

Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up With Subjective and Objective Assessment

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Objective: To assess the efficacy and morbidity of bipolar radiofrequency thermal ablation of the inferior turbinates in patients with nasal obstruction caused by turbinate hypertrophy. **Study Design:** Prospective, nonrandomized study and outpatient treatment. **Methods:** Twenty patients (age range, 23–77 y; median age, 52 y) enrolled in the study. There was one dropout. All the patients had nasal blockage despite medical treatment. Bipolar radiofrequency thermal ablation was delivered to inferior turbinates at 100 kHz with a voltage root mean square value of 168 to 182. The preoperative and postoperative nasal functions were investigated by immediate and long-term visual analogue scale (VAS) scores of symptom parameters, olfactory thresholds, saccharine transit time, rhinomanometry, and acoustic rhinometry. The follow-up was conducted at 1 week and 3, 6, and 12 months. **Results:** The VAS scores of subjective complaints (nasal discharge, itching, sneezing, crusting) decreased, and the VAS scores of evaluation of the effectiveness (frequency of nasal obstruction, degree of nasal obstruction, and patient satisfaction) increased statistically significantly in the 12-month follow-up without relapses. There were no adverse effects on nasal epithelial clearance time and olfactory functions. In rhinomanometry the changes in total nasal resistance and response to the vasoconstrictor agent were not statistically significant. In acoustic rhinometry the change in the sum of both nasal cavity volumes from nostril to 5 cm was statistically significant 6 and 12 months after the treatments. The difference between the preoperative and postoperative va-

soconstrictive effect was not statistically significant. **Conclusion:** The bipolar radiofrequency thermal ablation of inferior turbinates is a promising alternative, which should be considered when planning inferior turbinate interventions. **Key Words:** Bipolar radiofrequency thermal ablation, inferior turbinates, long-term follow-up.

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INTRODUCTION

Nasal obstruction in chronic hypersensitive rhinitis is frequently caused by mucosal hypertrophy. Several methods have been used to treat this hypertrophy. Intranasal steroids, antihistamines, chromones, and sympathomimetics have been suggested.^{1–3} Injections of corticosteroids provide a satisfactory relief of nasal obstruction in some patients, but they have no role in the treatment of chronic rhinitis because of a risk of severe complications.⁴ Thus, many patients with nasal obstruction caused by noninfective chronic rhinitis may become candidates for surgical turbinate interventions.

In their review, Hol and Hiuzing⁵ evaluated 13 surgical techniques that have been used for inferior turbinate hypertrophy over the past 130 years and concluded intratubinal turbinate reduction to be the method of choice. Any of the described techniques ought to achieve optimal volume reduction with preservation of function. However, it was difficult to draw a firm conclusion because of lack of controlled studies. The surgical methods are associated with varying morbidity, and the outcome of the various procedures is variable. The patient discomfort, cost of the treatment, and frequency and severity of complications related to these procedures must be weighed carefully. To date, it appears that there is no method of treatment which could be considered satisfactory for hypertrophied inferior turbinates.⁵

In recent years, office-based inferior turbinate reduction has regained popularity. Radiofrequency energy delivery can be performed on outpatient basis using local

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anesthesia without nasal packing, and it can be repeated if necessary. Radiofrequency thermal ablation (RFTA) treatments have been shown to be suitable for outpatient-based treatment of turbinates.^{6–8} Submucosally (intratubally) delivered radiofrequency energy in the inferior turbinate creates a focal lesion with no damage to adjacent structures (e.g., turbinate bone or mucosal surface).⁸ The circumscribed area of submucosal necrosis is replaced over time by fibroblasts as part of normal wound repair process. Wound contraction leads to turbinate volumetric reduction and relief of nasal obstruction. The other intent of tissue volume reduction is to induce submucosal fibrosis of the turbinate, which adheres the mucosa to the turbinate periosteum and reduces blood flow to the turbinate, rendering it less prone to swelling and edema. The work by Elwany et al.⁷ proved that RFTA induces fibrosis in the stroma of the turbinate while conserving the overlying epithelium.

