Quality of life in nasal polyposis

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Background: Nasal polyposis (NP) is a frequent inflammatory chronic disease of the upper respiratory tract, which may impair quality of life (QOL). The NP impact, which is frequently associated with lower respiratory disorders, has never before been studied.
Objective: We initiated this prospective study to establish internal validity and reliability of the generic SF-36 questionnaire in NP and to determine to what level daily functioning becomes impaired as a result of NP.
Methods: Forty-nine consecutive patients with NP were included. They were assessed for the severity of nasal symptoms and underwent pulmonary function tests. The QOL profiles in patients with NP were compared with those of patients with perennial rhinitis (n = 111) and healthy subjects (n = 116).
Results: Cronbach's coefficient α demonstrated the high reliability and validity of the SF-36 questionnaire for patients with NP (α = .89). NP impaired QOL more than perennial allergic rhinitis (P < .05). The impairment of QOL was greater when NP was associated with asthma (P < .05). SF-36 scores appeared highly correlated to pulmonary function (FEV_1, maximal midexpiratory flow, forced vital capacity), suggesting relationships between QOL in NP and associated bronchial obstruction. Severity of nasal symptoms were not related to QOL scales. In addition, sequential evaluations of QOL, nasal symptoms, and pulmonary function were performed 10 months after the first evaluation in 28 patients with NP. These evaluations demonstrated that NP treatment either with nasal steroids or endonasal ethmoidectomy significantly improved both nasal symptoms and QOL without significant change of pulmonary function.
Conclusion: Our study clearly demonstrated that the SF-36 questionnaire presented a high internal validity and reliability in patients with NP. NP impaired QOL to a greater degree than perennial allergic rhinitis. QOL improvement after NP treatment is related to nasal symptoms improvement. (J Allergy Clin Immunol 1999;103:79-84.)

Key words: *Nasal polyposis, quality of life, SF-36 questionnaire, perennial allergic rhinitis, asthma, endonasal ethmoidectomy*

Abbreviations used

BP:	Body pain
FEF_{25-75}:	Maximal midexpiratory flow
FVC:	Forced vital capacity
GH:	General perception of health
HT:	Health transition
MCS:	Mental component summary
MH:	Mental health
NP:	Nasal polyposis
PAR:	Perennial allergic rhinitis
PCS:	Physical component summary
PF:	Physical functioning
QOL:	Quality of life
RE:	Role limitation caused by emotional problems
RP:	Role limitation caused by physical problems
SF:	Social functioning
VT:	Vitality

Nasal polyposis (NP) is a chronic inflammatory disease of the nasal mucosa, leading to a protrusion of edematous polyps in nasal and paranasal cavities. Like perennial allergic rhinitis (PAR), NP causes nasal symptoms, such as nasal obstruction, anosmia, sneezing, rhinorrhea, and itching. Patients are also bothered by sleep disorders, headaches, and irritability. Furthermore, NP can take part in different syndromes or diseases, including asthma or cystic fibrosis.[1,2] For NP, like PAR, mortality is nonexistent, and repercussions over time are limited. However, patients with NP experience disabilities in their daily activities, possibly as a consequence of their nasal symptoms. Therefore improving patient well-being or quality of life (QOL) is the primary goal of NP treatment.

There is increasing recognition that measures of health-related QOL provide unique information about the impact of an illness and its treatment. Correlations between markers of nasal inflammation and the patient measures of QOL are weak to moderate.[3] In this context measures of QOL provide information that is more meaningful than that obtained by using conventional medical indices. Therefore assessment of QOL in clinical practice is an additional parameter that may be used to evaluate the effectiveness of various treatments.

Assessment of QOL can be performed by using 2 types of questionnaires. First, there are questionnaires that are specific for a group of patients, a particular function (eg, pain), or a disease. Second, there are generic questionnaires that are designed to be applicable to patients of any health status. The most commonly used

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TABLE I. Characteristics of 49 patients with NP

Mean age (y)	42 ± 1.8
Sex (M/F)	25/24
Nasal score*	7.3 ± 0.4
Duration of nasal symptoms (y)	10.8 ± 1.4
Asthma†	23 (47)
Aspirin intolerance†	5 (10)
FEV_1 (mL)	3077 ± 125
FEV_1 (%)	92 ± 2.6
FVC (mL)	4084 ± 128
FVC (%)	103 ± 2.1
FEF_{25-75} (mL/sec)	2909 ± 212
FEF_{25-75} (%)	71 ± 4.2

Values are expressed as means ± SEM where applicable.
*Nasal score represents severity of nasal symptoms. It is the sum of scores for itching, anosmia, rhinorrhea, sneezing, and nasal obstruction. Each symptom is scored from 0 to 3 (0, no symptom; 1, mild symptom; 2, moderate symptom; and 3, severe symptom), and the maximum nasal score is 15.
†Results are expressed as number of patients (percentage).

