ORIGINAL CONTRIBUTION

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Comparative study on the effectiveness of Coblation-assisted turbinoplasty in allergic rhinitis*

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SUMMARY

Objectives: *To evaluate the efficacy of adding Coblation-assisted inferior turbinoplasty to a medical treatment regimen for symptoms associated with hypertrophic inferior turbinates.*

Study design/setting: *Prospective, open-label, non-randomized trial with outpatient treatment. Patients were assigned to treatment groups in order of enrolment into the study.*

Subjects and Methods: *From June 2007 to June 2008, 220 patients with allergic rhinitis and hypertrophic inferior turbinates were enrolled and assigned into two groups: the surgical group who received radiofrequency thermal ablation inferior turbinoplasty and medical therapy, and the medical group who received medical therapy only. Groups were further divided into two allergen types based on antigen sensitivity: perennial and seasonal. Subjective complaints (nasal obstruction, itching, rhinorrhea, sneezing), clinical rhinoendoscopy and rhinomanometry tests results were recorded at the start of the study and 2 months post-treatment. Effect sizes for the mean improvements after treatment were tabulated for all groups.*

Results: *All study outcomes improved within all groups. Comparison between medical and surgical groups showed higher improvement in both perennial and seasonal, respectively, in nasal obstruction, sneezing, rhinomanometry, and rhinomanometry after NPT. Itching improved only in perennial allergen type. Rhinoendoscopy clinical score showed improvement in surgical group over medical group in both allergen types.*

Conclusion: *Coblation-assisted turbinate reduction is a promising adjunct to medical therapy in patients with persistent symptoms associated with allergic rhinitis. Patients undergoing this surgery had greater reduction of symptoms than patients receiving medical therapy alone, where patients with perennial allergies appeared to benefit most.*

Key words: allergic rhinitis, perennial, seasonal, bipolar radiofrequency, turbinoplasty

INTRODUCTION

Allergic rhinitis (AR) can significantly reduce nasal airflow and quality of life. A number of European and US studies have reported that 10% to 25% of the population experiences chronic nasal obstruction due to allergy [1-3]. Inferior turbinate hypertrophy (ITH) is a common finding in this setting. Drug therapy, including modern antihistamine therapies and/or nasal steroids, allergen avoidance, and desensitization are common methods of treatment, but for calcitrant cases, surgical therapy is indispensible. There are many different invasive approaches to ITH treatment including total or partial turbinectomy, submucosal turbinectomy, turbinoplasty, and turbinate tissue ablation using laser, cryosurgery, or electrocautery [4,5]. All of these surgical methods typically satisfactorily relieve the nasal obstruction, but can be accompanied by a multitude of adverse effects such as bleeding, pain, crust formation, synechia, and empty nose syndrome [4,6].

The effectiveness and complications of using electrosurgery for surgically treating patients with allergic rhinitis has recently been reported [7]. Although surgical results are generally considered satisfactory, study investigators often utilize subjective measures to assess outcomes, and few if any of the studies included a control group. The aim of this study was to determine whether patients with allergic rhinitis and ITH would experience a greater reduction in signs and symptoms once submucosal surgical treatment of inferior turbinates was added to standard medical therapy. The efficacy of the treatment was measured by evaluating subjective nasal symptoms, rhinomanometric values after specific nasal provocation tests (NPTs), and rhinoendoscopy.

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MATERIALS and METHODS

Study subjects

Between June 2007 and June 2008, 220 patients (137 male) over the age of 18, having persistent moderate to severe AR as based on Allergic Rhinitis and its Impact of Asthma document and the European Academy of Allergology and Clinical Immunology criteria (ARIA/EAACI) [8] with turbinate hypertrophy, were enrolled into the study. All participants had positive skin tests for perennial house-dust mites allergens (*Dermatophagoides pteronyssinus* or *Dermatophagoides farinae*) or seasonal plant allergens (*Graminacee* or *Parietaria*) and had specific IgE for the major allergen 3-4 class (Rast-CAP System EIA method, Pharmacia, Uppsala, Sweden). Patients did not receive any continuous medical therapy (maximum 6 antihistamine tablets and/or 10 steroid nasal puffs/nostril per month) for their allergy for six months preceding the study. All patients met the following criteria before being included in the study: nasal symptoms (nasal obstruction, hydrorhinorrea, sneezing, and itching) with a score of 5 and higher on a visual analogue scale 0-10 (VAS); nasal resistances values of greater than 0.25 (measured at rhinomanometry in basal condition and after NPT); and an endoscopic clinical score greater than 2 (1 = small turbinate with no contact with septum or nasal floor; 2 = mild hypertrophic turbinate with contact with septum; 3 = moderate hypertrophic turbinate with contact with septum and nasal floor; 4 = severe hypertrophic turbinate with contact with septum, nasal floor and superior compartment with complete nasal blockage). Patients with non-AR turbinate hypertrophy or nasal obstruction due to other reasons such as septal deviations, as well as those with coagulopathy disorders, severe systemic disease, infection, and oncological diseases were excluded from this study. The study was approved by the Review Board of the Eugenio hospital in Rome, Italy. All participants signed informed consent.

