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Medical management of nasal polyposis: a study in a series of 152 consecutive patients*

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SUMMARY

Background: *The management of nasal polyps is undoubtedly a controversial subject. The medical treatment remains the undisputed therapeutic mainstay but most of the publications are aimed at the registration of new molecules from the pharmaceutical industry which explains why they are confined to a single agent.*

Design: *The aim of this study is focused on the evaluation of a dual modality on a series of 152 subjects treated according to a standardized protocol combining a short-term administration of prednisolone and the daily intranasal spraying of beclomethasone.*

Results: *Over the follow-up period of one year, this modality proved to be successful in 68.5% of the subjects; only 31.5% had to undergo surgery after its failure. In the former group, after a six months period, the average symptom reduction reached an improvement rate varying from 35 to 80%, according to the symptom type. During the ensuing six months follow-up period, the improvement was maintained. The average utilization of prednisolone and beclomethasone was assessed for each individual patient.*

Conclusion: *Management of nasal polyps should be primarily medical. Resorting to surgical procedures should not be envisaged before a six months trial of dual steroid therapy under strict compliance to treatment.*

Key words: nasal polyposis, corticosteroid, prednisolone, beclomethasone.

INTRODUCTION

Nasal polyposis occurs as a result of a multifocal edematous degeneration, which originates from an inflammatory mucosal reaction of the paranasal sinuses (Larsen and Tos, 1997). Granted that it has a multifocal origin, its starting point is chiefly located in the ethmoid cells, particularly in their anterior portion. The cause of the inflammation is unknown but in all likelihood several factors are involved.

Nasal polyposis is the most incapacitating illness of the nasal cavity and paranasal sinuses (Radenne et al., 1999). Various severe symptoms attached to this condition testify to the serious alteration of the naso-sinusal function: airway blockage, loss of the senses of smell and taste, anterior and posterior rhinorrhea, sneezing episodes, stuffiness and facial pain. The discomfort is often such that everyday life activities become hampered, forcing the subjects to go on sick leave and to endure a precarious nasal condition.

The management of nasal polyposis has been the subject of frequent controversial debates for many decades. This study aimed at assessing the efficacy of a standardized drug administration protocol. It was based on a short-term oral steroid prescription, combined with a daily and long-term administration of steroid spray in a series of 152 consecutive patients. They were examined and treated by the same physician for the entire duration of the study.

MATERIALS AND METHODS

Materials

One hundred and fifty two new consecutive patients suffering from nasal polyposis were followed up for a one-year period after an enrolling period of one-year (september 1998 – september 1999). Patients having already benefited either from ethmoidal surgery or from a previous medical treatment were not included. The diagnosis of nasal polyposis was based for all patients on the two following criteria:

1. The visualization of bilateral polyps in the nasal cavities on endoscopic examination (Stammberger, 1997)
2. The existence on CT-scans of bilateral opaque areas located

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in the ethmoidal sinuses, whether in the anterior or the posterior ethmoid portion (Zinreich, 1994).

The examination was performed without contrast medium (axial et coronal planes).

The population having entered the study included 85 males and 67 females. The mean age was 48 years (SE 1.2). Forty nine patients (32%) were suffering from asthma. Nineteen patients were free from this illness but bronchial abnormal reactivity to methacholine was noted when ventilatory function investigations were performed (Bramann et al., 19987). Twenty-one patients had typical hypersensitivity reactions to aspirin or to NSAIDs. An allergy detection test ("Phadiatop") (Paganelli et al., 1998) was performed in 118 patients and it was shown to be positive in 22 of them (19%). No complementary allergic tests were performed (*i.e.*, skin prick-test or radioallergosorbent test). Therefore, the most common allergens could not be defined in the allergic subjects.