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

Items	No. of questions	Definition
Functional status		
PF	10	Interference with some physical daily activities (eg, sports, carrying groceries, climbing of stairs, and walking)
SF	2	Interference with normal social activities (eg, visiting friends during past month)
RP	4	Interference with usual daily activities (eg, accomplished less than would like)
RE	3	Interference with usual daily social activities (eg, accomplished less than would like)
Well-being		
MH	5	General mood: depression, anxiety and psychologic well-being during the past month
VT	4	Tiredness, energy level
BP	2	Bodily pain in the past month
Overall evaluation of health		
GH	5	Overall rating of current health in general
HT	1	Evolution of general perception of health during the past year

Modified from Ware JE, Sherbourne CD. *Med Care* 1992;30:473-83.

are the Sickness Impact Profile,[4] the Nottingham Health Profile,[5] and the SF-36.[6-8] These generic questionnaires allow comparisons of the relative burden of different diseases. For instance, the effects of illness experienced by patients with rhinitis can be compared with those of patients with asthma or even healthy subjects. These generic questionnaires assess the main concepts of health-related QOL: mental health, physical and social activities, functional aspects, and general health perception. The SF-36 is a generic questionnaire that contains 36 questions. The SF-36 questionnaire was developed from psychometric analysis of scores obtained from a battery of questions answered by a cohort of patients (n >20,000) in the American general population in the Medical Outcome Study.

The SF-36 questionnaire was translated into several languages during the International Quality Of Life Assessment project to allow the use of the SF-36 in different countries, where it could be an index of health production.[7-10] The validity and the reliability of the SF-36 French version has been demonstrated in different chronic diseases.[11,12] PAR and asthma are associated with impaired QOL as compared with healthy subjects.[13,14] QOL impairment related to NP has never been studied.

The aims of our prospective study were to establish the internal validity and reliability of the SF-36 as applied to patients with NP, to determine the level of impairment in daily functioning as a result of NP, and to determine whether treatment produces an improvement.

METHODS

Patients and methods

Forty-nine consecutive patients with NP were included from October 1995 to June 1997. They were initially recruited during the first ear, nose, and throat examination for NP, which was performed as a result of nasal symptoms and their discomfort, and then examined by a pneumologist in an academic center. The mean age was 42 ± 12.4 years (range, 19 to 65 years), and there were 25 men and 24 women in the study population. Nasal polyps were identified in all patients by use of the following criteria: nasal symptoms (obstruction, anosmia, sneezing, rhinorrhea, and itching) and visualization of polyps by anterior rhinoscopy. Each nasal symptom was scored from 0 to 3: 0 for no symptom, 1 for mild symptom (just noticeable), 2 for moderate symptom (annoying), and 3 for severe symptom (distress); the maximal nasal score was 15 of 15. Patients demonstrated nasal symptoms for 10 ± 8 months (range, 2 to 19 months). Characteristics of the patients are shown in Table I. They were not treated at the time of entry into the study. Patients with infectious sinusitis were excluded from the study.

Two others groups were studied as control groups[13]: 116 healthy volunteers and 111 patients with PAR. Healthy control subjects were of both sexes, ranging in age from 18 to 50 years (30.6 ± 8.4 years). Inclusion criteria included good health without symptoms of rhinitis, absence of disease, and lack of treatment that might have affected the QOL. One hundred eleven patients of both sexes with PAR were also recruited, ranging in age from 18 to 50 years (mean, 31.5 ± 8.8 years); 48% were men and 52% were women. To be included, patients had to present clinical evidence of nasal symptoms (runny nose, itchy nose, sneezing, and stuffy nose). The clinical severity of these symptoms was scored from 0 to 5 (“no symptom” to “severe symptom”). Only patients with at least 2 symptoms scored as moderately severe to severe were included. The allergic origin of rhinitis was recognized by a clinical history of perennial allergy and the presence of serum-specific IgE against house dust mites, animal dander, or both as determined by using the Phadebas RAST (Pharmacia Diagnostics, Fairfield, NJ). The diagnosis of allergic rhinitis had to be known for more than 1 year before inclusion.