Study design

This was a prospective, open-label, non-randomized trial with outpatient treatment. Patients were assigned to treatment groups in the order of their enrollment. Participants were assigned to two matched homogenous groups (surgical and medical) of 110 patients each. During the study, both groups received standard allergy medications (desloratadine 5 mg tablet and mometasone nasal spray 50 mcg/nostril daily) for 60 days. Prior to the start of pharmacotherapy, patients in the surgical group underwent surgical reduction of the inferior turbinates. Both groups were asked to report side effects during the study.

Procedure

Carbocaine on a cotton swab was used topically to anesthetize the inferior turbinate mucosa. This was followed by an injection of the same anesthetics into the inferior turbinate. The Coblation II controller was used with Reflex Ultra 45 wand as the study device (ArthroCare, Austin, TX, USA). The controller power level was set to 6 and a small amount of saline solution was applied to the tip of the wand. A nasal endoscope 0° was used to access and view the nasal cavity, and the wand was inserted at the anterior part of the inferior turbinate. The wand was activated on ablation mode and moved on the medial, superior, and inferior compartments, toward the posterior aspect of the turbinates. Caution was exercised to avoid the lateral portions of the turbinates due to their important physiologic role [9]. The wand was only inserted once to reduce the mucosal damage (single insertion site technique, SIS).

Clinical outcomes

At the beginning of the study (time T_0), participants were asked to score the severity of the subjective outcomes (nasal obstruction, hydrorhinorrea, sneezing and itching) from 0 to 10 on a visual analogue scale (VAS). Objective outcomes (basal rhinomanometry and nasal provocation test rhinomanometry) were measured to determine the nasal passage resistance.

Rhinomanometry (RM) measures nasal airflow and pressure during respiration [10-12]. These measurements allow the calculation of the mean pressure, volume, work, and resistance associated with each breath. By comparing resistances between the nasal passages as well as the total nasal resistance, the physician can determine the level of involvement of each nasal passage in the patient's symptoms [13]. This study used active anterior RM. Active airflow RM mimics nasal physiology by using the patient's own respiration [13]. The anterior approach places a transducer in the nostril not being tested. Transnasal pressure differences and nasal airflow are recorded at the same time for each side and the dynamic changes of airway resistance are assessed. This method is usually well tolerated [13].

The nasal provocation test (NPT), used to determine the change in nasal allergen sensitivity [14], was performed by administering the offending antigen to the nasal cavity and measuring the mucosal response. A rhinoendoscopic clinical score was determined for each participant at the beginning

Table 1. Patient demographics.

	Perennial Allergen			**Seasonal Allergen**		
	Medical (n=60)	Surgical (n=60)	p-value	Medical (n=50)	Surgical (n=50)	p-value
Sex						
Male	40 (67%)	37 (62%)	0.57	31 (62%)	29 (58%)	0.68
Female	20 (33%)	23 (38%)		19 (38%)	21 (42%)	
Age						
(Mean ± SD)	39.03 ± 7.68	41.43 ± 6.98	0.08	39.42 ± 6.26	41.14 ± 6.05	0.17
	[23-54]	[23-54]		[25-51]	[27-51]	

Table 2. Subjective treatment outcomes for each study group and allergen subgroup.

		Medical Group			Surgical Group			Between Groups	
	Symptom	Improvement	Within Group p-value	Within Group Effect Size	Improvement	Within Group p-value	Within Group Effect Size	Between Group p-value	Between Group Effect Size
Perennial Allergen	Nasal Obstruction	3.87 ± 1.50	<0.001	4.08	7.58 ± 1.40	<0.001	11.06	<0.001	2.47
	Itching	4.20 ± 1.60	<0.001	3.67	5.07 ± 1.40	<0.001	5.37	0.002	0.54
	Rhinorrhea	4.75 ± 1.61	<0.001	4.08	5.33 ± 1.30	<0.001	6.40	0.058	0.36
	Sneezing	3.75 ± 1.40	<0.001	3.26	4.48 ± 1.80	<0.001	3.39	0.012	0.52
Seasonal Allergen	Nasal Obstruction	3.54 ± 2.03	<0.001	2.36	7.06 ± 1.42	<0.001	7.76	<0.001	1.73
	Itching	4.36 ± 1.71	<0.001	4.00	4.94 ± 1.63	<0.001	4.02	0.122	0.34
	Rhinorrhea	4.60 ± 1.55	<0.001	4.74	5.20 ± 1.44	<0.001	7.32	0.076	0.39
	Sneezing	3.88 ± 1.22	<0.001	3.84	4.26 ± 2.03	<0.001	2.58	0.041	0.31

