

Original article

Nasal polyposis and its impact on quality of life: comparison between the effects of medical and surgical treatments

Background: Nasal polyposis (NP) is not a life-threatening disorder but may have a great impact on the quality of life (QoL). The objective of this study: (i) to investigate the health burden incurred by NP compared with the Spanish general population using the Short Form-36 Health Survey (SF-36) questionnaire; (ii) to compare the QoL outcome after medical or surgical treatment; and (iii) to assess and compare the effect of medical and surgical treatment on nasal symptoms.

Methods: About 109 patients with nasal polyps were included. Fifty-three patients were randomly allocated to receive oral prednisone for 2 weeks and 56 to undergo endoscopic sinus surgery. All patients administered intranasal budesonide for 12 months. Patients were evaluated for nasal symptoms, polyp size, and QoL.

Results: In comparison with the Spanish general population, patients with NP had worse scores on all SF-36 domains except for physical functioning. Non-asthmatic patients with NP had better QoL than asthmatic patients with NP on role physical functioning, body pain, and vitality ($P < 0.05$). At 6 and 12 months, a significant improvement on all of SF-36 domains was observed after both medical and surgical treatment reaching the levels of general population ($P < 0.05$). Nasal symptoms and polyp size improved after both medical and surgical treatment at 6 and 12 months ($P < 0.05$).

Conclusion: These results suggest that NP has considerable impact on a patient's QoL and that both medical and surgical treatment led to similar effects in improving QoL.

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Key words: asthma; endoscopic sinus surgery; nasal polyposis; quality of life; steroids.

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Accepted for publication 29 July 2004

Nasal polyposis (NP) is a chronic inflammatory disease of the nasal and paranasal sinus mucosa that, despite different hypotheses of its cause, remains poorly understood (1). The NP is often associated with asthma and other respiratory diseases such as cystic fibrosis, primary ciliary dyskinesia, and aspirin sensitivity (2–4).

Primary symptoms of NP are nasal blockage, loss of smell, rhinorrhea, and sneezing. A global evaluation of nasal polyp patients must include, together with nasal endoscopy, nasal symptoms, and computed tomography (CT) scan, the measurement of quality of life (QoL) (5). To assess QoL, specific and generic questionnaires may be used. Specific instruments are restricted to a particular disease, a selected population, or a specific function or problem. Several specific questionnaires for patients with chronic sinusitis such as Rhinosinusitis Disability Index, Chronic Sinusitis Survey Score, and SinoNasal Outcome Test-16 have been developed (6). Recently, Baiardini

et al. (7) developed Rhinasthma a new specific QoL questionnaire for patients with rhinitis and asthma.

Generic questionnaires are applicable to all health conditions and they allow a comparison of QoL impact in different diseases as well as healthy and diseased subjects. One of the most widely used generic questionnaires is the Short Form-36 (SF-36) showing good reproducibility and validity (8–11).

The management of NP has been the topic of frequent controversial debates for many decades. Most authors agree on the fact that management of NP should be primarily based on a medical approach to be completed by surgical procedures only in the case of drug failure (12–15).

The aims of this study were: (i) to investigate the health burden incurred by NP compared with the Spanish general population using the SF-36; (ii) to assess and compare the effect of medical and surgical treatment on QoL; and (iii) to assess and compare the effect of medical and surgical treatment on nasal symptoms.

Methods

Study population

A total of 109 patients with massive NP [score 2 or 3 of Lildholdt classification (16)] were included in this prospective study from February 1999 to November 2002. The mean age was 50.1 ± 1.4 years (ranging from 22 to 84 years). Thirty-five patients (32%) were female and 74 (68%) were male (Table 1). Regarding age and gender, there were no differences between the medical and surgical treatment groups. All patients were examined and treated by the same otorhinolaryngologist for the whole duration of the study at the Departments of Otolaryngology of Hospital Clinic of Barcelona.

