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RHINOLOGY

Comparison of the effect of endoscopic sinus surgery versus medical therapy on olfaction in nasal polyposis

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Abstract Chronic rhinosinusitis is a common inflammatory condition in western countries. Nasal polyposis has different symptoms such as nasal obstruction, anterior or posterior nasal drip, reduced sense of smell, and facial pain. Medical and endoscopic treatments are the two main treatments for nasal polyposis. Our aim was to compare the efficacy of different methods on olfactory function. This is a non-randomized clinical trial study that was done on 60 patients who were divided into two groups (medical and surgical). Patients were matched based on age, history of smoking, and the severity of obstruction. The radiologist score of Lund-Mackay staging system was used to match patients in two arms of the trial based on the severity of nasal obstruction. Patients in surgery groups underwent functional endoscopic sinus surgery under general anesthesia and then received Fluticasone propionate nasal spray for 8 weeks (400 mcg bd). Patients in the medical group were only prescribed with Fluticasone propionate with the same duration and same dose as mentioned. As a result of treatment protocol, both medical and surgical group experienced improvement in olfactory function but statistical analyses revealed that surgery resulted in better resolution of symptoms. Our observation revealed that combined treatment had a better effect than medical treatment in restoring olfaction in patients with nasal polyposis.

Keywords Endoscopic sinus surgery · Medical therapy · Olfaction · Nasal polyposis · Non-randomized clinical trial

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Introduction

Chronic rhinosinusitis is a common inflammatory condition in western countries. It is reported that this disorder affects nearly 2–4 % of the population [1, 2]. Nasal polyposis can negatively influence the quality of life [3] and have different symptoms such as nasal obstruction, anterior or posterior nasal drip, reduced sense of smell, and facial pain [4]. The underlying cause for developing nasal polyposis is unclear but it is thought that different factors including genetics, allergic, and inflammatory factors are responsible [5, 6].

Steroids play an important role in the management of nasal polyposis. Topical and systemic steroids are widely used to resolve or diminish symptoms [7]. If medical treatment failed, the second choice of treatment is

functional endoscopic sinus surgery (FESS) that has an impressive effect in resolution of symptoms and helping patients to achieve complete remission. Although, there is a chance of recurrence [8].

Previous studies reported high frequency of reduction in sense of smell among patients with nasal polyposis [9, 10]. Few studies have compared the efficacy of medical treatment with combined surgical and medical treatment for restoring the olfactory function. Their results were controversial. Hence, our aim was to design a study to compare the efficacy of these methods. In order to gain more reliable results, we matched patients in medical and surgical groups for age, smoking history, and severity of nasal obstruction.

Patients and methods

Patients

To compare the efficacy of FESS and medical therapy for treatment of nasal polyposis, a prospective non-randomized clinical trial was initiated in Shahid Sadoughi hospital in Yazd, Iran. Sixty patients with bilateral nasal polyps who were older than 18 years were enrolled in this study. Patients were excluded from the study if they were immunosuppressive, had a history of corticosteroids consumption in the past month, history of anti-histamine, or nasal steroid administration in past 15 days and history of nasal surgery or severe asthma that need systemic corticosteroids. All patients received written informed consent and ethics committee at Shahid Sadoughi University of medical sciences confirmed the study protocol. The radiologic score of Lund-Mackay staging system was used to match patients in medical and surgical groups based on the severity of nasal obstruction [11]. This staging system was developed to aid treatment decision. It consists of symptom, radiology and endoscopy scores; the one which is widely used is radiologic scoring based on computed tomography scan images. Patients were also matched based on age and history of smoking.

Assessment

Olfactory function of each patient was evaluated subjectively according to a ten-point scale: 0, no sense of smell and 10, well identification of different odors. Smell function was also evaluated objectively using the olfactory test described by Connecticut Chemosensory Clinical Research Center (CCCRC) [12], which is composed of an odor threshold component, an odor identification component, and a composite score. The patients were divided into different groups based on the composite score of CCCRC: normal olfactory function (6≤), hyposmia ($2 \leq x < 5$), and anosmia (2>). Hyposmia was also divided into three different levels: mild ($5 \leq x < 6$), moderate ($3 \leq x < 5$), and severe ($2 \leq x < 3$). Baseline assessment of olfactory function was performed for all patients prior to the study with both subjective and objective tests. Patients in surgery groups underwent FESS under general anesthesia and then received Fluticasone propionate nasal spray for 8 weeks (400 mcg bd). Patients in medical group were only prescribed with Fluticasone propionate with the same duration and dose as mentioned. Patients underwent olfactory assessment 8 and 12 weeks after treatment course. If the patients score after treatment rose to higher than six (normal olfactory function group), these cases were considered as complete remission.