Pulmonary evaluation

All 49 patients with NP underwent clinical evaluation for atopy, asthma history (as described by the American Thoracic Society criteria),[15] and aspirin intolerance. Medical treatment and previous history of nasal surgery were noted. Skin prick tests for common allergens (house dust mite, animal dander, grass pollens, and mold) were performed. Pulmonary function tests were performed, with all measurements made in the sitting position. FEV_1, forced vital capacity (FVC), and maximal midexpiratory flow (FEF_{25-75}) were obtained from flow-volume curves by using a Medgraphics spirometer (St Paul, Minn). The largest values of FVC, FEV_1, and FEF_{25-75} from the first 3 technically satisfactory forced expirations were selected. All data were expressed in absolute values and in percent of predicted normal values.[16]

QOL evaluation

All patients had to fill in the SF-36 questionnaire. The investigator left the patient alone during the response period and collected the filled questionnaire at the end of the consultation. This generic questionnaire contains 36 questions measuring 3 general notions of health-related QOL: functional status, well-being, and overall evaluation of health. Nine items are specified and shown in Table II. For each item, a score ranging from 0 to 100 was calculated. Greatest is the score, best is QOL for the item. The scales are scored in 3 steps according to the standard SF-36 scoring algorithms established by J. E. Ware and coworkers as part of the Medical Outcomes Study.[17,18] First, the scores are coded from the patient's responses and then summed and transformed. Each SF-36 scale is standardized with transformation by using the SF-36 scales means and SDs obtained from the general US population. There is no global scale for the whole questionnaire, but 2 summary scales can be defined. These summary scales are the physical component summary (PCS) and the mental component summary (MCS), which represent, respectively, physical health and mental health and range from 0 to 100. PCS and MCS are obtained from the 8-item scales (excluding health transition [HT]). PCS highly correlates with physical functioning (PF), role limitation caused by physical problems (RP), body pain (BP), and general perception of health (GH); MCS highly correlates with vitality (VT), social functioning (SF), role limitation caused by emotional problems (RE), and mental health (MH). HT is a particular item composed of only 1 question, which is more difficult to interpret and analyze and does not count for scoring the PCS and MCS.[18]

Procedure

In our prospective study clinical nasal scores and QOL SF-36 scores were calculated at first evaluation. At the same time, the pulmonary evaluation was performed (evaluation for atopy, asthma history, and skin prick test responses) for the 49 patients with NP. Then a medical treatment with intranasal steroids (beclomethasone, 600 μg/day) was initiated. Clinical nasal scores were reevaluated after a 6-week treatment for all patients; medical treatment was judged successful if the nasal score decreased by more than 4 of 15 points. If the medical treatment was successful, it was continued. In case of no clinical improvement (no response to topical steroids), surgery was undertaken (intranasal ethmoidectomy) followed by 8 days of treatment with oral steroids. Topical steroids were continued after surgery to prevent nasal polyp recurrence.

A sequential evaluation (T2) was performed within 10 months (range, 2 to 19 months) after the first evaluation (T1) in 28 of the 49 patients with NP, including evaluation of QOL, nasal score, and pulmonary parameters. In this group of 28 patients, 14 were treated with topical steroids (responders) and 14 were treated with topical steroids and surgery (nonresponders).

TABLE III. Coefficient α of Cronbach consistency according to the SF-36 scales in NP

Items	α
PF	.89
RP	.88
RE	.87
SF	.88
MH	.88
VT	.87
BP	.88
GH	.88
SF-36	.89

The minimal value needed to prove good validity and reliability in the psychosocial domain is an α value of .7.

Statistical analysis

Statistical analysis was performed by using the SAS Logiciel.

Internal validity and reliability of the SF-36 questionnaire. The scores of the 8 items of QOL, PCS, and MCS (HT excluded) were determined according to the recommendations of the American authors in 3 steps.[17,18] The results were expressed as means and SDs. Lower scores of the SF-36 reflected poorer health.

For patients with NP, the internal validity and reliability of the SF-36 questionnaire was examined by using the internal consistency coefficient α of Cronbach.[19] This coefficient ranges from 0 to 1, and a minimum coefficient of 0.7 is required to ensure a good internal validity.[20] The coefficient α allows verification that the questionnaire really measures what it is supposed to measure so that scores of QOL are reliable and interpretable. It cannot be calculated for items composed of only 1 question, such as HT, and therefore it was determined for 8 of 9 items (PF, RP, RE, SF, MH, VT, GH, and BP).[12]

Between-group comparisons and sequential comparisons. Three groups were compared: group 1, healthy volunteers (n = 116); group 2, patients with PAR (n = 111); and group 3, patients with NP (n = 49). The Kruskall-Wallis ANOVA was applied first to the data of groups; when it was significant, each pairing was examined by means of the Mann-Whitney *U* test. Paired groups were compared by using the nonparametric Wilcoxon's test. A level of significance of .05 was used for all comparisons.

