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Long-term Results of Radiofrequency Turbinoplasty for Allergic Rhinitis Refractory to Medical Therapy

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Objective: To study the long-term outcomes of radiofrequency (RF) turbinate surgery for the treatment of allergic rhinitis refractory to medical therapy.

Design: A retrospective review of a prospective data set.

Setting: Tertiary referral center.

Patients: A total of 146 patients with allergic rhinitis refractory to medical therapy undergoing RF turbinoplasty were included.

Main Outcome Measures: A standard 0 to 10 visual analog scale (VAS) was used to assess the allergic symptoms including nasal obstruction, rhinorrhea, sneezing, itchy nose, and itchy eyes prior to RF turbinoplasty and at 6 months and 5 years postoperatively. The long-term clinical benefits and complications were reviewed. Statistical analysis was determined by repeated measures of analysis of variance.

Results: No adverse reactions such as bleeding, infection, adhesions, or olfactory change were encountered. Of the 146 patients, 119 were followed up at least 5 years postoperatively. Five years after treatment, 101 patients had complete data available for analysis. They reported improvement of nasal obstruction, with the mean (SD) VAS score decreasing from 6.65 (1.92) to 4.45 (2.54). The mean (SD) VAS score changed from 5.90 (2.79) to 3.79 (2.97) for rhinorrhea; from 5.15 (2.77) to 3.50 (2.77) for sneezing; from 3.67 (3.03) to 2.41 (2.30) for itchy nose; and from 2.94 (3.02) to 2.02 (2.42) for itchy eyes (all $P < .001$, paired t test with Bonferroni correction).

Conclusion: This long-term study has demonstrated that the RF turbinoplasty for allergic rhinitis appears to be an effective and safe tool for treating allergic rhinitis refractory to medical therapy.

Arch Otolaryngol Head Neck Surg. 2010;136(9):892-895.
Published online July 19, 2010.
doi:10.1001/archoto.2010.135

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RADIOFREQUENCY (RF) SURGERY has increased in popularity for the treatment of otolaryngological diseases. Radiofrequency preserves the overlying mucosa, decreases operative morbidity, causes only minor postoperative discomfort, and has a low risk of complications for patients.[1-3] Radiofrequency provides a new surgical tool, designed to create a well-circumscribed submucosal scar that heals normally without the removal of tissue. The target site is stably formed with tissue-reduced volume at approximately 3 weeks postoperatively.[4] Since Li et al[5] first reported the outcomes of RF volumetric tissue reduction for treatment of turbinate hypertrophy, the safety and efficacy of this procedure has been well demonstrated with respect to not only subjective improvement of symptoms but also objective changes in the nasal function.[6] Radiofrequency surgery is already in widespread clinical use.

In 2003, we further demonstrated the feasibility and efficacy of RF turbinate surgery in patients with allergic rhinitis refractory to medical therapy.[7] Most of the published literature on RF turbinate surgery has a relatively short follow-up. However, only long-term studies will ultimately determine whether this novel strategy results in valuable outcomes. To our knowledge, the long-term efficacy of RF turbinate surgery in patients with nasal allergy has not been addressed in the literature. The purpose of this study was to evaluate a group of patients treated with RF turbinoplasty with respect to allergic symptoms, patient satisfaction, and long-term complications after a minimum 5-year follow-up period.

METHODS

STUDY DESIGN

Following institutional review board approval, a prospective study was conducted on patients with allergic rhinitis refractory to medical therapy who underwent RF turbinoplasty from February 2000 to April 2003 at the Chang Gung Memorial Hospital–Kaohsiung Medical

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Center, Kaohsiung, Taiwan. Since 2000, all of our patients treated with RF turbinate surgery have undergone routine assessment at our clinic before and after treatment. This assessment includes evaluation of common allergic symptoms such as nasal obstruction, rhinorrhea, sneezing, itchy nose, and itchy eyes. Patients were asked to complete a global patient assessment (GPA) questionnaire designed to monitor satisfaction after undergoing a procedure. Patients who did not return for follow-up were contacted by telephone. Only those patients who completed both preoperative and postoperative surveys and postoperative GPA forms at least 5 years after the procedure were enrolled.