Methods

The same physician examined each patient every time. Assessments were conducted at baseline, three months (M3), six months (M6), and twelve months (M12). At each visit, the nasal function was checked on the basis of five criteria: airway obstruction, anterior rhinorrhea, posterior rhinorrhea, facial pain and loss of the sense of smell. The severity of each symptom was evaluated according to a three-grade scale: "0", "1" and "2" (Bonfils et al., 1998): grade 2 was noted when the symptom was either the reason for consulting or else spontaneously mentioned by the patient. Grade 1 applied to a symptom being revealed by specific questioning. Grade 0 was assigned to the absence of any symptom. In regard with the particular case of disorders concerning the sense of smell, anosmia was noted as grade 2, hyposmia as 1, and normal function as 0. It must be stressed that this systematic rating was not applying to the patient's condition at the visit time but instead to his/her nasal status during the entire preceding quarterly period. The physician paid due attention to this particular point. The grading was performed each time prior to any clinical, endoscopic and CT-scan examination.

Polyp grading was based on the endoscopy findings (rigid optic 30°, Storz, Germany): grade 0: absence of polyps, grade 1: polyps to be seen only under the middle turbinate, grade 2: polyps protruding below the middle turbinate, grade 3: massive invasion (MacKay and Lund, 1997).

Three different therapeutic measures were applied: (i) lavage of the nasal cavities, (ii) steroid spray, and (iii) oral steroid administration. Lavage of the nasal cavities was carried out twice a day with a physiological solution and a 20-cc syringe. Intranasal steroid spray (beclomethasone) was started at a daily dosage of 1500 μg (500 μg t.i.d.) in each nasal cavity. Beclomethasone was the main local steroid disposable and widely utilized in France at the beginning of the study. Moreover, at this period, an important number of French rhinologists used such high doses of beclomethasone in the medical treatment of nasal polyposis. Systemic steroid treatment was systematically prescribed to all patients at study entrance with the exception of those subjects to whom it was contraindicated; the regimen was 1 mg/kg of bodyweight/day for an initial five days period. At every consulting time the physician kept track of the precise drug consumption over the preceding three months period, with due attention paid to the compliance to the prescribed regimen. Other possible additional prescriptions from family doctors were also taken into account and put down on record.

At every quarterly consulting time, the regimen was tailored to the patient's needs. Whenever possible, *i.e.* every time the symptoms had been reduced to a compatible state with near normal life with little or no impairment of the patient's activities, the steroid spray administration was lowered. The dosage reduction was achieved progressively by levels of 250 μg. However if the patient's condition was clearly threatening to fall off to some worsening of his/her physical state, the prescribing physician resorted to a new course of systemic steroid administration. Furthermore, if the need for more than three systemic courses of prednisolone proved to be necessary a surgical option was proposed.

Statistical analysis

The severity of each symptom (0, 1 or 2) was recorded for each patient at the end of every quarterly period: baseline, M3, M6 and end point. At each visit, a clinical global severity index was derived; it represented the mean score of the five symptoms

Table 1. Severity mean of each symptom (SE) at baseline and M6 (all patients being medically treated n=152), and also at M12 (to the exclusion of the 48 surgical patients (n=104).

Symptoms	NO	AR	PR	FP	SL
Baseline					
Total (n=152)	1.48 (0.06)	0.77 (0.07)	0.54 (0.06)	0.47 (0.05)	1.63 (0.05)
Surg (n=48)	1.64 (0.09)	1.19 (0.12)	0.98 (0.12)	0.72 (0.11)	1.75 (0.07)
Non surg (n=104)	1.41 (0.07)	0.58 (0.07)	0.34 (0.06)	0.35 (0.06)	1.57 (0.07)
M6 (n=152)	0.20 (0.05)	0.09 (0.04)	0.22 (0.06)	0.11 (0.04)	0.60 (0.08)
M12 (n=104)	0.25 (0.06)	0.11 (0.04)	0.07 (0.04)	0.07 (0.03)	0.54 (0.08)

NO: nasal obstruction, AR: anterior rhinorrhea, PR: posterior rhinorrhea, FP facial pain, SL: sense of smell loss.

under analysis: nasal obstruction, anterior rhinorrhea, posterior rhinorrhea, facial pain, hyposmia-anosmia. The polyp grade was also recorded at each examination: baseline, M3, M6 and M12.

