

# Quality of Life Assessment in Thai Patients with Allergic Rhinoconjunctivitis using the SF-36 Questionnaire (Thai version)\*

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## SUMMARY

*The health related quality of life (QOL) of patients with allergic rhinitis and/or conjunctivitis (ARc) as measured by the SF-36 questionnaire, has been shown to be impaired in a similar way to that of asthmatic patients in France and several other countries. We used the SF-36 questionnaire (Thai version) to evaluate the QOL of Thai ARc patients compared to healthy subjects. The SF-36 questionnaire (Thai version) consists of 36 items covering 8 dimensions and one health transition report question. Higher scores indicated better QOL. The internal consistency reliability of the questionnaire was analysed using Cronbach's alpha-coefficient. A total of 705 healthy persons and 900 ARc patients were included in this study. The mean difference of the scores between healthy and ARc groups in each dimension showed higher scores in the healthy group. This difference was statistically significant ( $p < 0.05$  and  $p < 0.001$ ) for all dimensions, except for the Social Functioning dimension. The internal reliability of the SF-36 questionnaire was confirmed by Cronbach's alpha-coefficient which was above 0.7 for seven of the dimensions; the exception was the Social Functioning dimension. Men were shown to have higher scores than women in several dimensions. In conclusion, this study has confirmed that the SF-36 questionnaire is sensitive enough to discriminate ARc patients from healthy persons with high reliability. QOL of ARc patients was significantly more impaired than healthy persons and hypertensive patients in several dimensions. These findings were similar to reports from other countries using the same instruments. Therefore the SF-36 questionnaire (Thai version) can be a useful tool in evaluating the impact of ARc on a patient's QOL and the improvement in QOL after therapeutic intervention in Thai patients.*

*Key words: health related quality of life, allergic rhinoconjunctivitis, generic questionnaire, the SF-36 questionnaire (Thai version), Cronbach's alpha-coefficient*

## INTRODUCTION

During the past ten years, there has been an increasing interest in measuring the effect of allergic rhinitis/conjunctivitis symptoms on the health-related quality of life (QOL) of these patients, especially, after Bousquet et al., has shown that allergic rhinoconjunctivitis (ARc) has a similar impact on the QOL of affected individuals as does asthma in patients who have moderate to severe symptoms [1,2].

In Thailand, the prevalence of allergic rhinitis is about 20% in adults and about 40% in children [3-6]. The prevalence has increased considerably as was reported in the United States [7]. However, QOL has never been assessed in Thai patients with allergic rhinoconjunctivitis.

The SF-36 questionnaire, which is a standardized generic questionnaire developed from the Medical Outcomes Study surveys [8,9] has been translated into Thai with permission from the developer [10]. So the aim of this study was to use the SF-36 questionnaire (Thai version) to evaluate the QOL of Thai ARc patients as compared to healthy subjects.

## MATERIALS AND METHODS

This study was conducted by collaboration between the Department of Otolaryngology and the Department of Ophthalmology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok and Faculty of Pharmacy, Silpakorn University, Nakornpathom, Thailand.

**Questionnaire**

The SF-36 questionnaire consisted of 36 items covering 8 dimensions and 1 health transition report question. Scoring was computed according to the manual [11]. Possible scores range from 0 to 100 and a lower score indicates poorer health status.

**Subjects**

Adult patients were recruited from the ENT Allergy Clinic, Siriraj Hospital, Bangkok. The diagnosis was allergic rhinitis with or without conjunctivitis based on medical history, physical examination and standard skin prick testing to 12 common aeroallergens. Their symptoms at that period were mild to moderate without concurrent asthma. All patients were informed about the objective of the questionnaire and gave their consent to participate in the study.

Healthy subjects included university students, skilled workers and other members of the general population in Bangkok and its vicinity. They were also informed about the objective of the questionnaire and agreed to participate in the study.

Both ARc patients and healthy persons were instructed to fill in the SF-36 questionnaire by themselves. Then all questionnaires were checked for completeness by our research assistants.

**Statistical analysis**

Comparison between ARc patients and healthy persons on the SF-36 questionnaire scores was made by an unpaired t-test and Chi-square test where applicable.

The internal consistency reliability of the questionnaire was analysed by Cronbach's alpha coefficient. The  $\alpha$  coefficient ranges from 0 to 1, and a coefficient of 0.70 was accepted as a standard of good internal consistency reliability.