of the study by characterizing the obstruction based on the contact of the inferior turbinate with the nasal septum, where 1 = small turbinate with no contact with septum or nasal floor; 2 = mild hypertrophic turbinate with contact with septum; 3 = moderate hypertrophic turbinate with contact with septum and nasal floor; and 4 = severe hypertrophic turbinate with contact with septum, nasal floor and superior compartment with complete nasal blockage. All of the study questionnaires and tests were repeated two months after initiating care (time T_1).

Statistical analysis

For all subjective and objective outcomes, the Wilcoxon non-parametric test was used to evaluate the differences between T_0 and T_1 within each group, while the Mann-Whitney non-parametric test was used to evaluate the mean differences between surgical and medical groups. Chi-square or the Wilcoxon Signed Ranks were used to evaluate the rhinoendoscopy clinical scores. The data was stratified by allergen type (perennial and seasonal) for analysis. Significance level was set at 0.05 to test the null hypothesis that there would be no significant difference in reduction of objective and subjective nasal symptoms between surgical and medical groups.

Effect sizes between the groups were calculated by dividing the difference between the mean improvements of the surgical group and the medical group by the standard deviation of the medical group. Effect sizes are often categorized into small [0.2], moderate [0.5], and large [0.8]. Based on these numbers, Kazis [15] infers that when comparing two groups (alpha = 0.05 and power = 0.80), detection of a small effect size will require 400 subjects per group. This number decreases to 64 for a moderate effect size and to 26 for a large effect size.

Statistical analyses were conducted using the SPSS Statistics software, version 17.0 (Chicago, IL, USA).

RESULTS

The study included 220 patients, who ranged in age from 23-54 years (Table 1). At baseline statistically significant differences were detected between treatment groups for itching (perennial allergen: medical: 8.90 ± 1.15, surgical: 9.30 ± 0.94, p = 0.05; seasonal allergen: medical: 8.86 ± 1.09, surgical: 9.14 ± 1.23, p = 0.08) and rhinorrhea (seasonal allergen: medical: 9.10 ± 0.97, surgical: 9.54 ± 0.71, p = 0.02), but the differences in scores did not appear clinically important.

Participants reported no pain during the procedure. Paracetamol (500 mg) was prescribed for post-procedure pain on an as-needed basis. A few participants reported minor itching at the site of the procedure. None of the participants experienced any major side effects during or after the procedure, including bleeding, synechia formation, and rhinitis sicca. Only a small crust at the point of insertion of the device was noted in some (perennial = 6, seasonal = 6) patients 5-7 days post operatively. During the post-surgical evaluation, shrinkage of the inferior turbinate was apparent in all cases.

For subjective complaints (nasal obstruction, sneezing, rhinorrhea, and itching), the improvement was significant within each group, with higher improvements observed in the medical group (Table 2). When the surgical group was compared to the medical group, the differences reached statistical significance with high effect sizes for nasal obstruction for both perennial [2.47] and seasonal [1.73] allergen types. For other subjective complaints such as itching and sneezing, symptoms tended to be significantly improved, with a medium effect size in the surgical group over the medical group for both perennial and seasonal allergen types.

The improvements shown by rhinomanometric assessments with and without NPT within each group were significant with high effect sizes (Table 3). The highest effect sizes (0.78 for rhinomanometry and 1.04 for rhinomanometry with NPT) were seen in the perennial allergen type where the between group p-values were significant ($p < 0.001$). For patients with seasonal allergies, the effect attributed to surgical treatment was of medium size.

The rhinoendoscopy clinical scores were improved by 2 or 3 levels in 90% of the patients in the surgical group compared to 9-12% of patients in the medical group (Table 4).

DISCUSSION

Concurrent use of surgical ITR along with medical therapy was found to be more beneficial than medical therapy alone in patients with allergic rhinitis and turbinate hypertrophy. With

Table 3. Objective (rhinomanometry) outcomes for each study group and allergen subgroup.