Statistical analysis

Statistical analyses were done using SPSS for windows, version 17.0. Baseline characteristics were compared between two groups using independent sample *t* test and Chi square test. Paired *t* test and Wilcoxon-signed rank was used to perform within a group and between group treatment comparisons, respectively. Repeated measures analysis of variance (rANOVA) was employed to compare treatment results between two arms of trial. In all tests, p value <0.05 was considered as statistically significant.

Results

A total of 60 patients with nasal polyps were enrolled in this non-randomized clinical trial. Patients were divided into two groups and underwent endoscopic sinus surgery or received only medical treatment. Each group consisted of 30 patients.

Surgery group

This group consisted of 11 (36.7 %) women and 19 (63.3 %) men with a mean age of 37.93 ± 11.92 years (ranging from 18 to 65 years old). The mean value of Lund-Mackay score for nasal obstruction in this group was 9.76 ± 1.45 (ranging from 8 to 12) (Table 1).

In the baseline subjective assessment of olfactory function, the mean score for patients in surgery group was 2.6 ± 2.23 (ranging from 0 to 6). Eight weeks after treatment, the value elevated to 6.1 ± 2.4 and 12 weeks after treatment course the value was 6.8 ± 2.23. Statistical analyses revealed that FESS resulted in significant improvement in olfactory function after 8 ($p < 0.001$) and 12 weeks ($p < 0.001$). Also, significant improvement was observed between 8 and 12 weeks ($p < 0.001$) (Table 2; Fig. 1).

Table 1 Demographic information about medical and surgical group

	Medical	Surgical	*p* value
Mean age	37.46 ± 9.56	37.93 ± 11.92	0.868
Mean Lund-Mackay score	19.52 ± 2.9	19.52 ± 2.9	1.00
Sex			
Female	14 (46.7 %)	11 (36.7%)	0.432
Male	16 (53.3%)	19 (63.3%)	
Smoking			
Active	4 (13.3%)	4 (13.3%)	1.00
Passive	7 (23.3%)	5 (16.7%)	0.519

Table 2 Subjective assessment of olfactory function prior to study, 8 weeks and 12 weeks after treatment

	Medical Mean ± SD	Surgical Mean ± SD	*p* value[a]
Baseline	2.63 ± 1.9	2.6 ± 2.23	
After 8 weeks	4.8 ± 2.7	6.1 ± 2.4	
p value[b]	<0.001	<0.001	
After 12 weeks	4.7 ± 2.58	6.8 ± 2.23	
p value[c]	<0.001	<0.001	
p value[d]	0.796	<0.001	0.035

[a] *p* value calculated for comparison of treatment results between two groups at the end of the trial (using rANOVA)

[b] *p* value calculated for within group comparison after 8 weeks

[c] *p* value calculated for within group comparison after 12 weeks

[d] *p* value calculated for within group comparison between 8 and 12 weeks

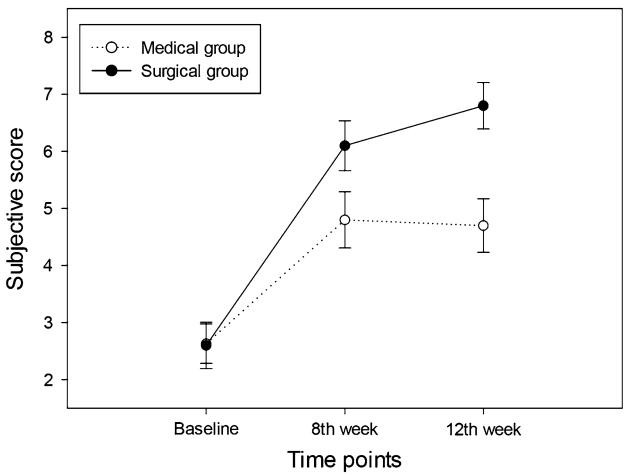

Fig. 1 Subjective assessments of olfactory function were performed after 8 and 12 weeks in all patients, both groups reported improvement after surgical or medical treatment. Statistical analysis showed that patients who underwent surgery had better sense of smell ($p < 0.035$). Data are presented as mean and standard error of the mean (SEM)

Connecticut Chemosensory Clinical Research Center test was also performed for objective assessment of olfactory function. The mean baseline score was 2.23 ± 1.78 (ranging from 0 to 6). Eight weeks after treatment, the test was performed again and the mean composite value was 5.56 ± 1.64 and 12 weeks after treatment mean score of smell function was 5.8 ± 1.24. The difference between baseline scores and scores measured after 8 ($p < 0.001$) and 12 weeks ($p < 0.001$) was statistically significant. No significant improvement was observed between 8 and 12 weeks ($p = 0.758$) (Table 3; Fig. 2).

