefore,

careful interpretation of this dimension should be taken. Internal consistency reliability was found to be satisfactory. Floor and ceiling effects were shown to be low, indicating that the instrument would be able to cover all possible impacts. Further study is required to confirm the test-retest reliability and the responsiveness of the final version. These issues were studied and will be subsequently reported.

It is concluded that using a standard internationally-recommended procedure, we have systematically developed a disease-specific quality of life questionnaire for Thai patients with rhinoconjunctivitis. The final questionnaire which has 36 items is called the Rcq-36. This questionnaire is easy to use and understand and the analysis of validity and reliability has proved satisfactory.

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APPENDIX

Rhinoconjunctivitis Quality of Life Questionnaire (Rcq-36)

This questionnaire is designed to find out how your health and well-being have been affected by rhinoconjunctivitis. The aim is to learn how your health and general life is affected in order to develop a treatment which can alleviate these problems, or symptoms, in the future. It should not take you long to complete the form.

Please answer each question by putting a check mark in the space provided on the right. If you are uncertain, please give the answer that best describes your condition.

Response options for item 1-7: Not at all = 1, Slightly = 2, Moderately = 3, A lot = 4, Extremely = 5

1. and 2. During the past 2 weeks, how much have you been bothered by the following symptoms?
   - 1.1 Runny nose
   - 1.2 Itchy nose
   - 1.3 Stuffy (congested) nose
   - 1.4 Sneezing
   - 1.5 Cough
   - 1.6 Dry throat/Dry mouth
   - 1.7 Phlegm
   - 1.8 Itchy eyes
   - 1.9 Irritated eyes
   - 1.10 Watery eyes (tears running)
   - 1.11 Tired (heavy) eyes
   - 2.1 Hard to think (Can't stay focused on idea)
   - 2.2 Fatigue
   - 2.3 Tired easily
   - 2.4 Body aches (all over)
   - 2.5 Headaches
   - 2.6 Sleepy all the time

3. During the past 2 weeks, have the symptoms in 1 and 2 caused you the following problems?
   - 3.1 Must stop work or studies
   - 3.2 Unable to concentrate on work or studies
   - 3.3 Causes a disturbance in work, such as interrupted working

4. In the past 2 weeks, how much have the symptoms in 1 and 2 caused you problems in the following activities?
   - 4.1 When playing sports or doing a heavy work or participating in an activity that requires a lot of strength or energy.
   - 4.2 When playing sports or having a regular work or participate in an activity that requires average strength or energy.
   - 4.3 When walking ½ kilometer

5. In the past 2 weeks, how have the symptoms in 1 and 2 affected your sleep?
   - 5.1 Sleep and wake up often during the night
   - 5.2 Difficulty getting to sleep
   - 5.3 Do not sleep deeply

6. In the past 2 weeks, how much do the symptoms in 1 and 2 cause problems when you are with others or meeting with others?
   - 6.1 Loss of confidence when meeting others
   - 6.2 Reduce the meetings or activities with others
   - 6.3 Feel like you do not want to go out

7. In the past 2 weeks, how much have the symptoms in 1 and 2 caused you to feel the following?
   - 7.1 Annoyed with self
   - 7.2 Worried (anxious)
   - 7.3 Frustrated
   - 7.4 Irritated
   - 7.5 Annoyed to have to carry tissue papers or handkerchief more than usual

8. What do you think of your general health right now (Please mark only one answer)
   Response options: Very Good Good Moderate Poor Very poor

9. How many days per month are you absent from work or school because of the symptoms in 1 and 2, that you have now?