Correlation analysis. Correlation between scores of QOL and demographic characteristics (age and sex), nasal symptoms (nasal score), and pulmonary function test results (FEV_1, FVC, and FEF_{25-75}) were assessed by using Pearson's coefficient correlation test.

RESULTS

Internal validity and reliability of the SF-36 questionnaire

Table III displays the consistency coefficient α of Cronbach determined for the 8 QOL items. All obtained data were higher than 0.7, demonstrating the high validity and reliability of the SF-36 questionnaire applied to patients with NP. For the whole questionnaire, the α value was 0.89.

QOL profile in patients with NP and between-group comparisons

The SF-36 scores are represented in Table IV. As previously published, for each of the items, the scores in PAR were significantly lower than those found in the

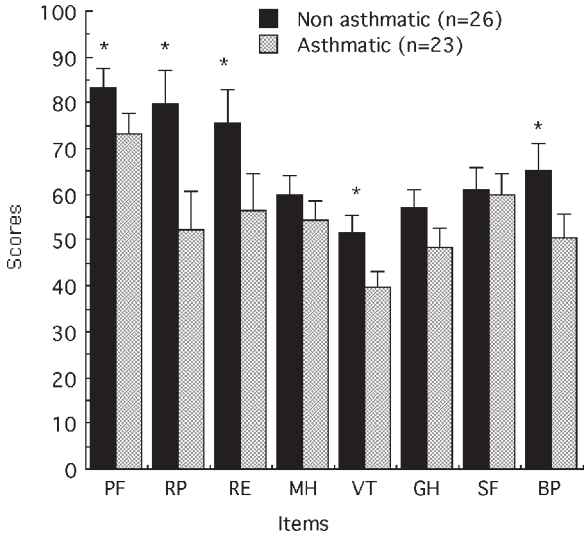

FIG 1. Comparison of SF-36 scores between asthmatic and nonasthmatic subjects with nasal polyposis. *Significantly different from asthmatic patients ($P < .05$). Data are represented as means ± SEM.

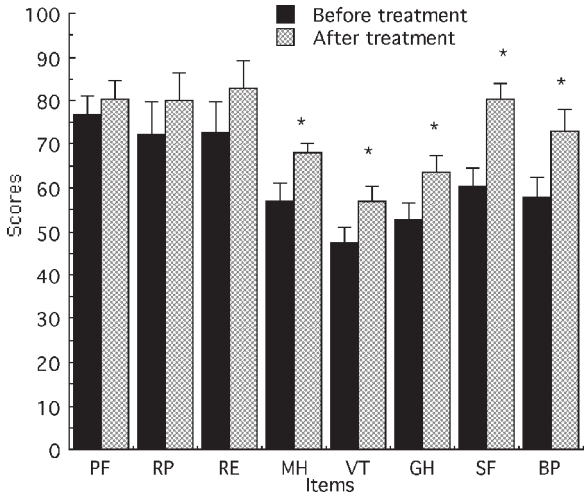

FIG 2. Sequential evaluation of QOL profile in 28 patients with nasal polyposis. Results are expressed as means ± SEM.

TABLE IV. SF-36 scores in healthy subjects, patients with PAR, and patients with NP

Items	Groups 1 (healthy)*	Group 2 (PAR)*	Group 3 (NP)*	*P* value (1-2)†	*P* value (1-3)†	*P* value (2-3)†
PF	95 ± 0.56	88 ± 1.23	78 ± 3.14	.0001	.0001	.0148
RP	92 ± 1.58	60 ± 3.60	67 ± 5.85	.0001	.0001	NS
RE	86 ± 2.13	64 ± 3.70	66 ± 5.43	.0001	.0001	NS
MH	73 ± 1.48	65 ± 1.90	57 ± 3	.0005	.0001	.0258
VT	72 ± 1.30	54 ± 2.28	46 ± 2.71	.0001	.0001	.0332
GH	82 ± 1.11	62 ± 1.90	53 ± 2.85	.0001	.0001	.0065
SF	91 ± 1.20	73 ± 2.18	60 ± 3.28	.0001	.0001	.0041
BP	90 ± 1.58	77 ± 2.47	58 ± 4	.0001	.0001	.0001