Inclusion and exclusion criteria

The diagnosis of NP was based on the following criteria: (i) visualization of polyps under endoscopic examination, and (ii) bilateral opacification of paranasal sinuses on CT scans (1, 17). Patients with inverted papiloma, antrochoanal polyps, cystic fibrosis, or cerebrospinal fluid fistula were excluded from the study. Patients with contraindications for treatment with oral steroids were also excluded. Approval for the study was obtained from the local Ethic's Committee of our institution and a signed informed consent was obtained from all patients.

Study design

After a 4-week washout period of intranasal and oral steroids all patients were randomly allocated to two treatment groups. The medical (M) group ($n = 53$) received oral prednisone for 14 days (30 mg daily for 4 days, followed by a 2-days reduction of 5 mg) and the surgical (S) group underwent endoscopic sinus surgery (ESS). Fourteen days later, patients from both groups started intranasal budesonide (400 µg/twice a day) for 12 months (Table 1).

An initial baseline evaluation (T0) before treatment was performed followed by two follow up evaluations, at 6 (T6) and 12 (T12) months after treatment. Nasal symptoms, polyp size, and QoL were all scored. All patients included in this study had undergone a pretreatment CT scan of paranasal sinuses.

Surgical procedure

The ESS was performed under general anesthesia. Endoscopic polypectomy plus anterior ethmoidectomy was performed in 56 patients, while added anteroposterior ethmoidectomy was performed in 49 patients. Extended surgery was required in 45 patients.

Table 1. Characteristics of patients with nasal polyposis in both treatment groups

	All patients	M group	S group
Patients with nasal polyposis	109	53	56
Age (year)	50.1 ± 1.4	50.7 ± 1.8	49.6 ± 2.0
Gender (M/F)	74/35	35/18	39/17
Duration of disease (year)	9.0 ± 0.7	9.5 ± 1.2	8.5 ± 0.9
Nasal polyposis without asthma	45	20	25
Nasal polyposis with asthma	64	33	31
Aspirin-tolerant	33	17	16
Aspirin-sensitive	31	16	15

M group, medical treatment with oral prednisone and intranasal budesonide; S group, surgical treatment with endoscopic sinus surgery followed by intranasal budesonide.

Eight postoperative complications (14.3%) were recorded: two patients had a postsurgical hemorrhage, and four patients showed exposure of the periorbital fat. One patient complained of epiphora, and one patient presented meningitis and a cerebrospinal fluid leak that was patched using ESS.

Quality of life (SF-36) assessment

The Health Survey SF-36 consists of 36 self-administered questions that cover eight health domains: physical functioning (PF), role physical (RP), bodily pain (BP), and general health (GH), vitality (VT), role emotional (RE), social functioning (SF), and mental health (MH). Scale scores range from 0 to 100 and higher scores indicate better QoL. For easy of interpretation, in the figures we present the deviation of the observed dimension score from the maximum score (100). In addition, the physical component summary (PCS) and the mental component summary (MCS) scores were calculated following the original authors' recommendations (18). The PCS and the MCS are calculated from the eight health dimensions of the questionnaire, which are standardized and aggregated using factor loads and finally transformed in order to obtain a mean of 50 and a SD of 10 in the Spanish general population (10).

Nasal symptom scores

Nasal obstruction, loss of smell, rhinorrhea, and sneezing were recorded. The severity of these symptoms was assessed and scored as follows: 0, no symptom; 1, mild but not troublesome symptom; 2, moderate symptom somewhat troublesome but not enough to interfere with the daily activity or sleep; and 3, severe and troublesome symptom that interferes with the daily activity or sleep.

Polyp size score

Using endoscopy, polyp size was scored from 0 to 3 for each nasal cavity: 0, no polyps; 1, mild polyposis (small polyps not reaching the upper edge of the inferior turbinate); 2, moderate polyposis (polyps between the upper and lower edges of the inferior turbinate); 3, severe polyposis (large polyps reaching the lower edge of the inferior turbinate) (16).