In the final analysis, the amount of steroid consumption was sorted out into two separate subsets: oral treatment (prednisolone, mg) on one hand and topical therapy (beclomethasone, μg) on the other hand. The average quantity of each steroid subset was in turn analyzed for the preceding quarterly period at M3, M6 and M12 for every patient, whether strictly treated by steroids or having undergone surgery. Comparison of the mean drug consumption between the two categories of patients was based on the classical calculation of the *t*-Test applied to the difference of two means (ε). The selected level of statistical significance was achieved ($p<0.05$).

RESULTS

Analysis of baseline data

Table 1 shows the severity mean of each individual symptom at baseline. The two most disabling symptoms were found to be anosmia and nasal obstruction. The mean of clinical global severity index over the entire population was found to be 1 (SE 0.04) whereas the mean polyp grade was observed to be 1,7 (SE 0.06).

Analysis of the population undergoing surgery (n=48)

Resorting to surgery after failure of the medical treatment concerned forty-eight patients (n=48, 31,5%). The mean of clinical global severity index at baseline was 1,26 (SE = 0.06, n=48) as opposed to 0,85 (SE 0.03, n=104) in the "non surgical" group (Figure 1). Between the two groups there is a significant difference ($p<10^{-3}$). This difference points out to the predictive interest of this index.

Table 1 shows the comparison of the severity mean of each symptom at baseline between the exclusively medical group and the surgical one. A significant difference was noted for all symptoms: nasal obstruction ($p<0.02$), anterior rhinorrhea ($p<10^{-4}$), posterior rhinorrhea ($p<10^{-4}$), and facial pain ($p<10^{-2}$). No statistically significant difference was recorded between the two groups as regard to the sense of smell alterations.

As to the comparative polyp size index at baseline, it turned out to be significantly higher ($p<0.01$) in the surgical group (1.87, SE 0.14, n=48) than in the exclusively medical one (1.4, SE 0.8, n=104). The percentage of patients who had to undergo surgery increased with polyp size: grades I: 20%, II: 35.8%, III: 58.3%. Surgery was performed in all patients.

Pattern of improvement under exclusive medical treatment during the first six months

Clinical data

Figure 1 shows clearly the change of the mean of clinical global severity index at M3 and M6. At six months, it was 0.25 (SE 0.04, n=104). Compared to the baseline figure (0.85, SE 0.03), it shows a significant improvement ($p<10^{-3}$) (Figure 1).

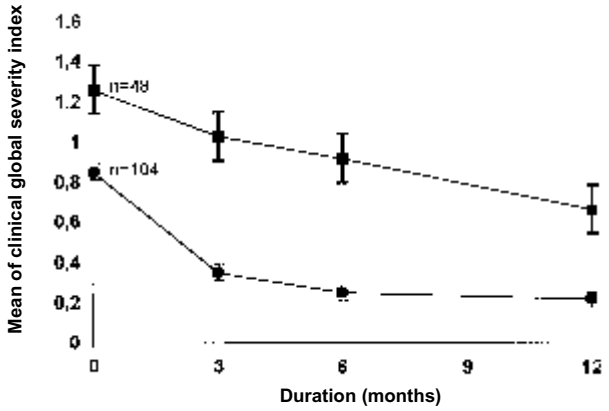

Figure 1. Mean of clinical global severity index according to treatment duration (months) in the exclusively medical group (●, n=104) and in the surgical group (■, n=48) with 95% confidence intervals of the two means.