NS, Not significant.
P value (1-2), Statistical difference between healthy volunteers and patients with PAR; *P value (1-3),* statistical difference between healthy volunteers and patients with NP; *P value (2-3),* statistical difference between patients with PAR and patients with NP.
*All data are expressed as means ± SEM.
†As determined by the Mann-Whitney *U* test. Statistical significance, $P < .05$.

healthy volunteers.[13] For each of the QOL concepts, the scores observed in the NP group were significantly lower than those found in the healthy group ($P < .0001$). The scores of patients with NP were lower for PF, MH, VT, SF, GH, and BP than those observed for patients with PAR ($P < .05$), but not for RP and RE. In the NP group VT, BP, and GH displayed the lowest scores, meaning NP impaired vitality, pain, and general perception of health. The MCS (41 ± 10.3) was lower than the PCS (45.6 ± 9.2) in patients with NP, suggesting that NP impaired more mental health than physical health. Women experienced more pain than men ($P < .05$) and had a poorer general perception of health ($P < .05$). Daily physical activities were more impaired by NP for women than for men ($P < .05$).

Correlation analysis between SF-36 scores and characteristics of the patients with NP

There was a significant correlation between FEV_1 (expressed in percentage as well as in absolute values) and all the SF-36 scores in the NP group ($P < .05$). FEF_{25-75} and FVC positively correlated with most of the SF-36 scores. Age and nasal scores were not statistically related to SF-36 scores.

QOL scores in patients with NP according to existence of asthma are shown in Fig 1. PF, RP and RE, VT, and BP scores were significantly lower in asthmatic than in nonasthmatic subjects.

Sequential analysis of QOL

Treatment of NP significantly improved nasal symptom score in all patients (from 7 ± 0.6 at T1 to 4.8 ± 0.6 at T2). In contrast, results of pulmonary function tests did not significantly change between T1 and T2. FEV_1, FVC, and FEF_{25-75} values were 3233 mL, 4265 mL, and 3162 mL/sec at T1 and 3294 mL, 4199 mL, and 3123 mL/sec at T2, respectively.

All scores of QOL were higher at T2 compared with T1 (Fig 2), demonstrating that treatment of NP improved QOL. The difference between the 2 evaluations was sta-

tistically significant for the more altered parameters (MH, VT, GH, SF, and BP) for the 28 reviewed patients (14 responders and 14 nonresponders).

At T1, VT and BP scores in the 14 steroid nonresponders were significantly lower ($P < .05$) than in the 14 steroid responders. At T2, all scores were similar between responders and nonresponders.

DISCUSSION

Our prospective study showed that the SF-36 questionnaire, a generic health-related QOL scale, is capable of detecting impairment of daily activities in patients with NP and that this questionnaire is highly reliable in this population.

Validity and reliability are the main psychometric properties of QOL questionnaires required for their use and interpretation.[20] For the SF-36 questionnaire, we had to consider the 9 items and ensure that each of them really measured what it proposed to measure independently of the others. The questions measuring the same concept had to have approximately equal variance. The internal validity was reached by using the consistency coefficient α of Cronbach,[18,19] which is widely used and must be used when only one evaluation of QOL was performed for a specific population. Validity and reliability are considered acceptable for group comparison when coefficient α is higher than 0.7, which is the minimal value required for all studies in the psychosocial domain.[20] In our study α ranged above 0.7 for each item and even for the overall SF-36 questionnaire itself. Therefore we demonstrated the high validity and reliability of the SF-36 when used in a population of patients with NP. Further studies are needed to assess the external validity of the SF-36 questionnaire by using a test of reproducibility or a test-retest, which verifies the obtainment of the same scores of QOL at 2 different times in the same conditions, completing the demonstration of SF-36 reliability in patients with NP.

The SF-36 questionnaire was chosen to assess QOL in NP because it is simple, easy to use, and allows comparisons between different samples of patients. The questionnaire was translated into French, and the quality of translation has been assessed.[12] Its reliability and validity were examined in different chronic diseases[9,11,16] and also in asthma and PAR.[13,14] Therefore we could compare QOL in asthma, allergic rhinitis, and NP by using the SF-36 questionnaire.