The aim of the present study was to assess the subjective and objective efficacy and morbidity of bipolar radiofrequency thermal ablation (bRFTA) during a 12-month follow-up on an outpatient basis in patients with nasal obstruction caused by turbinate hypertrophy resulting from noninfective chronic rhinitis.

MATERIALS AND METHODS

The present study was a prospective, nonrandomized clinical trial. The study protocol was reviewed and approved by the Research Ethical Committee of the Department of Otorhinolaryngology—Head and Neck Surgery, University Central Hospital

of Helsinki (Helsinki, Finland). Written informed consent was obtained from all patients.

Study Group

The study included 20 patients with nasal obstruction resulting from noninfective chronic rhinitis and hypertrophied inferior turbinates. The median age of the patients at the time of the treatment was 52 years (age range, 23–77 y). Sixteen patients had noninfective, nonallergic rhinitis, and four had noninfective, allergic rhinitis. Six patients had had cryosurgery previously with dissatisfying results. All the patients had symptoms of nasal obstruction despite varying medical treatments (intranasal steroids, antihistamines, and/or sympathomimetics). The preoperative evaluation included a complete history and physical otorhinolaryngological examination with nasal endoscopy included. Nasal endoscopy was performed in each patient at the treatment day and 3 months after the treatment. Patients with other major nasal disease such as significant septal deviation, septal perforation, ala collapse, paranasal sinusitis, sinonasal tumors, middle turbinate disease (hypertrophy or concha media bullosa), or nasal polyposis were excluded. Additional exclusion criteria were history of rhinitis medicamentosa, nasal cancer and radiation therapy, oral steroid use, coagulation disorder, cardiac pacemaker, and anosmia.

Bipolar Radiofrequency Thermal Ablation Procedure

The treatments were delivered on an outpatient basis in the Department of Otorhinolaryngology—Head and Neck Surgery at Helsinki University Central Hospital. The patients had no restrictions in diet before surgery. No premedication was given. One otorhinolaryngological specialist (L.J.J.B.) performed all the