The severity mean of each symptom at M6 is shown in Table 1. There is a statistically significant difference between the baseline data and the indices recorded at M6 in the case of nasal obstruction ($p<0.05$), and for the other symptoms ($p<10^{-3}$). With regard to airway obstruction and anterior rhinorrhea, the reduction was found to be over 80%. As to facial pain and smell loss, the decrease ranged from 60% to 70%. The posterior rhinorrhea index diminished by 35%.

The polyps baseline and M6 volume grades (Table 2) underwent a statistically different change ($p<10^{-4}$) in strictly medical patients.

Table 2. Mean polyp grades in patients under exclusive medical treatment, at baseline, M6 and M12.

	Mean grade	SE
Baseline	1.40	0.08
M6	0.69	0.08
M12	0.69	0.08

Steroid consumption data

The prednisolone cumulative consumption of prednisolone tablets (mg) and that of beclomethasone aerosol (μg) are shown in Table 3.

Due to the existence of associated illnesses (active peptic ulcer, non-properly controlled diabetes, etc.), fourteen patients were initially restricted to receive the topical treatment alone during the first three months. After ulcer healing, proper glycemia management and other appropriate measures, the subjects were switched to the standard combined treatment, i.e. topical and systemic. At M3 and M6, a significant difference ($p<10^{-2}$) in the quantities of the orally administered prednisolone was found between the surgical and the exclusively medical groups. The former received more of the oral corticosteroid than the latter.

Table 3. Total drug administration.

	Surgical patients		Exclusive medical patients	
Period	Dosage	SE	Dosage	SE
Prednisolone (total cumulative dosage, mg)				
0-6 mths	1168	62	751	14
6-12 mths	651	170	327	22
Beclomethasone (mean spray dosage/cavity/day, μg)				
0-6 mths	1500	0	1500	0
6-12 mths	1375	68	1138	41

Mean cumulative Prednisolone administration (mg) (SE).
Mean dosage of Beclomethasone spray (μg) per nasal cavity/day.

All the patients benefited from a beclomethasone spray administration. During the first six months, the mean quantities were identical in both groups.

Pattern of improvement under exclusive medical treatment between M6 and end point

Clinical data

The mean of clinical global severity index (Figure 1) at end point was found to be 0.22 (SE=0.04, n=104). No statistically significant difference was detected between this value and the one recorded at mid-study.

For all symptoms, no significant difference was derived from the comparison between the M6 and the M12 data as regard to the severity mean of each symptom (Table 1), with the exception of the posterior rhinorrhea improvement ($p<0.05$).

Similarly, in the exclusively medical group, the mean grade of polyp volume did not vary significantly during the same period, *i.e.* from M6 to M12 (Table 2).

Steroid consumption data

The oral administration of prednisolone was prescribed only to those patients who were spontaneously complaining about their nasal condition. The mean total amount of orally administered prednisolone was statistically different between the surgical and the exclusively medical groups ($p<0.05$). Thus during the M6-M12 period, systemic steroid therapy was used to a higher degree by the surgical patients (Table 3).

In contrast, during the same period, with regard to topically administered beclomethasone, no difference whatsoever could be traced between the two groups.

DISCUSSION

Our series includes 152 consecutive subjects. From baseline to endpoint, they were all examined and followed up by the same otolaryngologist. The characteristics of the population are close to those usually found in the literature, in reference to age (mean = 48 years), sex ratio (1.25), prevalence of associated asthma (32.6%), and sensitivity to aspirin (13.6%). In the literature (Brown et al., 1979; Drake-Lee et al., 1984; Larsen and Tos, 1994), these characteristics range between the following figures: age (40-50 years), prevalence of associated asthma (25-45%), and sensitivity to aspirin (5-25%).

The therapeutic efficacy was assessed exclusively on the basis of the modification of the most frequently encountered clinical symptoms in nasal polyposis (Bonfils et al., 1998; Radenne et al., 1999): nasal obstruction, anterior and posterior rhinorrhea, facial pain, smell disorders with special reference to anosmia. However difficult it may be to reach a mean score - since a symptom weighted average is impossible to get - we devised a method by which a clinical global severity index was derived. Each symptom carried the same weight. Such an index, arguable as it may be, constitutes nevertheless a practical tool to grade and grasp the global nasal comfort of a given patient.