For each of the eight dimensions, mean and standard deviation of the scores, the percentage of subjects scoring the minimum value (% Floor), and the percentage scoring the maximum value (% Ceiling) were calculated. The spread of scores was good when almost all of the scores are in the range from minimum to maximum values with low ceiling and floor effects.

This study was approved by the Ethical Clearance Committee on Human Rights relating 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".

**RESULTS**

A total of 705 healthy subjects and 900 ARc adult patients completed the SF-36 questionnaire (Thai version) from July 1999 to May 2002. Characteristics of the two groups of subjects are shown in Table 1. The mean age of healthy persons was significantly lower than that of ARc patients ( $25.3 \pm 8.9$  vs  $34.8 \pm 12.5$ ) because most of the healthy subjects were university students.

The male-to-female ratio was also significantly different in both groups. The preponderance for females was a typical finding for ARc.

Table 1. Characteristics of healthy subjects (n=705) and ARc patients (n=900).

	Healthy subjects		ARc patients	
	n	%	n	%
Total = 1,605	705	43.9	900	56.1
Age (year) mean (s.d.)	25.3 (8.9)		34.2 (12.5)	
20	209	29.6	104	11.6
20-30	320	45.4	264	29.3
31-40	79	11.2	256	28.4
41-50	23	3.3	171	19.0
51-60	12	1.7	72	8.0
61-70	2	0.3	22	2.4
>70	60	8.5	9	1.0
Sex				
male	161	23.2	327	36.4
female	532	76.8	571	63.6

ARc = allergic rhinoconjunctivitis

A very low missing item (0.5 item/questionnaire) was observed in both groups. ARc patients took longer time to fill in the questionnaire than healthy persons averaging 9 vs 6 minutes respectively.

The average score for each dimension of the two groups is shown in Figure 1.

The mean difference of the scores between healthy persons and ARc patients in each dimension indicates that the scores in the healthy group were higher than those in the ARc group. This difference was statistically significant ( $p < 0.05$  and  $p < 0.001$ ) for all dimensions, except for the Social Functioning dimension.

The scores of healthy male subjects were significantly higher than those found in female subjects for the Physical

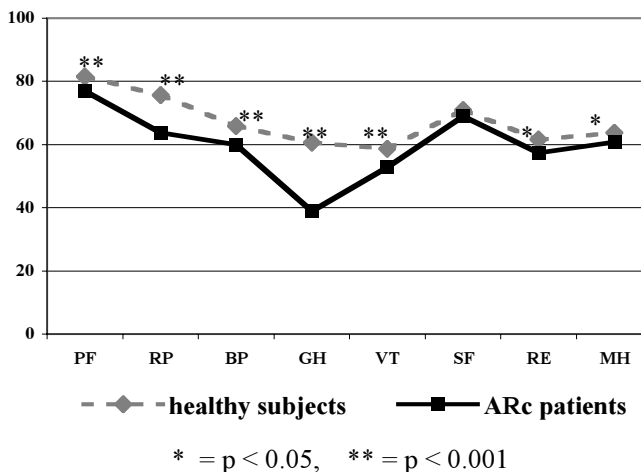


Figure 1. Mean SF-36 scores of each dimension of healthy subjects (n = 705) and ARc patients (n = 900) (high score indicates better health status).

- ARc = allergic rhinoconjunctivitis
- SF-36 = Short Form-36 questionnaire
- PF = Physical Functioning
- RP = Role-Physical
- BP = Bodily Pain
- GH = General Health
- VT = Vitality
- SF = Social Functioning
- RE = Role-Emotional
- MH = Mental Health

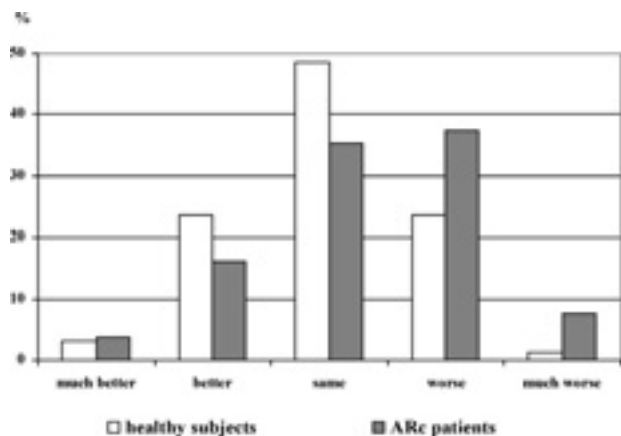


Figure 2. Percent of healthy subjects and ARc patients indicating their health status compared with last year.