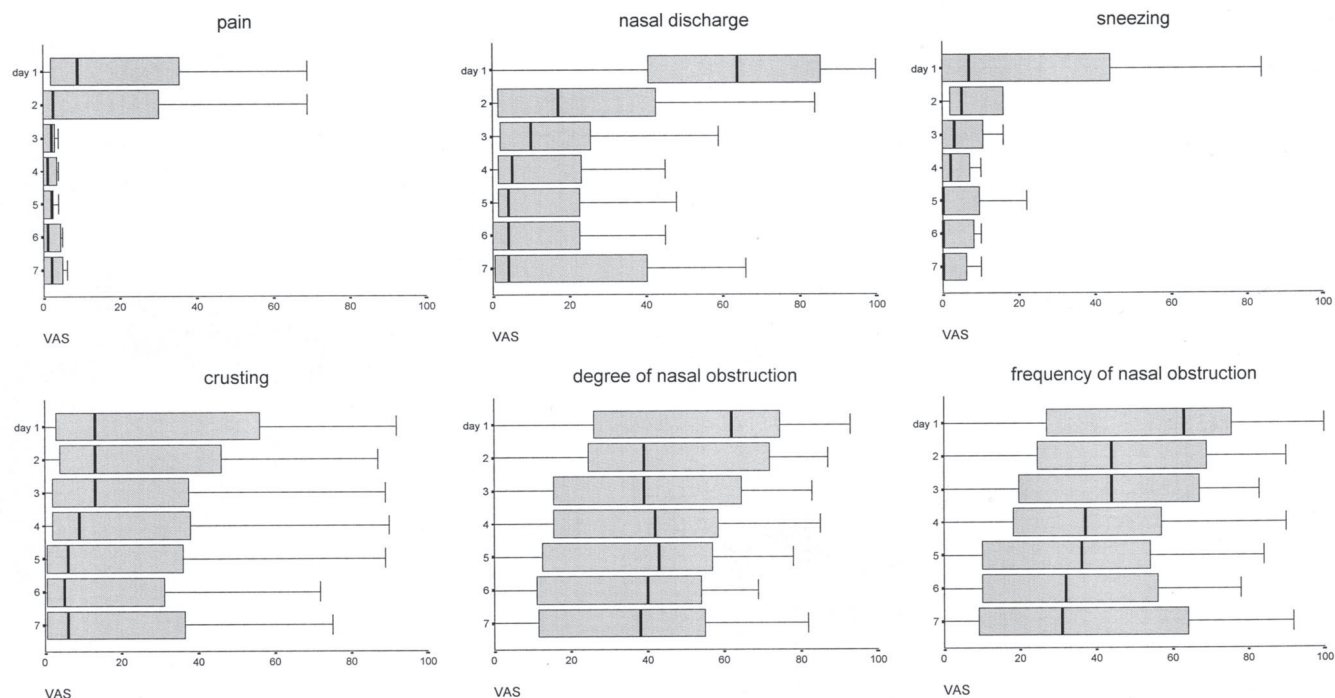


Fig. 1. Visual analogue scale (VAS) scores (0 = no symptoms, satisfied with the situation; 100 = extremely difficult, dissatisfying situation) of immediate postoperative nasal symptoms (pain, nasal discharge, itching, sneezing, crusting, frequency of nasal obstruction, and degree of nasal obstruction) related to the submucosal bipolar radiofrequency thermal ablations of the inferior turbinates (box plot). Day 1 = the treatment day; 2–7 = the days following the treatment day.

treatments. The nasal cavity was sprayed with lidocaine (10 mg/dose) (Xylocaine, AstraZeneca, Sweden) as a topical anesthetic. Local anesthetic, 40 mg/mL lidocaine hydrochloride (Lidocain, Orion, Finland), was applied in the sphenopalatine ganglion, ethmoidal area, and inferior meatus. In addition, a 24-gauge needle was used to inject 10 mg/mL lidocaine hydrochloride with 2 to 3 mL epinephrine (Lidocain) into the anterior and medial parts of the inferior turbinate. We used the ENTec Coblator Plasma Surgery System (Arthrocare Corp., Sunnyvale, CA) with a voltage range of 96 to 312 voltage root-mean-square (Vrms) value at 100 kHz and the ENTec Hummingbird wand. The patient was in supine position. The wand was damped with 2% lidocaine hydrochloride gel (Lidocain) to permit the plasma field to form during insertion. The intracellular saline maintains the plasma field during the insertion. The needle of the probe was inserted submucosally in the inferior half of the turbinate longitudinally. The electrode was inserted with a 90° angle in relation to the mucosa to get as small an entry as possible. The first entry was in the mid anterior part of the inferior turbinate, and the additional two entries were performed medially. Coblation power level of 4 (168–182 Vrms) was used, and the wand was kept in position for 15 seconds; withdrawal was performed at coagulation mode. The patients were allowed to leave the office a few minutes after the completion of the treatment. No medications were pre-

scribed, but the patients were advised to use ibuprofen or ketoprofen if needed.

Evaluation of Postoperative Morbidity and Efficacy

Each patient used a 100-mm visual analogue scale (VAS) to grade immediate postoperative nasal symptoms for a week's time (pain, nasal discharge, itching, sneezing, crusting, frequency of nasal obstruction, and degree of nasal obstruction). In addition, the patients graded the development of long-term symptoms using VAS before the treatments and at 3, 6, and 12 months postoperatively (nasal discharge, itching, sneezing, crusting, frequency of nasal obstruction, degree of nasal obstruction, and patient satisfaction).