A staging system was necessary to have meaningful results in the treatment of nasal polyposis. Several systems have been proposed, mainly based on CT evaluation. MacKay and Lund (1997) introduced a staging system for rhinosinusitis particularly appropriate when used to score the extent of disease in nasal polyposis. This system was recommanded for the quantification for staging sinusitis by the faculty of the Staging and Therapy group of the International Conference on Sinus Disease: Terminology, Staging, Therapy in 1995. However, at the meeting of Davos in 1996, it was felt that although there was some virtue in using this sheme, that in the case of assessing the extent of nasal polyposis there should be an additional grade 3 for patients with massive diffuse disease as there is a considerable difference between patients with nasal polyps protruding immediatly below the middle turbinate, and those patients who have no airway at all. A recommandation on endoscopic appearance was proposed in four levels: grade 0: no polyps, grade 1: polyps to be seen only under the middle turbinate, grade 2: polyps protruding below the middle turbinate, grade 3: massive invasion (MacKay and Lund, 1997). It is hoped by using this simple technique, in association with symptoms evaluation, that it will be possible to audit the outcome of the medical treatment of nasal polyposis.

In the present results, two symptoms of nasal polyposis towered above all the others; at baseline, the anosmia and nasal obstruction indices were respectively recorded as 1.63 and 1.48. The other clinical disorders (*i.e.*, anterior and posterior rhinorrhea, and facial pain) were much less frequent and/or less discomforting as demonstrated by their indices ranging from 0.47 to 0.77.

The type of treatment to apply to nasal polyposis has been very much in debate for several decades. On the whole, most authors agree on the fact that polyposis management should be based primarily on a medical approach to be completed by surgical procedures only in case of drug failure (Lund, 1997; Mygind, 1999; Badia and Lund, 2001; Blomqvist et al., 2001). The core of the medical management rests on corticosteroid therapy. An abundant literature has been dedicated to this modality but most of the studies were dealing with a single steroid, used either orally or in spray. Three major studies

(Lildholdt et al., 1988; van Camp and Clement, 1994; Lildholdt et al., 1997a) were dedicated to systemic steroid therapy which had a genuine efficacy on all symptoms and especially on anosmia, the improvement of which went usually in step with the polyps volume reduction. A short-term systemic steroid administration thus appears to have the same efficacy as polypectomy, but the improvement proves to be of short duration (*i.e.*, few weeks) (Virolainen and Puhakka, 1980; Lildholdt et al., 1997a).

Steroid topical therapy was repeatedly studied at the instigation of the pharmaceutical industry. Over a dozen placebo controlled studies were published but the therapeutic effect was mostly studied for periods restricted to a few weeks (Lildholdt et al., 1997b, Mygind, 1999; Badia and Lund, 2001; Blomqvist et al., 2001). Topical therapy has a definite beneficial effect on the clinical disorders and, to a certain degree, on the polyp size but shows little activity on the sense of smell dysfunction.

A combined treatment consisting of systemic steroid treatment followed by long-term spray administration has been widely used in France for many years. The rationale of this sequential procedure is based on the fact that the initial volume of polyps does not allow a rapid and significant effect of the topical therapy, let alone a full one. This key point might well be one of the prime reasons for the failure of the sole spray treatment (Slavin, 1991). Initial systemic steroid therapy which induces a rapid polyp size reduction opens up the full efficacy of topical therapy in a second phase (Slavin, 1991). In our study, intranasal steroid spray (beclomethasone) was started at a daily dosage of 1500 μg (500 μg t.i.d.) in each nasal cavity, in agreement with a large number of French rhinologists in this period. Beclomethasone was the main local steroid disposable and widely utilized in France at the beginning of the study. To assess the hypothalamic-pituitary-adrenal axis after long-term of intranasal corticosteroid treatment in nasal polyposis, a short synacthen test have been performed in a series of 24 patients who received high doses of beclomethasone (*i.e.*, above 2000 μg/day). Morning plasma cortisol was normal in all patients before and after stimulation (Amanou et al., 2000).