Significant positive correlation was observed between subjective and objective improvement in olfactory function ($p < 0.001$).

Prior to the treatment, 13(43.3 %) patients in this group suffered from anosmia (olfactory score < 2), five (16.6 %) patients had severe hyposmia (2 ≤ score < 3), eight (23.3 %) patients had moderate hyposmia (3 ≤ score < 5), three (10 %) obtained mild hyposmia (5 ≤ score < 6), and one (3.33 %) carries normal olfactory function (Fig. 3).

The complete remission ratio was 60 % and 18 patients in the surgery group experienced complete remission after performing FESS. One (3.33 %) patient's smell function was worsened after surgery.

Medical group

Mean age of patients was 37.6 ± 9.56 years (ranging from 20 to 52 years of age). Fourteen (46.7 %) patients were women and 16 (53.3 %) were men. Mean Lund-Mackay score for nasal obstruction was 9.76 ± 1.45 (ranging from 7 to 12) (Table 1). Baseline mean subjective score for olfactory function was 2.63 ± 1.9 (ranging from 0 to 6). Eight weeks after conducting treatment protocol, the

Table 3 CCCRC scores for olfactory function prior to study, 8 weeks and 12 weeks after treatment

	Medical Mean ± SD	Surgical Mean ± SD	*p* value[a]
Baseline	2.16 ± 1.53	2.23 ± 1.78	
After 8 weeks	3.53 ± 2.15	5.56 ± 1.64	
p value[b]	<0.001	<0.001	
After 12 weeks	3.48 ± 2	5.8 ± 1.24	
p value[c]	<0.001	<0.001	
p value[d]	0.758	0.785	<0.001

[a] *p* value calculated for comparison of treatment results between two groups at the end of the trial (using rANOVA)

[b] *p* value calculated for within group comparison after 8 weeks

[c] *p* value calculated for within group comparison after 12 weeks

[d] *p* value calculated for within group comparison between 8 and 12 weeks

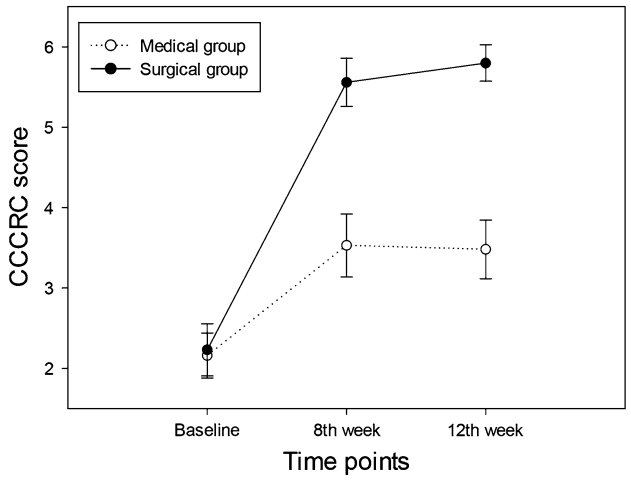

Fig. 2 Objective evaluation of sense of smell was done using CCCRC test. rANOVA revealed that patients in surgery group had significant higher scores compared to patients who received medical therapy ($p < 0.001$). Data are presented as mean and SEM

valuation ascended to 4.8 ± 2.7 and 12 weeks after treatment, the mean value was 4.07 ± 2.58. The differences between baseline scores and 8 ($p < 0.001$) and 12 weeks ($p < 0.001$) post-treatment scores were statistically significant (Table 2; Fig. 1). CCCRC test was also performed to assess objective olfactory function. The baseline mean score based on CCCRC test was 2.16 ± 1.53 (ranging from 0 to 4.5), 8 weeks after treatment, the mean score was 3.53 ± 2.15 and 12 weeks after treatment, the mean score was 3.48 ± 2. The improvement between baseline scores and scores evaluated after 8 ($p < 0.001$) and 12 weeks ($p < 0.001$) of treatment was statistically significant (Table 3; Fig. 2). Subjective scores positively correlated with CCCRC scores ($p < 0.0001$).