		Medical Group			Surgical Group			Between Groups	
	Sign	Improvement	p-value	Effect Size	Improvement	p-value	Effect Size	p-value	Effect Size
Perennial	Rhinomanometry (Pa*cc/s)	0.75 ± 0.20	<0.001	4.76	0.90 ± 0.20	<0.001	6.20	<0.001	0.78
Allergen	Rhinomanometry after NPT	1.40 ± 0.50	<0.001	9.94	1.92 ± 0.20	<0.001	19.06	<0.001	1.04
Seasonal	Rhinomanometry	0.73 ± 0.30	<0.001	4.80	0.87 ± 0.18	<0.001	5.73	0.04	0.47
Allergen	Rhinomanometry after NPT	1.71 ± 0.38	<0.001	12.29	1.90 ± 0.25	<0.001	11.94	0.012	0.50

the exception of itching in the seasonal allergen type and rhinorrhea in both allergen types, subjective complaints improved significantly more in the surgical group as compared to the medical group. Objective measures of nasal obstruction were also significantly improved in the surgical group over the medical group, with the greatest improvement occurring in endoscopic nasal obstruction score.

Submucosal radiofrequency ablation causes shrinkage of the inferior turbinates by destroying and vaporizing soft tissue. The effects are immediate volume reduction and tissue fibrosis in the longer term [16]. This fibrosis elicits contracture and anchoring of the mucosa to the periosteum, which will in turn reduce the possibility of swelling and congestion in turbinates. The blood sinusoids involved in congestion are also reduced. By sparing the glandular-rich lateral aspects of the inferior turbinates and applying the surgical treatment to medial and inferior aspects, minimal damage to the glandular structure occurs and the physiology of the inferior turbinates is largely maintained [9]. The post-procedure hypo-responsiveness of the mucosa is probably due to disruption of neurosensorial fibers and receptors of the nasal mucosa, as well as a reduction of inflammatory cells, which is a result of radiofrequency ablation of the submucosa. Reduction in erectile venous tissue of the inferior turbinates has also been suggested to play a role in sustained improvement [16].

Inferior turbinate mucosa plays an important role in the nasal physiology and protecting this tissue should be an important objective. Using submucosal reduction methods such as the one applied in this study greatly enhances preservation of the mucosa. Use of a minimally invasive wand entry method is likely to be beneficial. Back [16] has performed the procedure with 3 small entries at 90° angle in relation to the mucosa to reduce the mucosal damage as much as possible. In this study, we introduced the wand into the submucosa only once and treated all turbinate compartments (head, superior, medial, inferior, and posterior) from there. By limiting to only one entry (SIS), mucosal irritation is minimized, which we believe critical to treating AR patients.

Table 4. Rhinoendoscopy Clinical Score for each study group and allergen subgroup.

	Improvement	Medical Group	Surgical Group	p-value
Perennial	0	26 (43%)	0	<0.001
Allergen	1	29 (48%)	6 (10%)	
	2	5 (9%)	33 (55%)	
	3	0	21 (35%)	
Seasonal	0	20 (40%)	0	<0.001
Allergen	1	24 (48%)	5(10%)	
	2	6 (12%)	18 (36%)	
	3	0	27 (54%)	

A major problem in allergic rhinitis is mucosal reactivity to allergens; therefore reducing this reactivity is one of the goals of therapy. Submucosal ablation, as used here, disrupts neurosensorial fibers and receptors, reduces inflammatory cells, and destroys the venous sinusoids, which all play important roles in mucosal congestion, and as such reduces reactivity to stimuli. To better demonstrate turbinate tissue's decreased responsiveness to stimuli, specifically allergens, after the therapy, rhinomanometry was utilized after an NPT test [14]. In rhinomanometry, higher test results are indicative of more obstruction. The baseline values showed higher rhinomanometric values after NPT tests, as expected, compared to those without NPT in both allergen types; however, the differences between study groups for corresponding tests were not significant.

At two months, all rhinomanometry scores improved significantly in all study groups and allergen types, but improvement was significantly higher in the surgical group (Table 3). The improvement in rhinomanometry after NPT is much more pronounced than the one without NPT in both groups. This observation suggests that the treatment in general, with or without ITR, reduces allergen reactivity in the nasal cavity. The second point of interest is that the higher improvement in the rhinomanometry test is seen in perennial allergen type who underwent coblation ITR. This improvement can be explained by the nature of the allergen to which these patients are susceptible. Perennial allergens are present in the patients' environment all year round and cause a more sustained allergic response, which can lead to more pronounced hypertrophy and reactivity in the inferior turbinate submucosa compared to seasonal allergen. Due to this fact turbinate hypertrophy due to perennial allergy responds more favorably than that caused by seasonal allergy when treated with the soft tissue reduction caused by tissue ablation. Surgical reduction of this hypertrophic tissue in perennial allergy patients appears to result in a larger degree of improvement when compared to seasonal allergen patients.

CONCLUSION

Coblation-assisted inferior turbinoplasty, in conjunction with medical therapy, improves the nasal flow more effectively when compared to medical treatment alone in persistent moderate to severe AR. In particular, local reactivity, as measured with NPTs, was noticeably reduced. This reduction was more pronounced in patients suffering from perennial allergy than in those with seasonal allergy.

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