Along the same lines, Slavin (1991) asserts that the reasonable approach to nasal polyposis should be based on the oral prednisolone administration over a 10-14 days period followed by a course of intranasal spray of either beclomethasone or flunisolide. He tried this combination in a series of 147 patients for twelve months with a one-year follow-up. The results he reported underline the genuine efficacy of a strictly medical treatment provided that compliance to prescription is strictly observed. Recently, Blomqvist et al. (2001) realized a randomized controlled study evaluating medical treatment versus surgical treatment in addition to medical treatment of nasal polyposis. The aim of this study was to determine whether surgical treatment in fact has an effect additive to that of medical treatment of nasal polyposis. Thirty-two patients were randomized to unilateral endoscopic sinus surgery after pretreatment with oral prednisolone for ten days and local nasal budesonide bilaterally for one month. Postoperatively, patients were given local nasal steroids (budesonide). The authors concluded that medical treatment seems to be sufficient to treat most symptoms of nasal polyposis. Such randomized controlled study was difficult to realize in our series for two main reasons: two simultaneous treatments were prescribed, and doses of each treatment were modified as a function of the patient symptoms every three months.

The aim of our study was to evaluate the benefit of a frequently prescribed treatment of nasal polyposis in France. In our series, at M6, the clinical global severity index was significantly reduced, and so was the severity mean of each single symptom as testified by the following recordings of their declines: nasal obstruction and anterior rhinorrhea (over 80%), facial pain and anosmia (60-70%), posterior rhinorrhea (35%). In step with this trend, polyp size was also significantly reduced.

As stated previously, full-blown therapeutic efficacy was not reached until M6 (Figure 1) while the functional improvement was still being maintained at M12. Likewise polyp size remained stable.

The orally administered steroid amounts were higher during the first quarter and then could be progressively decreased every three months. This dosage reduction testifies to the clinical improvement since the oral route was resorted to only in case of persisting functional impairment. The recorded mean amounts were rather on the low side, notably in the exclusively medical group: 750 mg of prednisolone during the first six months, i.e. the practical equivalent of two therapeutic courses of five days of the following dosage: 1 mg/kg of bodyweight/day in the instance of a patient weighing 75 kg.

Topical steroid therapy was decreased as soon as the symptoms were properly checked, in most cases at M3. In the exclusively medical group, the mean beclomethasone amount/cavity/patient/day declined from 1500 μg at study entrance to 1138 μg at endpoint. Continuation of treatment under the same protocol was aimed at reaching the lowest possible useful daily dosage.

Recourse to surgery could not be avoided in 31.5% of the subjects. In this group, the total orally administered steroid consumption turned out to be larger than in the exclusively medical group. The clinical global severity index was also found to be higher. These findings suggest a certain degree of resistance or at least a decreased receptivity to glucocorticoid therapy in patients having to undergo surgery.

Closing remarks

The maximum efficacy was achieved after a six months period. It seems reasonable to suggest that this probationary time is enough to decide on the course of therapeutic action to be taken, either medical or surgical, depending on the global efficacy of the systemic and topical steroid therapy. A surgical procedure should be definitely proposed after six months on the face of inadequate results.

CONCLUSION

The study objective was the assessment of the potentialities and limits of the strictly medical management of nasal polyposis. Short-term steroid systemic courses of treatment combined with long-term steroid intranasal spray lead to satisfactory results in 70% of the subjects. In these favorable cases, the symptoms were such that the residual discomfort did not call for recourse to surgical procedures. In 31.5% of the cases however, the sole medical treatment fell short of the expected effects, and endonasal ethmoidectomy had to be considered.

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