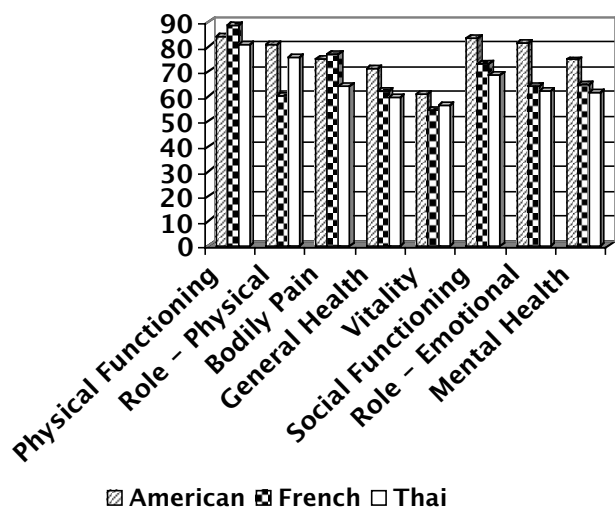


Figure 3. Mean SF-36 scores in each dimension of healthy people compared between American, French and Thai. (high score indicates better health status).

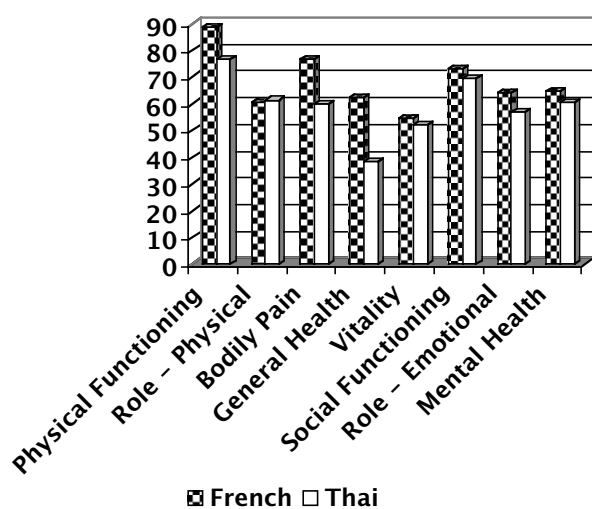


Figure 4. Mean SF-36 scores in each dimension of ARc patients compared between French (n=115) and Thai (n = 559).

Functioning ( $84.99 \pm 14.60$  vs  $80.48 \pm 13.26$ ,  $p < 0.001$ ), Bodily Pain ( $70.54 \pm 20.58$  vs  $64.53 \pm 16.96$ ,  $p < 0.001$ ) and Vitality dimensions ( $60.74 \pm 16.60$  vs  $57.90 \pm 14.45$ ,  $p < 0.05$ ).

In the ARc group, Physical Functioning ( $80.80 \pm 18.47$  vs  $74.89 \pm 19.06$ ,  $p < 0.001$ ), Bodily Pain ( $63.25 \pm 21.95$  vs  $58.11 \pm 22.46$ ,  $p < 0.01$ ), General Health ( $43.21 \pm 20.17$  vs  $36.52 \pm 19.03$ ,  $p < 0.001$ ) and Vitality ( $54.51 \pm 17.06$  vs  $51.73 \pm 17.53$ ,  $p < 0.05$ ) were more impaired for females than for males. With regard to the question about change in health, 45% of ARc patients indicated that their general health now was worse or much worse than last year compared as to 24.9% in the healthy subjects who indicated the same. When tested by Chi-square test, the difference between healthy and ARc groups was significant at  $p$  value  $< 0.001$ . The distribution of health transition reported by healthy persons and ARc patients is shown in Figure 2.

The internal reliability of the SF-36 questionnaire in both groups was analysed and found that the  $\alpha$ -coefficient of Cronbach was higher than 0.70 in all dimensions except for the Social Functioning dimension. The percentage of patients with a maximum score (% Ceiling different from 0) was low ( $< 20\%$ ) with the exception of the concepts of Role-Physical (43%) and Role-Emotional (43.5%). The percentage of patients with a minimum score (% Floor different from 0) was also low ( $< 20\%$ ) for all dimensions except in the Role-Emotional dimension (27.9%).

DISCUSSION

The results of this study, using the SF-36 questionnaire (Thai version) which is the frequently used generic questionnaire, clearly show that ARc patients have poorer QOL than healthy subjects. This finding is in accordance with a similar study in French people [1,2] which used the SF-36 questionnaire (French version), and thus confirms that the SF-36 questionnaire (Thai version) has satisfactory discriminative properties and is sensitive enough to discriminate ARc patients with mild to moderate symptoms from healthy subjects. Furthermore, our male subjects showed higher scores (better health) than female subjects in several dimensions as was also mentioned in another study [11].

