

Assessment of quality of life in patients with perennial allergic rhinitis with the French version of the SF-36 Health Status Questionnaire

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Background and aim: Perennial allergic rhinitis may impair social life. General scales of quality of life (QOL) are used to detect the importance of social life impairment, but the reliability and validity of QOL measures should be tested in patients with perennial allergic rhinitis. The extent to which QOL scores differ in patients with rhinitis and healthy subjects is unknown.

Methods: A cross-sectional study was carried out in 111 patients with moderate to severe perennial allergic rhinitis and 116 healthy subjects to assess the validity of a general QOL scale, the SF-36 Health Status Questionnaire. This scale is based on 36 items selected to represent nine health concepts (dimensions). The internal reliability of each dimension of the questionnaire was examined. The differences in QOL scores between patients with rhinitis and healthy subjects were studied.

Results: Most QOL scores were highly reliable. There was a significant impairment in eight of nine QOL dimensions in patients with perennial allergic rhinitis in comparison with healthy subjects.

Conclusions: The SF-36 Health Status Questionnaire allows discrimination between patients with perennial allergic rhinitis and healthy subjects. (*J ALLERGY CLIN IMMUNOL* 1994;94:182-8.)

Key words: Perennial allergic rhinitis, quality of life, social life, SF-36 questionnaire

Perennial allergic rhinitis is a disease that appears to cause variable restrictions on the physical, psychologic, and social aspects of the life of patients, as well as having an impact on their work functions. However, the exact impact of this disease on health-related quality of life (QOL) is unknown.

Although this is the first report of QOL impairment in perennial allergic rhinitis in which a standardized instrument was used, other tech-

Abbreviations used

QOL: Quality of life
SF-36: Short Form Health Survey

niques have been used to assess impairment for disease-specific instrument development.^{1, 2}

QOL is a concept including a large set of physical, psychologic, social, and functional aspects of a healthy or ill person's life.³ QOL scales should adhere to psychometric standards of reliability, and validity, but they should also be simple and easy to use. They can be either generic or specific. Generic scales are usually applicable to the general population, independent of health status (i.e., they can be used for any health condition), and are used to evaluate the population's "well-being." They are not specially designed (e.g., for patients with rhinitis) or specific to a particular group.¹ Several generic health status scales have been developed such as the

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Sickness Impact Profile with 136 items,⁴ the Nottingham Health Profile with 45 items,⁵ and the Medical Outcomes Study Short-Form Health Survey (SF-36) with 36 items.⁶⁻⁸ The SF-36 Health Status Questionnaire appears to be an appropriate measure of QOL because it is based on 36 questions selected to represent nine health concepts (physical and social functioning, role limitations in physical and emotional problems, mental health, energy/fatigue, pain, general perception of health, and change of health). It is widely used and validated.⁹⁻¹¹ Generic health measures are standardized and validated for different health conditions and make it possible to compare healthy subjects and patients.^{12, 13} Furthermore, if they are sensitive enough to changes in health condition, they may allow direct comparisons of efficacy among therapeutic interventions. Because, to our knowledge, there is no generic scale of QOL that has been validated in perennial allergic rhinitis, the SF-36 was chosen as a measure in this disease.

The aims of this study were: (1) to verify that the SF-36, a generic health scale, was sensitive enough to detect the QOL impairments of patients affected by perennial allergic rhinitis and selected only on the severity of their clinical symptoms, (2) to evaluate the discriminant power of this generic health scale in patients with perennial allergic rhinitis compared with healthy subjects, and (3) to assess the internal reliability of this questionnaire in the group of patients with rhinitis by using the α -coefficient of Cronbach.¹⁴

METHODS

Patients

One hundred eleven patients of both sexes with perennial allergic rhinitis, ranging in age from 18 to 50 years (mean $\pm$ SD: 31.5 $\pm$ 8.8 years), were recruited for the study by 11 allergists and five ear, nose, and throat doctors. To be included, patients had to show clinical evidence of perennial allergic rhinitis, which was investigated through suggestive symptoms (runny nose, itchy nose, sneezing, stuffy nose).