PATIENT SELECTION

All of the patients with allergic rhinitis had typical clinical symptoms and signs, as well as a high titer of specific IgE antibodies for house dust and/or other antigens. They had been previously treated with conventional medical management without satisfactory improvement for at least 3 months before surgery. Patients with systemic disease, previous turbinate surgery, severe nasal septal deviation, nasal polyposis or chronic rhinosinusitis, upper respiratory tract infection within a week preoperatively, a history of radiotherapy, or oral steroid use were excluded. Before surgery, the patients were also assessed by an ophthalmologist to exclude any ophthalmological disorder that may induce the symptom of eye pruritus such as trichiasis, entropion, blepharitis, blepharoconjunctivitis, keratoconjunctivitis, or dry eye syndrome.

The medical records and telephone survey of all patients with allergic rhinitis who responded poorly to medical therapy and were treated with RF turbinoplasty were reviewed. Patients with missing preoperative or postoperative data were eliminated from the study. Those patients who lacked postoperative surveys were contacted at a minimum of 5 years following their surgery to complete their data. Treatment was regarded to have failed if the patient underwent additional surgery to address his or her allergic symptoms following RF turbinate surgery, failed to improve in at least 1 of the specified common allergic symptoms, worsened in any 1 of the common symptoms, or did not satisfy the surgical results.

SURGICAL PROCEDURES

All procedures were performed with the use of local anesthesia by one of us (H.-C.L.). The surgical procedure was performed according to our previously described techniques.[7] Radiofrequency energy was delivered at a frequency of 465 Hz with an RF generator (model S2 Radiofrequency Control Unit; Somnus Medical Technologies Inc, Sunnyvale, California) and an SP 1100 turbinate handpiece (40-mm needle electrode, consisting of a 10-mm active portion, 30-mm insulated part, and 2 thermocouples).

ASSESSMENTS AND STUDY END POINTS

Patient surveys were conducted using a standard 0 to 10 visual analog scale (VAS), with 0 representing no symptoms and 10, the most severe symptoms. Symptoms assessed preoperatively and during follow-up visits included nasal obstruction, rhinorrhea, sneezing, itchy nose, and itchy eyes. All surgical candidates were given surveys prior to any surgical intervention.

At the 5-year postoperative follow-up, patients were also asked to complete a GPA questionnaire, which assessed patient satisfaction by asking (1) if given the choice, would the patient choose to undergo the same procedure (yes/not sure/no) and (2) how would the patient rank his or her overall experience on a scale of −5 to +5, with −5 being the worst outcome possible and +5 being the best outcome possible. Although the GPA questionnaire contained additional parameters, we chose to use only these 2 in the study prior to collecting or analyzing any data.

STATISTICAL ANALYSIS

Results were expressed as mean (SD). Comparisons of scores of the common symptoms of allergic rhinitis including nasal obstruction, rhinorrhea, sneezing, itchy nose, and itchy eyes generated with a 0 to 10 VAS with preoperative and 5-year postoperative anchor points were made using repeated analysis of variance. When significant differences were noted, individual means were compared using the paired *t* test with Bonferroni correction. Differences were considered to be statistically significant when the *P* value was less than .05.

RESULTS

As of April 2008, there were 146 patients with allergic rhinitis refractory to medical treatment who underwent RF turbinoplasty with more than 5 years of follow-up. Some patients experienced mild numbness over the teeth (27 of 146; 18.5%) during the operation. No immediate complications such as acute bleeding or infection were encountered, nor were any long-term adverse reactions, including recurrent epistaxis, synechiae, nasal dryness, bone necrosis, atrophic rhinitis, or olfactory change, encountered 5 years after surgery. Twenty-seven patients were lost to follow-up. We defined a favorable response as both improvement of a least 1 of the common allergic symptoms, without worsening of any of the remaining allergic symptoms and patient satisfaction with the surgical results. The 6-month and 5-year response rates were 77.3% (92 of 119) and 60.5% (72 of 119), respectively.