CT scan score

The CT scan opacification for each patient was blindly staged by the same radiologist using the Lund-Mackay score system (17). This system scores 0 for no opacity, 1 for partial opacity, and 2 for total opacity for each of the sinuses. In addition, the ostiomeatal complex scores 0 for no obstruction or 2 when obstructed. The system has a total score of 12 for each side.

Statistical analysis

Data analysis was performed with the statistical package SPSS 10.0 for Windows (SPSS Inc., Chicago, IL, USA). The data are presented as mean $\pm$ SEM. A P -value of <0.05 was considered statistically significant. Unpaired Student's t -test was used to compare the SF-36 scores of nasal polyp patients with the Spanish general population. Population-based norms have been obtained from 9984 individuals of whom 51.8% were females (10). There was no significant difference on the mean age between patients of our study and the Spanish general population. The QoL scores, after

treatment, were compared with T0 scores by two-tailed paired Student's *t*-test and differences between groups were assessed using the Student's unpaired *t*-test. Pearson correlation coefficients were used to examine the association between QoL scores and gender, age, nasal symptoms, and CT scores.

For each SF-36 scale, Cronbach's α coefficient was calculated to estimate internal consistency. This coefficient ranges from 0 to 1, and a minimum coefficient of 0.7 is recommended to ensure a good internal consistency (19).

Results

Fifty-three patients received oral prednisone and intranasal budesonide while 56 were treated with ESS followed by intranasal budesonide. From the 109 patients, follow up data was available for 95 patients (84%) at the end of this study.

Quality of life (SF-36) assessment

Before treatment and in comparison with the Spanish general population (10), patients with NP had significantly worse QoL scores in all SF-36 domains, except for physical functioning (patient's limitations to perform physical activity because of health problems) (Fig. 1). The MCS (39.2 $\pm$ 1.0) was significantly lower than the PCS (46 $\pm$ 1.3), keeping in mind that the Spanish general population had similar values for both MCS (79.7) and PCS (78.8) ($P < 0.05$), suggesting that NP impaired mental health more than physical health. Age, gender, nasal symptoms, polyp size, and CT scan scores were not

statistically correlated to SF-36 scores. Before treatment there was no difference in QoL between both treatment groups. At T6 and T12, patients with NP treated either medically or surgically showed a similar improvement on all SF-36 domains reaching the QoL levels of the Spanish general population (Figs 2 and 3). No significant differences were observed on QoL between T6 and T12.

At T0, asthmatic patients with NP had worse scores of QoL ($P < 0.05$) than nonasthmatic patients with NP on role physical, body pain, and vitality (Fig. 1). Also before treatment asthmatic patients showed lower PCS and MCS than nonasthmatic patients ($P < 0.05$). At 6 and 12 months, combined steroids as well as ESS had similar QoL improving for both PCS and MCS in asthmatic and nonasthmatic patients ($P < 0.05$) (Table 2).

Before treatment, aspirin-tolerant and aspirin-sensitive asthmatics in M and S group had similar QoL on both PCS (45.8 $\pm$ 1.7; 46.1 $\pm$ 1.7) and MCS (39.2 $\pm$ 1.2; 38.9 $\pm$ 1.3) respectively. No significant impact of aspirin sensitivity on QoL between M and S groups was observed at T6 and T12.

Analysis of internal consistencies for all SF-36 domains showed a Cronbach's α value higher than 0.7 (varied from 0.75 to 0.88) except for physical functioning (0.60).

Nasal symptom scores

Before treatment, no significant differences in nasal symptoms were found between both treatment groups. Patients scored loss of smell and nasal obstruction as the major complaints (Table 3). The mean duration