Our study clearly demonstrated that NP impairs QOL, supporting the claims of patients with NP when they express their difficulties with daily activities. Comparison of QOL profile between PAR and NP showed that the impact of NP on life is globally more important than the impact of rhinitis. Only RE and RP, respectively representing limitations of working life caused by physical health status and mental health status, appeared to be not statistically different in both groups of patients. NP did not seem to involve more waste of working time or more significantly alter daily physical activities (RP) than PAR. NP and PAR involve the same nasal symptoms, but anosmia and nasal obstruction are greater in NP. The consequences of more anosmia and more nasal obstruction in NP could explain the differences of QOL scores between the 2 nasal inflammatory diseases. Indeed, headaches, snoring, and sleep disorders are caused by nasal obstruction[21] and could explain the highest score of BP and the poorer scores of VT and SF in patients with NP compared with patients with PAR.

Juniper[22,23] previously showed that in allergic rhinitis symptoms like irritability, sleep disorders, and poor concentration are the first of which patients with allergic rhinitis complain and that they correlate better than nasal symptoms themselves to QOL impairment. Furthermore, the patient complaints about those consequent symptoms change according to age. Adolescents experience more concentrating difficulties and overall problems with schoolwork. Adults complain more of anosmia, and younger children are bothered by practical problems, such as carrying tissues and taking medications, but do not express the emotional problems experienced by adults. Their parents seem to be much more bothered by the disease of their children than the children themselves.[22,23]

In our study the mean age in the NP group was 42 years, which is comparable to the mean age of NP occurrence in the general population. We were unable to demonstrate any correlation between age, nasal symptoms, and SF-36 scores. Specific QOL questionnaires used and created by Juniper[22-24] allowed her to establish those relations between age and rhinitis symptoms. Specific questionnaires are better than generic ones to determine the impact caused by a specific symptom on QOL.[24] The specific questionnaires focus on the experience of daily practical problems, such as carrying tissues, which reflect on rhinorrhea. Thus they are much more responsive to clinically important changes in QOL and related to a specific symptom. We did not use specific questionnaire in our study. This could explain why there is no established relation in our study between QOL scales and nasal symptoms (sneezing, runny nose, itchy nose, nasal obstruction, or anosmia). Other studies could be useful in associating the SF-36 generic QOL scale with a disease-specific questionnaire related to NP to define better clinical changes in terms of QOL, specifically regarding symptoms. To date, there is no disease-specific scale for NP. This one should precisely assess nasal symptoms and their severity and also assess their consequences, such as sleep disorders and practical problems like using and carrying tissues.

In our study pulmonary function highly correlated to SF-36 scores. In agreement with this correlation, these findings suggest that there is a relationship between QOL impairment and bronchial obstruction. Bousquet and coworkers[13,14] showed that the SF-36 was reliable and valid when used for the assessment of QOL impairment in subjects with moderate asthma. QOL in subjects with NP associated with asthma was worse than that found in subjects with NP but without asthma. QOL scores in

asthmatic patients without NP[13] are better than those of our patients with isolated NP, suggesting that NP impairs QOL to a higher degree than asthma. However, NP and asthma seem to have a cumulative negative effect on QOL. These findings suggest that associated NP in asthmatic patients and bronchial obstruction in patients with NP should be considered because these two factors may alter QOL. Improvement of QOL in patients with NP and asthma implies the need to treat both nasal and pulmonary symptoms. Efficacy of ethmoidectomy[25,26] or nasal corticotherapy[27,28] in patients with NP has been widely established regarding nasal symptom severity and recurrence, but it has never been shown to improve QOL.

Sequential analysis of the SF-36 scores showed that treatment of NP either by nasal steroids alone or nasal steroids associated with endonasal ethmoidectomy improved both QOL and nasal symptoms without significant change in pulmonary function, suggesting that improvement of QOL in treated NP was independent from the course of pulmonary function. In a previous study ethmoidectomy was associated with the occurrence of a minor bronchial obstruction long after surgery in steroid nonresponders, although it was not clinically noticeable.[29] In our study pulmonary function was not significantly different in the 2 evaluations, but the second evaluation was performed soon after surgery. Additional studies are needed to assess the course of bronchial obstruction and long-term QOL after surgery.

In conclusion, our study demonstrated that the SF-36 questionnaire presented a high internal validity and reliability when it was applied to patients with NP. NP impaired QOL to a higher degree than PAR. NP treatment either by nasal steroids or by nasal steroids associated with endonasal ethmoidectomy improved QOL. Although pulmonary function tests tended to decrease after ethmoidectomy, QOL improvement soon after NP treatment appeared to be predominantly related to nasal symptom improvement.

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