Of the 119 patients (58 women and 61 men; mean age, 30.2 years), 17 went on to receive other additional nasal surgery including laser turbinectomy, submucosal resection of the turbinate, and alternative Chinese corrosive therapy because of no obvious response to the RF surgery. One patient was diagnosed as having hepatocellular carcinoma 3 months postoperatively. These 18 patients were excluded from the study. Thus, 101 patients (49 female and 52 male; mean age, 29.1 years) had a minimum follow-up of 5 years and complete data for the final analysis. Patients reported improvement in nasal obstruction, rhinorrhea, sneezing, itchy nose, and itchy eyes ($P<.001$ for all). The surgical results of these 101 patients are given in the **Table**.

Patient satisfaction with RF turbinoplasty was measured using the 5-year follow-up GPA form questionnaire. Favorable results were based on positive responses to the following 2 parameters: (1) whether patients would undergo the same procedure again and (2) how patients ranked overall experience with their procedure based on a scale extending from −5 ("worst outcome I could have expected") to +5 ("best outcome I could have expected"). Of the allergic patients, 58 (57.4%) responded yes to having the same procedure performed again, while 38 (37.6%) responded no and 5 patients (5.0%) were not sure. The mean (SD) score for the sec-

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Table. The VAS Scores of the Symptoms of Allergic Rhinitis at Each Follow-up After Radiofrequency Turbinoplasty[a]

Symptom	Pretreatment	6 Months	5 Years	*P* Value[b]
Nasal obstruction	6.65 (1.92)	2.74 (1.72)	4.45 (2.54)	<.001
Rhinorrhea	5.90 (2.79)	2.84 (2.47)	3.79 (2.97)	<.001
Sneezing	5.15 (2.77)	2.51 (2.12)	3.50 (2.77)	<.001
Itchy nose	3.67 (3.03)	1.51 (1.87)	2.41 (2.30)	<.001
Itchy eyes	2.94 (3.02)	1.09 (0.69)	2.02 (2.42)	<.001

Abbreviation: VAS, standard 0 to 10 visual analog scale.
[a] Data are given as mean (SD) unless otherwise specified.
[b] By repeated measures of analysis of variance.

ond question on the GPA was +2.40 (1.93), a significantly positive response. Results for both parameters revealed that patient satisfaction was still significant 5 years after the operation.

COMMENT

Radiofrequency surgery has become an increasingly popular alternative to classic turbinate surgery, such as cryosurgery, electrocautery, laser turbinectomy, partial or total turbinectomy, and vidian neurectomy. Its popularity is based on the perception of improved patient satisfaction and decreased postoperative morbidity and pain, as well as the possibility of avoiding direct mucosal manipulation. A previous study on allergic rhinitis showed significant improvement with a 1-year follow-up.[7] However, long-term follow-up is necessary to assess the true value and efficacy of this technology. We thus performed an assessment with a minimum follow-up of 5 years. To our knowledge, this series is the first reported long-term study of RF turbinate surgery for medically intractable allergic rhinitis. Our results showed that patients' improvement in symptom scores persisted 5 years after surgery.

Although this group of patients had a significant failure rate during the follow-up period, patients who had poor response to RF turbinoplasty were still candidates for additional classic turbinate surgery. Because RF is a minimally invasive technique, it does not preclude patients from undergoing secondary laser turbinectomy, submucosal resection of the turbinate, or other traditional procedures. For the 17 patients in this study who received additional nasal surgery to address their allergic symptoms, previous RF lesions did not hinder the additional turbinate surgery in any way. Furthermore, RF turbinoplasty was only performed once (1 procedure with 4 punctures) for each of the patients in this study. Whether repeated RF procedures can enhance surgical outcome will have to be determined by further investigation.

The increasing prevalence of allergic rhinitis and its impact on individual quality of life and social costs, as well as its role as a risk factor for related respiratory diseases, underscore the need for long-term improved treatment options for this disorder. Upper and lower respiratory diseases, including asthma, sinusitis, and otitis media with effusion, frequently complicate allergic rhinitis. The close association of nasal allergies with these conditions has been supported by extensive epidemiologic evidence.[8] The present study focused solely on the long-term outcomes of RF turbinoplasty with regard to the common symptoms of allergic rhinitis. Whether the benefits of this procedure could extend to patients with the aforementioned associated conditions to help prevent recurrent episodes and improve the response to therapy is a subject for further inquiry.