The CCCRC test revealed that from the total of 30 patients in this group, 13 (43.3 %) had anosmia, 5 (16.6 %) had severe hyposmia, 11 (36.6 %) had moderate hyposmia, and 1 (3.33 %) patient had mild hyposmia (classifications were done based on the scores previously mentioned for surgery group). After medical treatment, the complete remission ratio was 20 % and six patients experienced complete remission. Sense of smell was impaired in one (3.33 %) patient after treatment (Fig. 3).

Comparison

In comparing the treatment results between two groups, the difference between complete remission ratio of medical and surgery group was statistically significant ($p < 0.001$) (Fig. 3). rANOVA revealed that patients in the surgery group had higher response to treatment and better olfactory function based on both subjective and objective assessments ($p = 0.035$ and $p < 0.001$, respectively) (Tables 2, 3).

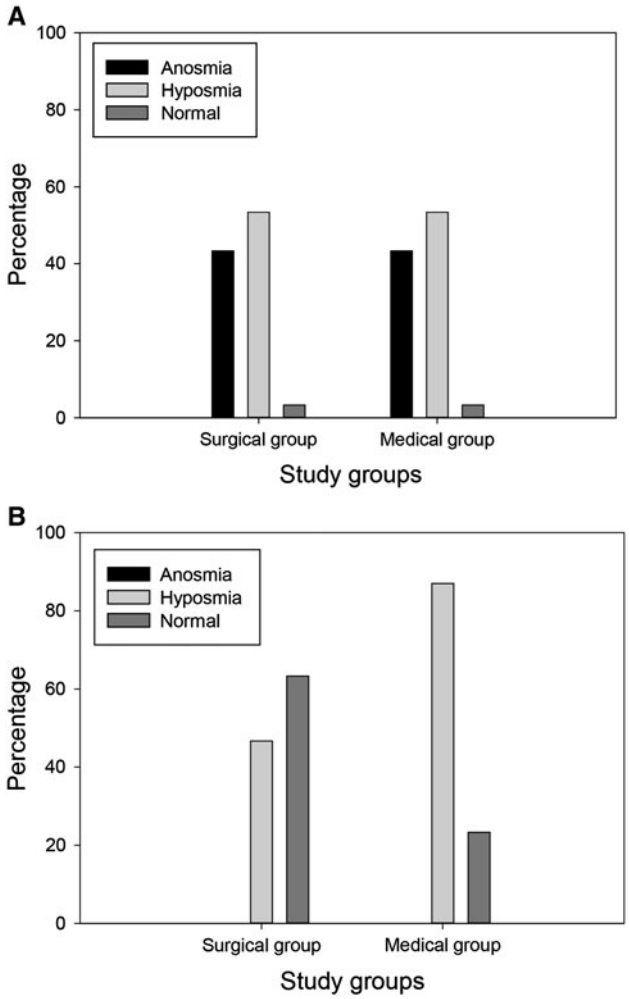

Fig. 3 Frequency of olfactory dysfunction based on CCCRC test results. Normal olfaction was defined as CCCRC score ≥ 6, hyposmia as 2 ≤ score < 5 and patients were considered as having anosmia if their scores were <2

The frequencies of complications in both groups are presented (Table 4).

Discussion

A non-randomized clinical trial was conducted to compare the efficacy of medical treatment versus endoscopic treatment on olfactory function in patients with nasal polyposis. In order to compare different treatment methods in a well-controlled study, we used Lund-Mackay staging system to match both groups based on the severity of nasal obstruction, also two groups were matched regarding sex, smoking, and age. Both subjective and objective assessments of olfactory function were performed to evaluate the olfaction status.

Topical and systemic steroids are the first choice of treatment for nasal polyposis and are additionally used to reduce the risk of recurrence [13, 14]. Steroids play an important role

Table 4 Frequency of treatment complications between both groups

	Medical	Surgical	*p* value
Headache			
Yes	4 (13.3 %)	2 (6.7 %)	0.317
No	26 (86.7 %)	28 (93.3 %)	
Nasal			
Yes	4 (13.3 %)	0 (0 %)	0.112
No	26 (86.7 %)	30 (100 %)	
Facial pain			
Yes	0 (0 %)	2 (6.7 %)	0.492
No	30 (100 %)	28 (93.3 %)	
Epistaxis			
Yes	2 (6.7 %)	3 (10 %)	0.931
No	28 (93.3 %)	27 (90 %)	

in the treatment of nasal polyposis through their anti-inflammatory effect and their ability to decrease the infiltration of eosinophils [15]. The efficacy of topical steroids has been investigated in different studies and nearly all of them showed that they can reduce patient's symptoms. Stjarne et al. [16] evaluated the efficacy and safety of Mometasone furoate spray. They investigated 310 patients with moderate nasal polyposis in a double-blind, randomized controlled trial. They observed that Mometasone furoate can significantly diminish symptoms and the size of polyps compared to placebo. The same results were reported in three other double-blind, randomized controlled clinical trials [17–19].