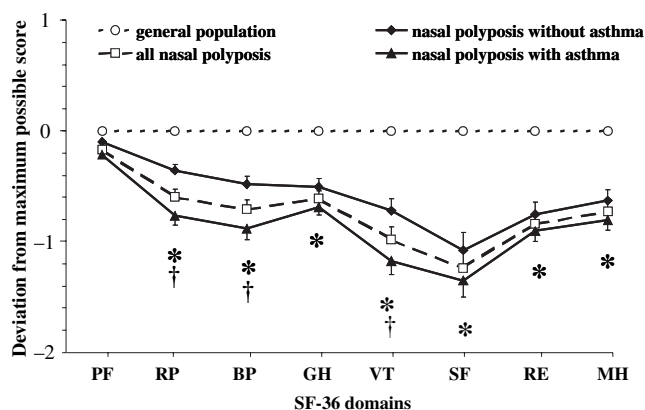


Figure 1. Quality of life in patients with nasal polyposis compared with the Spanish general population. Physical functioning (PF), role physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional functioning (RE), and mental health (MH). All patients (total, asthmatic, and nonasthmatic) had significantly worse scores in all Short Form-36 (SF-36) domains except for PF. Student's *t*-test was used. * $P < 0.05$, nasal polyp patients compared with the Spanish general population; † $P < 0.05$, comparison between asthmatic and nonasthmatic patients with nasal polyposis.

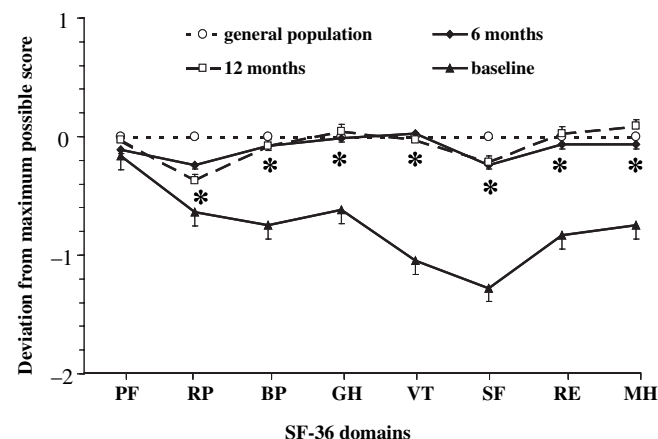


Figure 2. Quality of life improvement in patients with nasal polyposis receiving oral and intranasal steroids. Physical functioning (PF), role physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional functioning (RE), and mental health (MH). Student's *t*-test: * $P < 0.05$, 6 and 12 months of treatment compared with baseline.

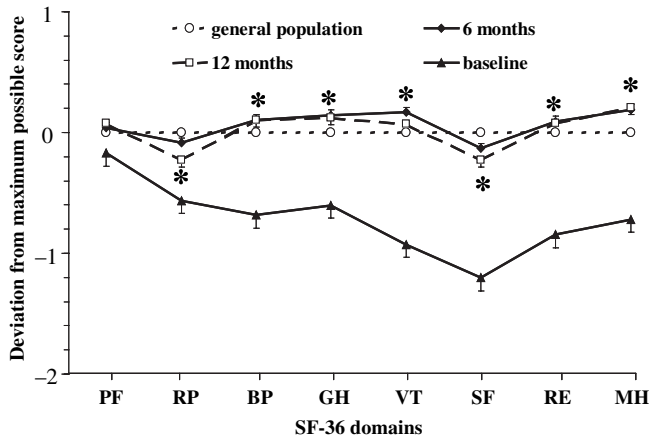


Figure 3. Quality of life improvement in patients with nasal polyposis underwent endoscopic sinus surgery followed by intranasal steroids. Physical functioning (PF), role physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional functioning (RE), and mental health (MH). Student's *t*-test: **P* < 0.05, 6 and 12 months of treatment compared with baseline.

time of nasal symptoms was 9.0 ± 0.7 years. At T6 and T12, all nasal symptoms significantly improved compared with T0 in both the medical and surgical treatment groups. Symptoms slightly increased at T12

compared with T6. In the M group, only rhinorrhea worsened at 12 months compared with 6 months. However, in the S group nasal obstruction, rhinorrhea, and the loss of smell worsened at 12 months compared with 6 months (Table 3). At T6, but not at T12, the improvement of nasal obstruction and the sense of smell were higher in patients treated with ESS than in patients treated only with steroids.