Allergic ocular symptoms, common in patients with allergic rhinitis, are associated with reduced quality of life and related economic costs.[9] In the conjunctival epithelium, an early type 1 hypersensitivity reaction occurs after allergen exposure. Progression to late-phase response, with recurrence of symptoms and infiltration of inflammatory cells, may occur 4 to 8 hours later.[10] Baroody et al[11] performed a double-blind, placebo-controlled clinical trial on 20 patients with allergic rhinitis challenged in 1 nostril with antigen. The response was monitored in both nostrils and in both eyes. They found that nasal allergen challenge releases histamine at the site of the challenge, which probably initiates both a nasonasal and a nasal ocular reflex. These reflexes are reduced by the application of an H_1-receptor antagonist at the site of the challenge. Reflex mechanisms within the nose have been shown to occur universally in response to nasal challenges with antigen. Nasal challenge with antigen induces a reflex in the contralateral nasal cavity, known as the nasonasal reflex. This reflex can be initiated by nasal challenge with cold, dry air, and histamine.[12,13] The eye symptoms of patients with allergic rhinitis arise via a combination of mechanisms, including direct contact of natural pollen with the conjunctiva and in response to stimulation originating in the nose via the naso-ocular reflex. Our clinical data indicate that the decrease of eye symptoms in 43 of the 101 patients (42.6%) with allergic rhinitis can be achieved by RF turbinoplasty 5 years after the surgery. Mechanisms of relief of allergic ocular symptoms following RF turbinate surgery include the following possibilities: (1) RF tissue volume reduction of the turbinates decreases the superficial surface area available for allergen contact. (2) Radiofrequency energy transduction within the submucosa of the inferior turbinate leads to scar formation, obliteration of the submucosal small vessels, and destruction of the submucosal glands. As the superficial submucosal layer of the inferior turbinate is thought to be the site of the allergic reaction,[14] disruption of this layer by RF may contribute to its effects on allergic ocular symptoms. (3) In addition, an inhibitory effect on the local immune response or naso-ocular reflex or disruption of the pas-

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sage of allergen and allergic mediators toward the eyes via nasolacrimal system may occur. Further investigations are needed.

The study suffered from many limitations. This is a prospective study in which patients served as their own control. The symptomatic improvements were compared with pretreatment levels of their allergic burdens. An ideal study would have been a prospective, double-blinded, controlled study, which is difficult and impractical to perform over the long term. A second limitation of this study is the number of patients who were lost to follow-up. Based on an "intent-to-treat" analysis of all 146 patients, the 5-year response rate drops to 49.3%. However, we believe that the "true" response rate after RF turbinoplasty is closer to the stated 60.5%. Though we have no data to support this, it is conceivable that many patients who were cured of their allergic symptoms were also those least likely to participate in long-term follow-up. Another limitation of this study was that we did not include long-term changes of objective nasal function or local allergic mediators to validate the clinical benefits after RF turbinoplasty. Ciprandi et al[15] have reported that a significant, very strong correlation has been observed between VAS scores for allergic symptoms and nasal airflow resistance via rhinomanometry. They concluded that the VAS for assessing allergic symptoms, especially in nasal obstruction, may be considered a reliable predictor in the absence of objective rhinologic examinations. Their study provides evidence to support the use of the VAS as an outcome variable in clinical practice or research. In this study, we used the VAS to quantify the improvement of the patients' allergic symptoms after RF turbinoplasty. The 6-month and 5-year response rates were 77.3% and 60.5%, respectively. More objective studies should be conducted to validate the clinical results in the future.

Although the outcome of RF turbinoplasty for patients with allergic rhinitis responding poorly to medical therapy declines with time, we found that the improvement in symptom scores in the group as a whole was still significant 5 years after the surgery. This study demonstrates the value of RF turbinoplasty as an effective and safe tool for treating allergic rhinitis refractory to medical therapy over the long-term.