Systemic steroids are administered in patients with advanced or refractory disease. They can cause to achievement of rapid and short-term remission. The efficacy of systemic steroids has been the matter of debate in several studies and all of them showed dramatic effects of systemic steroids [20, 21]. But due to complications of these medications, long-term prescription is not recommended and after resolution of symptoms, intranasal spray must be substituted to maintain the therapeutic effect [22, 23]. Vaidyanathan et al. [24] evaluated the efficacy of oral steroids followed by topical steroids in a double-blind clinical trial. They used pocket smell test for assessment of olfactory function and declared that combination therapy is more effective than inhaled steroids as the single treatment.

Despite the effectiveness of topical or systemic steroids, they cannot completely eradicate nasal polyps and many patients need to undergo endoscopic surgery to achieve complete remission [25] and FESS plays an important role in this setting. Several authors reported that FESS can acquire long-term remission for patients [26, 27].

As we aim to evaluate the efficacy of treatment on olfactory function, different authors assessed this effect in their studies but there are few trials that compare the results of combined therapy with medical monotherapy. Keith et al. [28] conducted a randomized controlled trial and examined the efficacy of Fluticasone propionate nasal spray in treatment of patients with nasal polyposis. The treatment was efficient in improving many symptoms but in contrast to our study they did not observe any significant changes in smell function of patients receiving Fluticasone compared to placebo groups. It is thought that topical steroid has minimal effect on the olfactory system [29]. On the other hand, systemic steroids have proven effects on restoring the smell function although the effect is not persistent [30].

Efficacy of different surgical methods has been compared by researchers. Schriever et al. [31] compared the impact of nasal sinus and nasal septum surgery on sense of smell, assessed by "Sniffin' Sticks" as odor identification test. Their results disclosed that sinus surgery has significant beneficial effects but patients who underwent nasal septum surgery did not experience such beneficiaries. In a large prospective study comprised of 775 patients, Pade and Hummel [32] reported improvement in olfactory function (Sniffin' sticks test) of 23 % of patients after nasal sinus surgery and 13 % of subjects following septum surgery.

The alteration of the olfactory system via endoscopic surgery was evaluated by Klimek et al. [33]. In 31 patients, they used CCCRC test to assess the smell function and they witnessed that 3 months after surgery the smell function has been improved as a result of treatment. Regarding the combined surgical and medical treatment, some endeavors are available; Bonfils et al. [34] observed that combined medical and surgical treatment can significantly improve the smell function in a 5-year follow-up period.

The study conducted by Blomqvist et al. [35] compared the efficaciousness of medical treatment and combined surgical and medical treatment in ameliorating the olfactory function. They claimed that topical and oral steroid restore the sense of smell and surgery had no additional effect. They performed ESS unilaterally in the same patients that received systemic steroids, then they compared the olfactory function between operated and non-operated side. Some problems can be noted in their work: (1) mean Visual Analogue Score of their patients was higher compared to ours, indicating better smell function in their sample. Also, they did not represent any data regarding the number of patients who suffer from anosmia or hyposmia. Based on the literature, it could be suggested that patients with normal or moderate smell function, benefit less from surgical intervention [36]. (2) Polyp scoring was done endoscopically and it was different in the two sides. The authors claim that they excluded patients with polyp scores differed by more than 1 point. However, patients subjectively indicate a higher rate of obstruction on the side that surgery has been performed.

In contrast, another study that has been conducted with the same methods as the previous study showed that operated side obtained better olfaction compared to non-

operated side [37]. Our findings were consistent with the latter one and exhibited greater effect of combined therapy compared to medical therapy alone.

In conclusion, our observation delineated that combined treatment had a better effect than medical treatment in restoring smell function in patients with nasal polyposis.

Conflict of interest The authors have no conflicts of interest to declare pertaining to this article.

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