Acoustic rhinometry (ARM) (A 1/2 Acoustic Rhinometer, GM Instruments Ltd., Glasgow, UK), and NR6–2 computerized active anterior rhinomanometry (RMM) (GM Instruments Ltd.) were performed at the evaluation visit preoperatively and in the morning before the procedure, to assess the day-to-day variation and to create an internal control. The measurements were repeated 3, 6, and 12 months after the procedure. We obtained the measurements at same time during the day with the patient in sitting position and with the same room temperature, and the

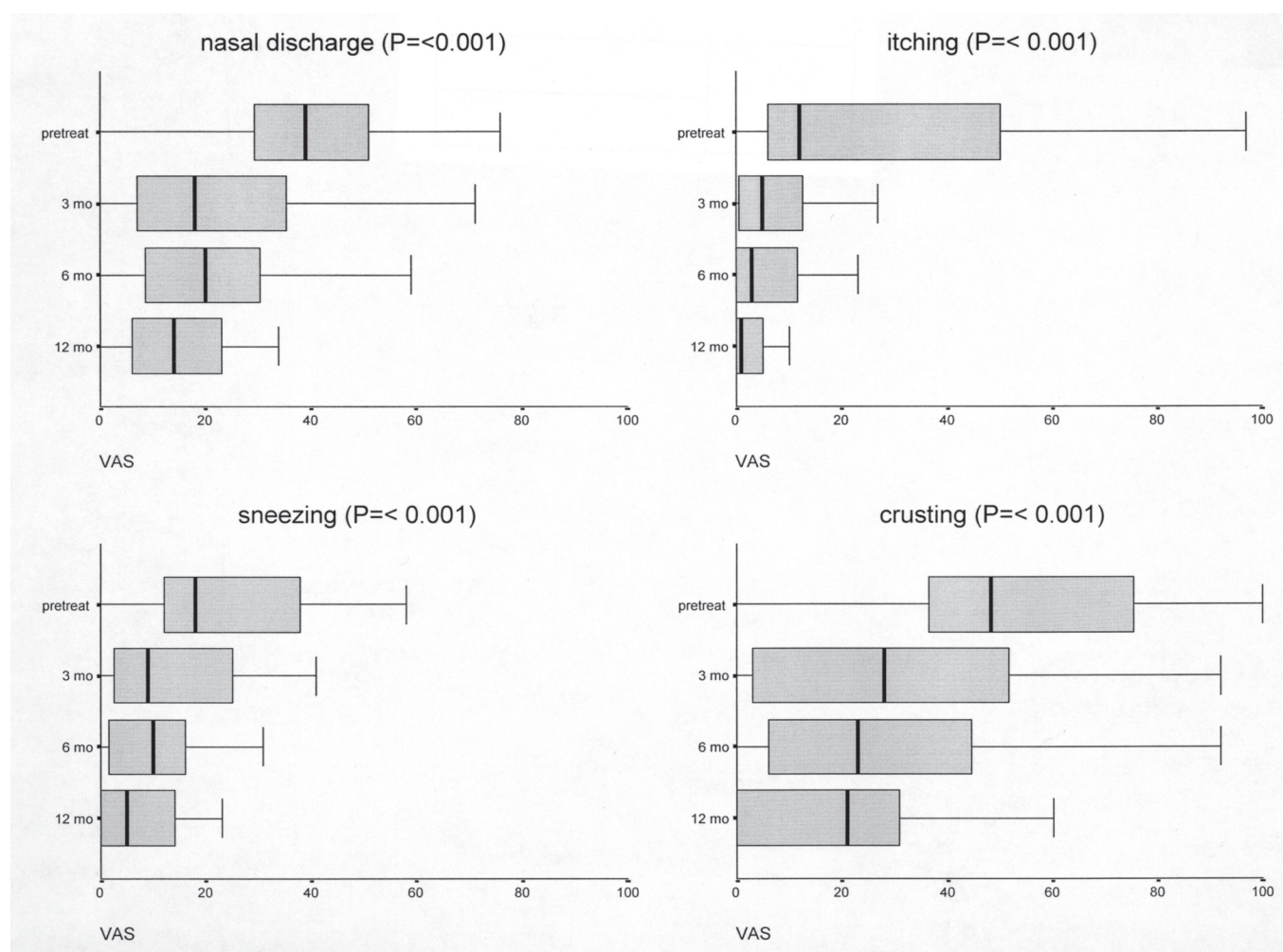


Fig. 2. Visual analogue scale (VAS) scores (0 = no symptoms, satisfied with the situation; 100 = extremely difficult, dissatisfying situation), of long-term symptoms (nasal discharge, itching, sneezing, crusting) related to the submucosal bipolar radiofrequency thermal ablations of the inferior turbinates (box plot). Pretreat = before the treatments; 3, 6, and 12 months = 3, 6, and 12 months after the treatments (postoperatively).

background noise was minimized. The patients were acclimatized for 15 to 30 minutes before this, to minimize all mucovascular variations attributable to the decongestive effect of physical exercise.⁹

The nasal resistance and cavity volumes were measured without and with decongestants. Spraying 0.5% xylometazoline hydrochloride (Nasolin, Orion, Finland) in both nasal cavities 15 minutes before obtaining the measurements decongested the nasal mucosa. In RMM, the nasal resistance was measured on each side of a Broms 200-unit circle, and the total resistance was calculated. In ARM, the sum of both nasal cavity volumes from nostril to 5 cm was obtained. The response to the vasoconstrictor agent was evaluated by calculating the differences between the total nasal resistance and cavity volumes before and after the decongestants.