The internal reliability of this questionnaire was also confirmed by the Cronbach's  $\alpha$ -coefficient which was above 0.70 for seven of the eight dimensions, the Social Functioning dimension being the exception, which was 0.65 for ARc group and 0.56 for healthy group. The Social Functioning dimension is also the only dimension in which the SF-36 QOL score is not significant different between the ARc and the healthy groups.

The advantage of using the same questionnaire translated into different languages in any survey is that it is possible to compare the QOL of people in various countries as measured with the same standard instrument. For example, health-related QOL scores of healthy American [12], French [1,2] and Thai people (this study) measured by the same instrument (the SF-36 questionnaire) were compared and shown in Figure 3. The health-related QOL comparison of French and Thai ARc patients measured by the SF-36 questionnaire is presented in Figure 4. The differences of the SF-36 scores seen in both fig-

ures were mostly attributed to differences in race, culture, environment and socioeconomic status of the people in each country. This finding may indicate a drawback in using the same questionnaire worldwide and the results should be interpreted with care.

As already known, one of the advantages of the generic questionnaire is that it can be used to compare the burden of illness of different diseases or different disease stages. In this case, we have compared the SF-36 scores of a group of ARc and hypertensive patients (unpublished data).

This is a preliminary attempt and is presented in Figure 5. It is surprising to see that ARc patients have significantly poorer QOL than hypertensive patients in four of the eight dimensions (General Health, Vitality, Social-Functioning and Mental Health). This is in contrast to our expectation that hypertension should have a greater impact on the QOL of the patients. However, Dereby and Berliner [11] also observed the same findings when they compared the SF-36 questionnaire scores of the allergy group with the scores of people with five other significant medical conditions (hypertension, congestive heart failure, diabetes type II, recent acute myocardial infarction and clinical depression).

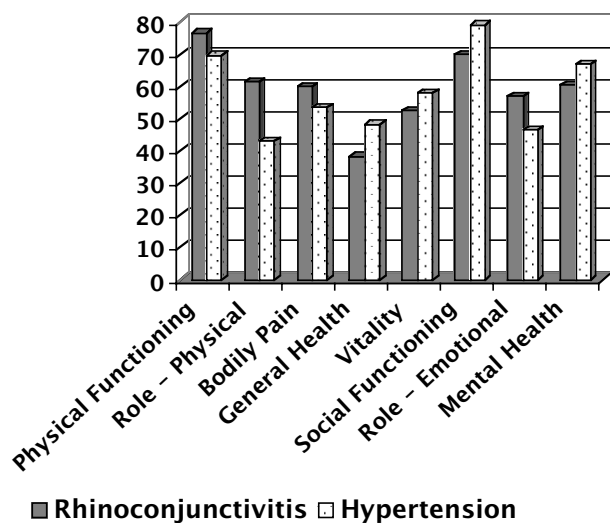


Figure 5. Comparison of the mean SF-36 scores in each dimension between ARc patients (n = 559) and hypertensive patients (n = 155).

The importance of evaluating health-related QOL in a non-life threatening disease such as ARc is now gradually accepted as part of the outcome assessment of the medical and/or surgical interventions and can be used to guide patient management and reimbursement decisions for other more serious diseases [11,13,14].

It is now generally recommended to use a health-related QOL assessment in parallel with conventional physiological outcome measures. For this reason, a disease-specific questionnaire may have a higher evaluative property than a generic questionnaire and thus would be a more desirable instrument to use in assessing more precisely the changes of QOL scores

after therapeutic intervention [15]. However, while a disease-specific questionnaire for ARc is being developed in the Thai language, the SF-36 questionnaire can be a good alternative. In the future, when the Rhinoconjunctivitis QOL questionnaire in Thai has been validated and available for general use, the SF-36 questionnaire can still be used as a supplement to assess the overall health-related QOL in ARc patients.

In conclusion, this study has confirmed that the SF-36 questionnaire (Thai version), classified as a generic questionnaire, is sensitive enough to discriminate ARc patients from healthy persons with high reliability. QOL of ARc patients was significantly more impaired than healthy persons and hypertensive patients in several dimensions. These findings were similar to reports from other countries using the same instrument. The SF-36 questionnaire can be used to evaluate the impact of ARc on QOL and to evaluate the therapeutic outcome in Thai patients.

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