The clinical severity of these symptoms was scored on a 5-point scale ranging from no symptoms to severe symptoms (Table I). Only patients with at least two symptoms scored as moderately severe or severe and persisting for more than 1 week were included (scores greater than or equal to 3 for at least two symptoms of rhinitis). Allergy was diagnosed by a suggestive history of perennial allergy and the presence of serum-specific IgE against house dust mites (*Dermatophagoides pteronyssinus*) and/or animal danders as determined by RAST (Pharmacia AB, Uppsala, Sweden). Only pa-

TABLE I. Scoring system for symptoms of rhinitis

Scoring	Definition
0	No symptom
1	Mild symptoms without discomfort
2	Moderate symptoms with discomfort but without impairment of daily activities
3	Moderately severe symptoms with impairment in daily activities (e.g., teacher with rhinorrhea; garage mechanic with nasal pruritus)
4	Severe symptoms inducing a severe impairment in daily activities and/or sleep (e.g., switchboard operator with a severe sneezing; severe nasal obstructions impairing sleep)

tients with a diagnosis of rhinitis known for more than 1 year were included.

One hundred sixteen healthy volunteers of both sexes, ranging in age from 18 to 50 years (mean $\pm$ SD: 30.6 $\pm$ 3.4 years), were recruited by six occupational doctors as a control group. To be included, volunteers had to be in good health (no symptom of rhinitis, not affected by a disease, not under treatment that might have affected their QOL).

Healthy subjects and patients with rhinitis were excluded if: (1) they did not understand the tasks to be performed, (2) they did not speak French fluently, or (3) they had recently experienced a major event that might have impaired QOL (e.g., death of a relative, work cessation).

QOL questionnaire

The SF-36 questionnaire was developed from the Medical Outcomes Study surveys.^{9, 10} It is standardized and composed of 36 items corresponding to nine health concepts, which assess three major health attributes (functional status, well-being, and overall evaluation of health) (Table II).⁶ The questionnaire can be completed by most persons in less than 15 minutes, and it has been validated and found to be reliable in several patient populations.¹¹ Moreover, it has been translated and is currently psychometrically tested in various languages, making it possible to use it in different countries.¹⁵

The SF-36 questionnaire was given by the investigators to both healthy subjects and patients after demographic data, details of medical history, and current treatments were recorded. Healthy subjects and patients had to fill in the questionnaire on their own at home on the day of the visit to the investigator and return it by mail (pre stamped, preaddressed envelopes).

The scoring system of the SF-36 was analyzed with the recommended two-step method. The first step in-

TABLE II. Definition of health concepts with the SF-36 questionnaire

Measure	Number of items	Definition
Functional status		
1. Physical functioning	10	Extent to which health interferes with a variety of activities (e.g., sports, carrying groceries, climbing of stairs, and walking)
2. Social functioning	2	Extent to which health interferes with normal social activities (e.g., visiting with friends during past month)
3. Role limitations attributed to physical problems	4	Extent to which health interferes with usual daily activities (e.g., accomplished less than would like)
4. Role limitations attributed to emotional problems	3	Extent to which health interferes with usual daily social activities (e.g., accomplished less than would like)
Well-being		
5. Mental health	5	General mood or affect, including depression, anxiety, and psychologic well-being during the past month
6. Energy/fatigue	4	Tiredness, energy level
7. Pain	2	Extent of bodily pain in past 4 weeks
Overall evaluation of health		
8. General perception of health	5	Overall rating of current health in general
9. Change of health	1	Evolution of general perception of health

Adapted from Ware JE, Sherbourne CD. *Med Care* 1992;30:473-83.**TABLE III.** Characteristics of healthy subjects and patients with rhinitis

	Healthy subjects	Patients with rhinitis	p Value*
Population	116	111	
Sex			
Male (%)	48	41	
Female (%)	52	59	NS (chi square test)
Mean age (yr)	30.6	31.5	NS (Mann-Whitney)
Employment status			
Worker/employee (%)	69	43	
Executive	16	30	
Unemployed	16	27	<0.001 (chi square test)
Marital status			
Married (%)	53	61	
Single (%)	43	35	
Divorced/separated (%)	3	4	
Widowed (%)	1	0	NS (chi square test)
Ethnic group			
White (%)	95	96	NS (chi square test)
Other (%)	5	4	
Level of education			
Primary school (%)	45	23	
High school (%)	23	35	
Graduate (%)	32	42	<0.002 (chi square test)

NS, Not significant.