In RMM, the coefficient of nasal resistance was chosen because it has the best validity, calculability, and reproducibility.⁹ In ARM, the 0- to 5-cm range was chosen because it includes the functional nasal valve and much of the septal and lateral erectile tissue.¹⁰ Also, the accuracy of nasal volume measurement decreases with increasing distance from the nares.¹¹ Nasal cycle, which is the spontaneous variation in patency of the nasal halves, is present in 70% to 80% of the patients.⁹ It is unilateral, so the

total nasal resistance or volume, which was used in our calculations, remains roughly unchanged.

Nasal epithelial function was evaluated before and 3, 6, and 12 months after the procedure with saccharine transit time (STT) by placing a saccharine particle on the anterior portion of the inferior turbinate, and the time until the patient felt sweetness was measured up to 30 minutes.

Olfactory threshold determination (OTH) was conducted in an odorless room under standard conditions using a commercially available smell test kit (OlfactoLabs, Berkeley, CA). The method has been described in detail.^{12,13} The threshold was expressed in arbitrary logarithmic units (ALU), designated as "decismels" (dS). The concentrations in use were -25, -15, -5, 5, 15, 25, 35, 45, and 55 ALU. In the statistical analyses, the value of 65 dS was used for those who could not identify the strongest concentration. During the postoperative period no other medications were used, but the patients were allowed to use their former medications if needed.

Statistical Methods

Friedman's repeated-measures analysis of variance (ANOVA) on ranks was used to determine whether changes from