At T0 asthmatic patients had higher scores of the loss of smell (2.5 ± 0.08) and nasal obstruction (2.4 ± 0.09) than nonasthmatic patients (1.9 ± 0.2 and 2.1 ± 0.1 , respectively) (*P* < 0.05). At T6 and T12, patients with polyps and asthma treated with combined steroids or ESS showed a similar improvement in all nasal symptoms, while in nonasthmatic patients ESS improved nasal obstruction and loss of smell significantly more than combined steroids (*P* < 0.05).

Polyp size score

Before treatment, no significant differences were found in the polyp size between patients in both treatment groups. At T6 and T12, both medical and surgical treatments caused a significant reduction of the polyp size when compared with T0, although the polyp size was smaller in the surgical group than in patients treated only with steroids (*P* < 0.05) (Table 3). No

Table 2. Physical and mental component summaries of asthmatic and nonasthmatic patients with nasal polyposis for all, M group, and S group patients

	M group (<i>n</i> = 53)			S group (<i>n</i> = 56)		
	All patients	Without asthma	With asthma	All patients	Without asthma	With asthma
Physical component summary						
Baseline (T0)	45.8 ± 1.9	47.6 ± 3.4	44.8 ± 2.2**	46.3 ± 1.9	48.3 ± 3.0	44.7 ± 2.1**
6 months (T6)	48.6 ± 0.9*	49.8 ± 1.5*	48.0 ± 1.1*	50.0 ± 1.2*	51.3 ± 1.8*	49.0 ± 1.4*
12 months (T12)	48.1 ± 1.3*	49.1 ± 2.4*	47.5 ± 1.4*	49.5 ± 1.3*	50.6 ± 2.0*	48.8 ± 1.6*
Mental component summary						
Baseline (T0)	39.1 ± 1.5	39.9 ± 3.0	38.5 ± 1.4**	39.4 ± 1.5	40.6 ± 2.6	38.4 ± 1.5**
6 months (T6)	49.5 ± 1.2*	50.2 ± 2.3*	49.2 ± 1.4*	50.4 ± 1.4*	51.9 ± 1.6*	50.5 ± 1.8*
12 months (T12)	50.8 ± 1.3*	51.5 ± 2.4*	50.9 ± 1.6*	50.2 ± 1.2*	51.6 ± 1.6*	50.3 ± 1.6*

M group, medical treatment with oral prednisone and intranasal budesonide; S group, surgical treatment with endoscopic sinus surgery followed by intranasal budesonide. Student's *t*-test: **P* < 0.05, T6 and T12 compared with T0; ***P* < 0.05, asthmatic compared with nonasthmatic patients; ****P* < 0.05, S group compared with M group.

Table 3. Nasal symptoms and polyp size scores in both medical and surgical treatment groups at baseline, and after 6 and 12 months of treatment

	Nasal obstruction	Rhinorrhea	Sneezing	Loss of smell	Polyp size
Medical group (<i>n</i> = 53)					
Baseline (T0)	2.3 ± 0.1	1.7 ± 0.1	1.4 ± 0.1	2.3 ± 0.1	2.6 ± 0.1
6 months (T6)	1.1 ± 0.1*	1.3 ± 0.1*	1.2 ± 0.1*	1.8 ± 0.1*	1.8 ± 0.1*
12 months (T12)	1.3 ± 0.1*	1.4 ± 0.1*,***	1.1 ± 0.1*	1.9 ± 0.1*	1.9 ± 0.1*
Surgical group (<i>n</i> = 56)					
Baseline (T0)	2.4 ± 0.1	1.6 ± 0.1	1.4 ± 0.1	2.3 ± 0.2	2.5 ± 0.1
6 months (T6)	0.8 ± 0.1*,**	1.0 ± 0.1*	1.0 ± 0.1*	1.4 ± 0.1*,**	0.2 ± 0.1*,**
12 months (T12)	1.0 ± 0.1*,***	1.2 ± 0.1*,***	0.9 ± 0.1*	1.5 ± 0.1*,***	0.4 ± 0.1*,***

Medical group, treatment with oral prednisone and intranasal budesonide; Surgical group, treatment with endoscopic sinus surgery followed by intranasal budesonide. Student's *t*-test: **P* < 0.05, T6 and T12 compared with T0; ***P* < 0.05, surgical group compared with medical group; ****P* < 0.05, T12 compared with T6.

significant differences in polyp size either between asthmatic and nonasthmatic patients were observed before treatment and at T6 and T12.