*Probability to observe such a distribution/difference under the null hypothesis.

volves the recoding of some items, and the second step combines the correctly coded items, providing a summary score for each of the nine health concepts. All of these concept subscales are converted into scores ranging from 0 to 100; a high score indicates a good health status.

Design of the study and statistical analysis

A cross-sectional study was carried out from October 1991 to January 1992 in patients with perennial allergic rhinitis and in healthy subjects. The discriminative power of the questionnaire between both groups was studied. Each of the nine scores of the questionnaire

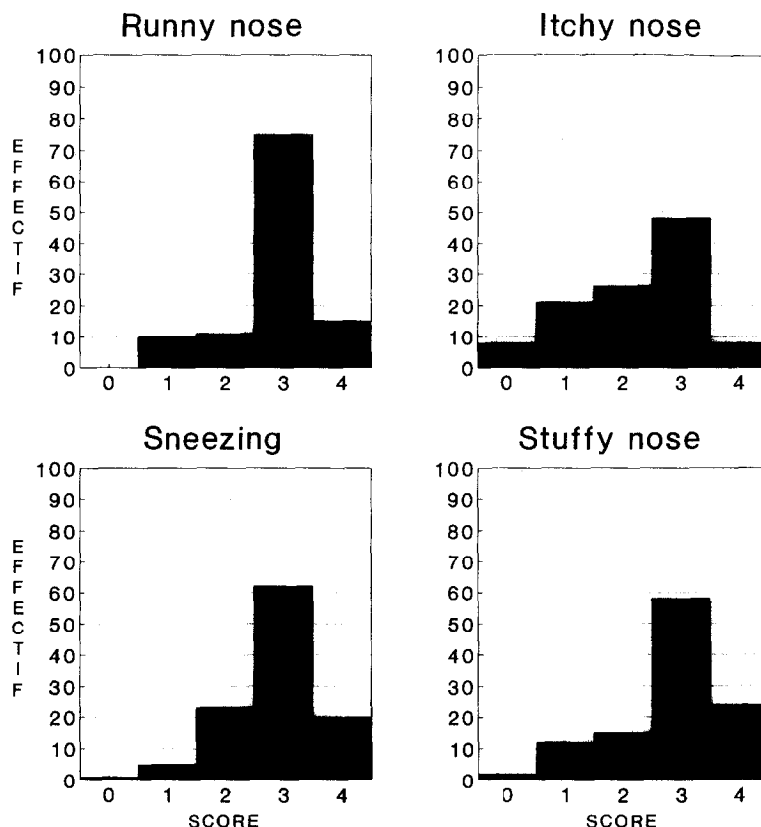


FIG. 1. Distribution of scores for four rhinitis symptoms (patients with rhinitis). 0 = no symptom; 1 = mild symptoms; 2 = moderate symptoms; 3 = moderately severe symptoms; 4 = severe symptoms. For exact definitions see Table I.

observed for each group was compared with nonparametric tests (Mann-Whitney test). In view of the number of variables measured and possible comparisons that could be made from them, a conservative significance level was established; that is, a null hypothesis associated with a p value was rejected if the p value was less than 0.006 (Bonferroni's correction).

Internal reliability. For patients with rhinitis, the internal reliability of the questionnaire¹⁶ was examined by using the internal consistency coefficient α of Cronbach.¹⁴ This coefficient ranges from 0 to 1, and a minimum coefficient of 0.70 is recommended to ensure a good internal reliability.

Floor and ceiling. In the patients' group, for each of the nine concepts, mean and standard deviation of the scales, the percentage of patients scoring the minimum value (% Floor), and the percentage scoring the maximum value (% Ceiling) were computed. The spread of scales is good when, for each concept, almost all of the score values are covered from minimum to maximum values with low ceiling and floor effects.

Transformation of the scores. To compare patients with rhinitis with healthy subjects more easily, scores for each of the nine concepts were transformed by means of z transformation. The difference between mean score for patients with rhinitis and mean score for

healthy subjects was divided by the standard deviation observed for the total population. Scores for healthy subjects were set to reference level 0.