Submitted for Publication: November 25, 2009; final revision received March 15, 2010; accepted April 29, 2010.
Published Online: July 19, 2010. doi:10.1001/archoto.2010.135
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Author Contributions: Dr H.-C. Lin had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* H.-C. Lin. *Acquisition of data:* H.-C. Lin, P.-W. Lin, Su, and Chen. *Analysis and interpretation of data:* H.-C. Lin, Friedman, Chang, and Pulver. *Drafting of the manuscript:* H.-C. Lin, P.-W. Lin, Su, and Chen. *Critical revision of the manuscript for important intellectual content:* Friedman, Chang, and Pulver. *Statistical analysis:* Chang. *Administrative, technical, and material support:* H.-C. Lin, P.-W. Lin, Su, and Chen.
Financial Disclosure: Dr Friedman received a grant from TriCord Pharmaceuticals for a study on treatment of chronic sinonasal symptoms and is a member of the speaker's bureau for GlaxoSmithKline.
Previous Presentation: This study was presented in part as a poster at the at the 2008 Annual Meeting of the American Academy of Otolaryngology–Head and Neck Surgery Foundation; September 21-24, 2008; Chicago, Illinois.
Additional Contributions: Chih-Ying Su, MD, Chang Gung Memorial Hospital–Kaohsiung Medical Center, assisted in the sample and data collections.

REFERENCES

1. Kezirian EJ, Powell NB, Riley RW, Hester JE. Incidence of complications in radiofrequency treatment of the upper airway. *Laryngoscope*. 2005;115(7):1298-1304.
2. Nease CJ, Krempl GA. Radiofrequency treatment of turbinate hypertrophy: a randomized, blinded, placebo-controlled clinical trial. *Otolaryngol Head Neck Surg*. 2004;130(3):291-299.
3. Stuck BA, Starzak K, Verse T, Hörmann K, Maurer JT. Complications of temperature-controlled radiofrequency volumetric tissue reduction for sleep-disordered breathing. *Acta Otolaryngol*. 2003;123(4):532-535.
4. Powell NB, Riley RW, Troell RJ, Blumen MB, Guilleminault C. Radiofrequency volumetric reduction of the tongue: a porcine pilot study for the treatment of obstructive sleep apnea syndrome. *Chest*. 1997;111(5):1348-1355.
5. Li KK, Powell NB, Riley RW, Troell RJ, Guilleminault C. Radiofrequency volumetric tissue reduction for treatment of turbinate hypertrophy: a pilot study. *Otolaryngol Head Neck Surg*. 1998;119(6):569-573.
6. Rhee CS, Kim DY, Won TB, et al. Changes of nasal function after temperature-controlled radiofrequency tissue volume reduction for the turbinate. *Laryngoscope*. 2001;111(1):153-158.
7. Lin HC, Lin PW, Su CY, Chang HW. Radiofrequency for the treatment of allergic rhinitis refractory to medical therapy. *Laryngoscope*. 2003;113(4):673-678.
8. Skoner DP. Complications of allergic rhinitis. *J Allergy Clin Immunol*. 2000;105 (6, pt 2):S605-S609.
9. Smith AF, Pitt AD, Rodruiguez AE, et al. The economic and quality of life impact of seasonal allergic conjunctivitis in a Spanish setting. *Ophthalmic Epidemiol*. 2005;12(4):233-242.
10. Naclerio R. Intranasal corticosteroids reduce ocular symptoms associated with allergic rhinitis. *Otolaryngol Head Neck Surg*. 2008;138(2):129-139.
11. Baroody FM, Foster KA, Markaryan A, deTineo M, Naclerio RM. Nasal ocular reflexes and eye symptoms in patients with allergic rhinitis. *Ann Allergy Asthma Immunol*. 2008;100(3):194-199.
12. Philip G, Jankowski R, Baroody F, Naclerio RM, Togias AG. Reflex activation of nasal secretion by unilateral inhalation of cold dry air. *Am Rev Respir Dis*. 1993; 148(6, pt 1):1616-1622.
13. Baroody FM, Wagenmann M, Naclerio RM. Comparison of the secretory response of the nasal mucosa to methacholine and histamine. *J Appl Physiol*. 1993; 74(6):2661-2671.
14. Fukutake T, Yamashita T, Tomoda K, Kumazawa T. Laser surgery for allergic rhinitis. *Arch Otolaryngol Head Neck Surg*. 1986;112(12):1280-1282.
15. Ciprandi G, Mora F, Cassano M, Gallina AM, Mora R. Visual analog scale (VAS) and nasal obstruction in persistent allergic rhinitis. *Otolaryngol Head Neck Surg*. 2009;141(4):527-529.

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