CT scan score

Before treatment, the CT scan score was 19.1 ± 0.4 for all nasal polyp patients and there was no difference between both treatment groups. Compared with nonasthmatic patients (17.6 ± 0.7), patients with NP and asthma (20.2 ± 0.4) ($P < 0.05$) were found to have a more extensive sinus disease. No significant differences on nasal symptoms, polyp size, and CT scan were observed between patients with aspirin-tolerant and aspirin-sensitive asthma.

Discussion

This study was developed to gain more insight into the effects of treatment of NP on QoL. All patients had massive polyposis [score 2 or 3 of Lildholdt classification (16)] and were treated by the same otorhinolaryngologist. The main findings of our study showed that: (i) patients with NP have a significantly worse QoL than the Spanish general population; (ii) steroid treatment and ESS lead to similar QoL improvement in NP, either with or without asthma; and (iii) both steroid and ESS treatments improve nasal symptoms in patients with NP.

There was a lack of evaluable data on NP and QoL, with no adequate randomized trials. Furthermore, there is only one study providing information about the effect of treatment of nasal polyps (20). However, the evaluation of NP is presently impeded by a lack of valid specific instruments to measure QoL. Also, there were insufficient data to assess the effect of gender, duration of therapy, or comorbidity with asthma or aspirin sensitivity on QoL.

This study demonstrates that QoL in patients with NP is impaired in all SF-36 domains except for physical functioning. The mental health was lower than the physical health. No correlation was found between QoL and age, gender, nasal symptoms, CT scan, and polyp size.

The management of NP should be primarily based on a medical approach to be completed by surgical procedures only in the case of drug failure (12–15). Radenne et al. (20) reported the unique study that has investigated the impact of NP demonstrating that nasal polyps impair QoL in all SF-36 domains. Using the SF-36 and compared with a healthy population, other studies has also demonstrated that chronic rhinosinusitis has a considerable impact on all SF-36 domains except for physical functioning (21–24).

Patients with NP had lower scores in all SF-36 domains except for physical functioning and general health than patients with chronic obstructive pulmonary disease (11), coronary artery disease (25), and asthma (26).

Furthermore, our findings supported the developer's claim of internal consistency for the SF-36 questionnaire because all the coefficients were at values above those recommended except for physical functioning.

A significant improvement was observed in all domains of SF-36 after medical and surgical treatment. Both mental and physical health reached population levels. Combined steroid treatment and ESS had similar long-term outcomes on QoL. Radenne et al. (20) showed that steroids and ESS improved the symptoms and the QoL in patients with NP especially in body pain, general health, vitality, social functioning, and mental health domains with no significant differences between both treatment regimes. van Agthoven et al. (27) investigated the influence of filgrastim administration on the QoL of patients with refractory chronic sinusitis. They found that SF-36 domains of the filgrastim group were better than the placebo group. Rechtweg et al. (28) failed to demonstrate significant improvement in the SF-36 in patients with acute rhinosinusitis treated with clarithromycin and amoxicillin/clavulanate. Gliklich and Metson (21) found that patients with chronic sinusitis presented a significant improvement after sinus surgery in six SF-36 domains reaching near-normative levels. Winstead and Barnett (22) showed a significant improvement at 6- and 12-months after ESS for all domains of SF-36 and, at follow up, QoL scores did not significantly differ from those of the American general population. Gliklich and Hilinski (29) used specific and generic questionnaires in chronic sinusitis concluded that disease-specific seems to be more sensitive than a generic instrument in following patients after ESS.