RESULTS

Characteristics of the subjects

The demographic characteristics of healthy subjects and patients with rhinitis are shown in Table III. Although the mean ages and the male-to-female ratio were similar in both groups, the patients with rhinitis were significantly more educated than the healthy subjects. The duration of rhinitis ranged from 1 to 25 years (mean $\pm$ SD: 7.74 ± 5.78 years). The distribution of scores for each of the four rhinitis symptoms evaluated is presented in Fig. 1. In the rhinitis group 44% of the patients were receiving treatments for their symptoms at the time of inclusion; 5% also had asthma.

Acceptability of the questionnaire and missing data

The percentage of questionnaires received was 91.35% in the patient group and 88.6% in the

TABLE IV. QOL scores and distribution

	Mean	SD	Q1	Median	Q3	p Value*
Physical functioning						
Healthy	95.88	6.21	92.5	97.5	100	<0.0001
Patient	88.56	13.61	85	92.5	97.5	
Energy/fatigue						
Healthy	71.94	14.65	62.5	75	85	<0.0001
Patient	54.55	24.38	35	60	75	
General health perception						
Healthy	81.72	11.86	77	82	92	<0.0001
Patient	62.41	20.55	45	67	77	
Social functioning						
Healthy	91.30	13.26	87.5	100	100	<0.0001
Patient	73.09	23.61	50	75	100	
Role limitations—physical						
Healthy	92.03	17.63	100	100	100	<0.0001
Patient	60.59	37.77	25	75	100	
Role limitations—emotional						
Healthy	86.67	22.86	66.67	100	100	<0.0001
Patient	64.24	38.77	33.33	66.67	100	
Mental health						
Healthy	73.41	16.15	64	76	88	=0.0005
Patient	64.79	20.38	48	64	80	
Pain						
Healthy	90.32	16.67	84	100	100	<0.0001
Patient	76.90	26.04	62	84	100	
Change in health						
Healthy	54.09	13.97	50	50	50	=0.177
Patient	49.77	19.51	50	50	50	

Q1, First quartile; Q3, third quartile.

*As determined by Mann-Whitney test.

healthy group. A very low missing item rate was observed, ranging from 0.52% per patient to 0.31% per healthy subject. Missing data were not restricted to several specific items but randomly spread out over all the items.

SF-36 scores in patients with rhinitis and healthy subjects

The scores of the nine dimensions are presented in Table IV. For each of the QOL concepts, the scores observed in the rhinitis group are lower than those in the healthy group. This difference is statistically very significant ($p < 0.001$) for eight of nine concepts.

To compare patients and subjects more easily, z transformation has been applied to the patients' scores. Health profiles for patients with rhinitis and healthy subjects (baseline) are compared in Fig. 2. ("Change in Health" has been omitted in this figure because this concept is not significantly different in patients with rhinitis and healthy subjects.)

Internal reliability and floor/ceiling effects of the questionnaire for the rhinitis group

The internal reliability of the questionnaire in the rhinitis group is presented in Table V. The α -coefficient of Cronbach ranged from 0.77 to 0.91.

From Table V, it can be seen that for each concept, there are some patients with a maximum score (% Ceiling different from 0). This percentage of patients with a maximum score is low ($<20\%$) except in the concepts of social functioning (27.5%), role limitations—physical (36.7%), role limitations—(46.8%), and pain (43.1%). This indicates that a substantial percentage of the sample reaches high function levels in the above subscales. The percentage of patients with a minimum score (% Floor different from 0) is very low ($<20\%$) for all concepts, and for six of them the minimum score is not reached.

DISCUSSION

The results of this study show that the SF-36 questionnaire, a generic health-related QOL