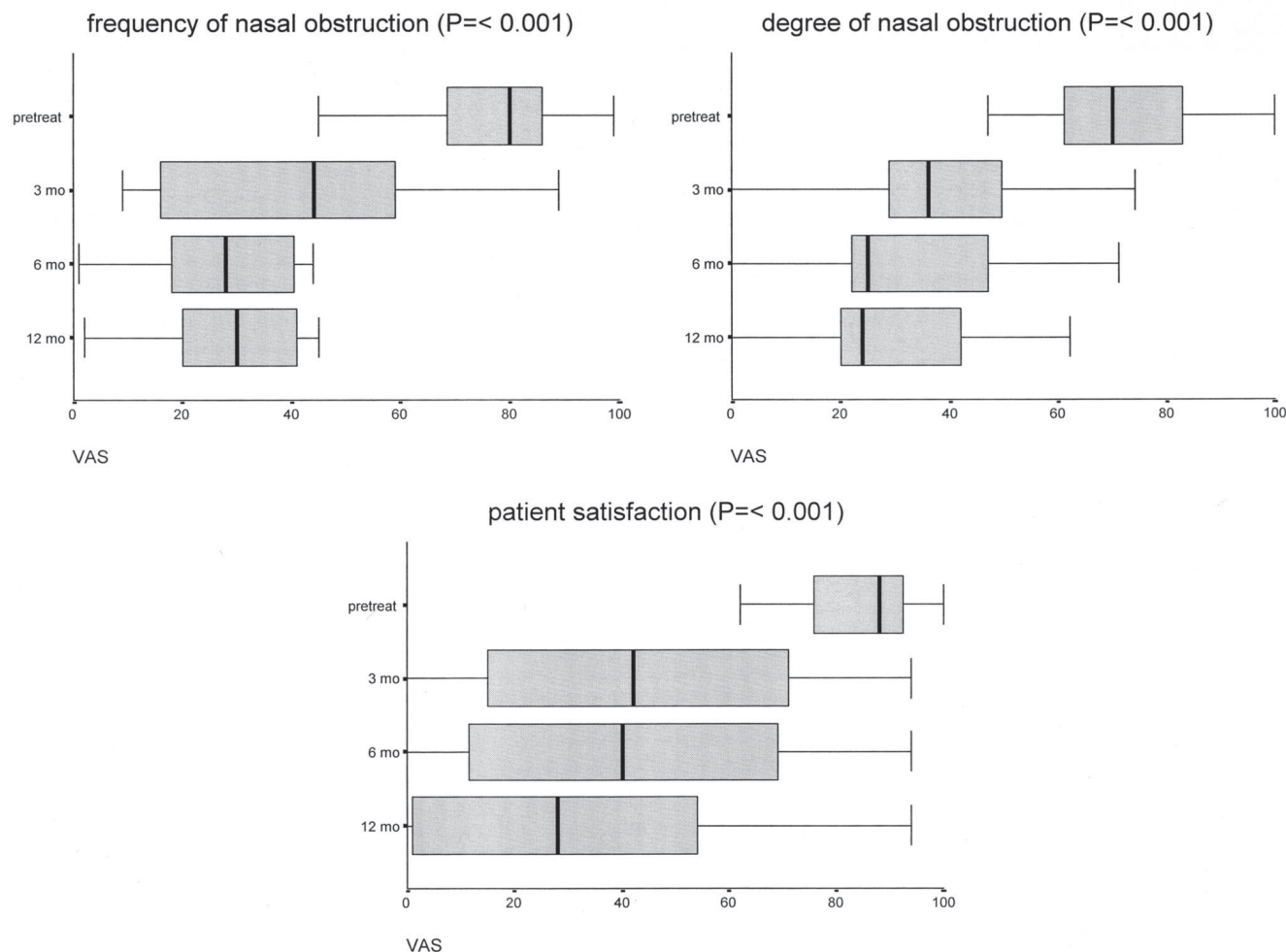


Fig. 3. The evaluation of the long-term effectiveness (frequency of nasal obstruction, degree of nasal obstruction, and patient satisfaction) of the submucosal bipolar radiofrequency thermal ablations of the inferior turbinates using visual analogue scale (VAS) scores (0 = no symptoms, satisfied with the situation; 100 = extremely difficult, dissatisfying situation) (box plot). Pretreat = before the treatments; 3, 6, and 12 months = 3, 6, and 12 months after the treatments (postoperatively).

the baseline to the final measurements in the questionnaires and measurements were significant. Pairwise multiple-comparison procedures with Dunnett's method were performed if the change was significant. Results are expressed as medians and range, and they were generated using a computerized statistical package (SPSS, version 9.0, and SigmaStat, version 2.0, SPSS science, Chicago, IL). The *P* value below .05 was considered statistically significant.