Before treatment, the two most disabling symptoms were nasal obstruction and the loss of smell but no significant differences in nasal symptoms were found between M and S groups. All nasal symptoms clearly improved after steroid or ESS treatments with no differences between both treatment regimes. Patients treated medically or surgically had similar scores of nasal symptoms after 12 months of treatment.

After 2 weeks of oral steroids, van Camp and Clement (30) showed a clear improvement on nasal symptoms especially for nasal obstruction and loss of smell. Holmberg et al. (31) demonstrated that intranasal fluticasone or beclomethasone are effective in reducing nasal symptoms when compared with placebo. Combined oral and intranasal steroids seem to be effective to treat NP by improving the sense of smell, nasal obstruction, and other symptoms (32). Several studies using ESS have reported excellent subjective improvements of nasal symptoms in patients with nasal polyps (33, 34). In the study of Lildholdt et al. (35) the effectiveness of both medical and surgical treatment were considered alike although surgery was limited to removal of the visible polyps. Blomqvist et al. (36) found that nasal symptom scores improved significantly with medical treatment alone, but surgery had addi-

tional beneficial effects on nasal obstruction and secretion. Jankowski and Bodino showed that nasal obstruction was a major complaint of NP patients and the long-lasting correction of olfactory dysfunction can be achieved through the combination of nasalization and low dose of nasal steroids (37, 38).

Before treatment, there were no differences in polyp size between patients of both medical and surgical treatment groups. Combined steroids and ESS resulted in a reduction of the polyp size but this effect was significantly higher in patients treated by ESS when compared with steroid therapy alone. Many studies demonstrated that intranasal steroids are more effective than placebo on polyp size reduction (31, 39). Bonfils et al. (40) reported a 56.4% reduction of polyp size after 1 year of combined steroids treatment. Blomqvist et al. (36) reported more reduction in polyp size after ESS than steroid treatment.

Before treatment, no significant differences on CT scan between patients treated by combined steroids and ESS were observed. However, Winstead and Barnett (22) demonstrated a trend of lower SF-36 scores for patients with NP associated to extensive sinus disease demonstrated by CT scan. Krouse (41) failed to demonstrate any association between CT stage and patient QoL using the Rhinosinusitis Disability Index.

Before treatment, asthmatic patients had a higher nasal symptom score and worse QoL for both PCS and MCS than nonasthmatic patients especially on role physical, body pain, and vitality. Patients with NP and asthma had more extensive sinus disease on CT scan than nonasthmatic patients, while polyp size scores were similar in asthmatic and nonasthmatic patients.

This study provides additional evidence that the degree of abnormality on CT scan is not associated with impairment of QoL.

In nonasthmatic patients, ESS improved nasal symptoms more than a combined steroid treatment while asthmatic patients treated with combined steroids or ESS scored a similar improvement. Asthmatic and nonasthmatic patients scored similar QoL domains for both PCS and MCS after steroid therapy and ESS. No significant differences on nasal symptoms, polyp size, CT scan, and QoL between aspirin-tolerant and aspirin-sensitive asthmatics before and after medical or surgical treatment were observed.

Radenne et al. (20) also reported greater impairment of QoL when NP was associated with asthma. These authors showed that physical functioning, role physical, role emotional, vitality, and body pain scores were significantly lower in asthmatic than in nonasthmatic patients. However, Gliklich and Metson (21) showed that the presence of asthma was not predictive of a poor outcome in patients with chronic sinusitis. Winstead and Barnett (22) demonstrated that asthma had an adverse impact on vitality and general health compared with rhinosinusitis alone, but they had no significant differences in postoperative SF-36 scores from patients with rhinosinusitis alone. Uri et al. (42) also showed that ESS improved nasal breathing and QoL on asthmatic patients with massive NP.

In conclusion, these results suggest that NP has a considerable impact on QoL and that both medical and surgical treatment are effective in reducing nasal symptoms and polyp size leading to similar effects in improving QoL in nasal polyp patients.

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