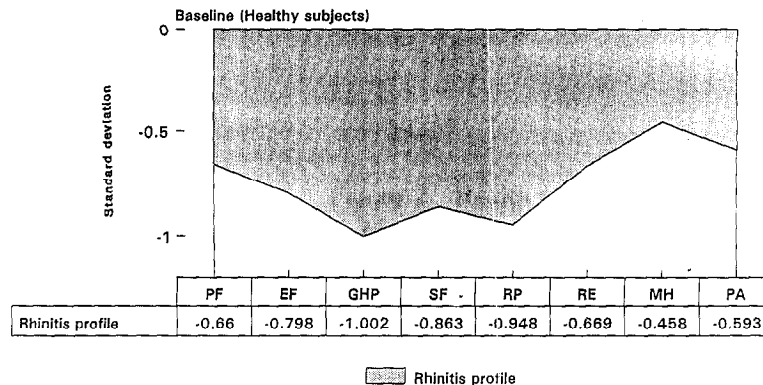


FIG. 2. Health profile for patients with rhinitis. *PF*, Physical functioning; *EF*, energy/fatigue; *GHP*, general perception of health; *SF*, social functioning; *RP*, role limitations attributed to physical problems; *RE*, role limitations attributed to emotional problems; *MH*, mental health; *PA*, pain.

scale, is sensitive enough to detect the impairments of patients affected by perennial allergic rhinitis in their daily activities and that this questionnaire is reliable in this population. Moreover, this study shows for the first time that perennial allergic rhinitis impairs the QOL of patients with moderate to severe rhinitis compared with healthy subjects.

QOL scales can be divided into generic scales, making it possible to compare patients who have any disease with healthy subjects, and into disease-specific scales, which may have a higher probability of detecting interventional risks in clinical trials.^{1, 2} Although it is important to assess precisely the change of QOL with scores adapted to a specific disease during clinical trials, it may be equally important to find out whether a therapeutic intervention may improve QOL in such a way that the patient may recover a normal social life. Thus QOL studies combining a general scale with disease-specific scales would be favored. This is one of the advantages of SF-36 because it may be used as part of an overall outcome assessment system to which disease-specific instruments more specific to rhinitis may be added. The SF-36 QOL score is widely used throughout the world and is already validated for healthy subjects and for patients with a variety of chronic diseases.^{9, 13, 17} Although its superiority over generic scores of QOL such as the Sickness Impact Profile⁴ or the Nottingham Health Profile⁵ was not tested, we decided to use the SF-36 for the following reasons: (1) the questionnaire was translated into French with the quality of the translation assessed, (2) it is simple, easy to use, and can be completed in about 15 minutes, (3) it can be self-administered, (4) its reliability has been ex-

TABLE V. Internal reliability and spectrum of sensibility in patients with rhinitis

	α -Cronbach	% Floor	% Ceiling
Physical functioning	0.90	0	18.3
Energy/fatigue	0.91	0	2.8
General health perception	0.78	0	0.9
Social functioning	0.80	0	27.5
Role limitations – physical	0.79	16.5	36.7
Role limitations – emotional	0.77	17.4	46.8
Mental health	0.84	0	3.7
Pain	0.89	0	43.1
Change in health	ND	3.7	4.6

ND, Not done.

amined,⁶ (5) it may be used as part of an overall outcome assessment system that may include additional disease-specific scales more pertinent to rhinitis, and (6) its spectrum of responsiveness is wider than that of the Nottingham Health Profile.

The results of this study show in the group of patients with rhinitis a high internal reliability of the questionnaire with the α -coefficient of Cronbach always ranging above 0.70; this indicates that the scores of the questionnaire may be used to reliably assess the QOL of such patients. These results are in agreement with those of a previous study in asthma in which coefficient of α -Cronbach was found to be similar for eight of the concepts of the SF-36.¹⁸

In this study each of the nine scores of the SF-36 questionnaire observed for the patients with rhinitis is reasonably distributed over all the

possible values; mean SF-36 scores never reached, for each concept, the maximum value of 100 in patients with rhinitis nor in healthy subjects. Mean SF-36 scores were, for each concept, lower in patients with rhinitis than in healthy subjects. This difference is significant for eight of nine concepts of the SF-36. QOL scores can thus discriminate patients with moderate to severe perennial rhinitis from healthy subjects.

Attempts were made to examine the discriminative properties of the SF-36 with respect to the severity of rhinitis (four symptoms scored on a 5-point scale). Such properties, to be interpreted correctly, need more data and a more diverse patient population not restricted to subjects with moderate or severe rhinitis.

This study demonstrates the discriminative properties of the SF-36 in perennial allergic rhinitis and suggests use of this questionnaire in clinical trials to evaluate the effect of therapeutic intervention on the QOL of patients affected by this disease. However, to use it in clinical trials, this instrument must be responsive enough to within-patient change over time. Further data are needed for this purpose.

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