RESULTS

Twenty patients, 10 men and 10 women, fulfilled the initial inclusion criteria for enrollment to the study. One patient did not come to the follow-up visits. In 14 patients inferior turbinates were treated bilaterally, in 5 unilaterally. One patient did not perform his ARM and RMM, but his subjective assessments are included. Two patients were not satisfied with the results 6 months after the treatment, and a turbinoplasty was performed; their evaluations at 12 months are not included.

All the patients tolerated the bRFTA procedure well, and the repeat-treatment acceptance was 17 of 19 (89%). No patient had mucosal erosion, bleeding, or adherent crust formation. The most common complaints were pain and nasal discharge immediately after the treatment, which gradually decreased in 2 days (Fig. 1). Minor transient changes in crusting and sneezing were accounted for (Fig. 1). Although the treatment induces mild to moderate edema, it did not adversely affect the scores in degree or frequency of nasal obstruction immediately after the treatment (Fig. 1).

The VAS scores of subjective complaints (nasal discharge, itching, sneezing, crusting) in the 12-month follow-up decreased statistically significantly (Fig. 2). The evaluation of the effectiveness (frequency of nasal obstruction, degree of nasal obstruction, and patient satisfaction) of the treatment showed statistically significant changes without significant relapses (Fig. 3).

In RMM, the total nasal resistance and response to the vasoconstrictor agent diminished during the follow-up period, but the changes were not statistically significant (Fig. 4). However, in ARM the change in the sum of both nasal cavity volumes from nostril to 5 cm was statistically significant 6 and 12 months after the treatments (Fig. 5). The difference between the preoperative and postoperative vasoconstrictive effect in ARM diminished up to 6 months after the treatment. However, the high variation of the values at 12 months made the overall statistical change not significant (Fig. 5).

According to the STT and OTH determinations, there were no adverse effects on nasal epithelial clearance time and olfactory functions (Fig. 6). In fact, the values were better 6 months after than before the treatments.

All the patients used nasal steroids or antihistamines, or both, before the surgery, but 12 of the patients used this medication occasionally and 7 did not use any medication at all during the follow-up period.

DISCUSSION

Radiofrequency thermal ablation is a minimally invasive treatment modality acting with low temperature

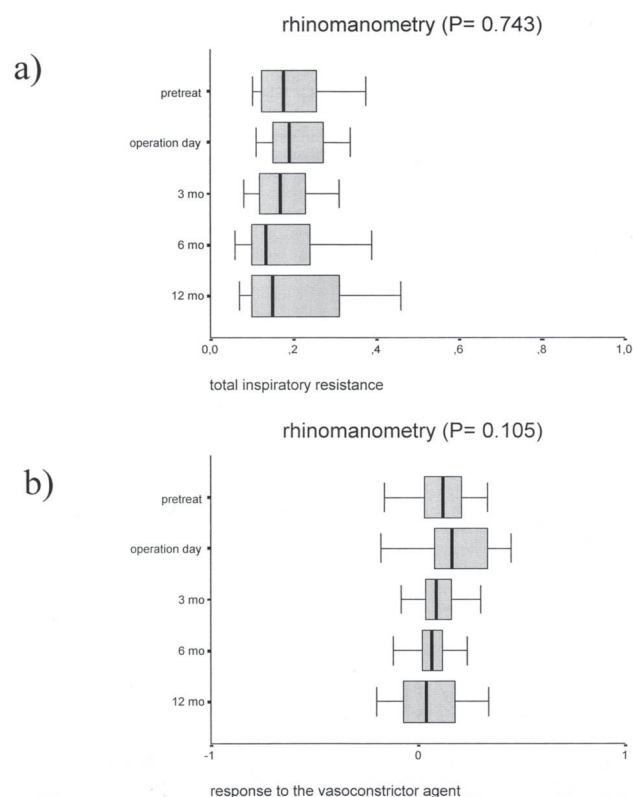


Fig. 4. The total nasal resistance (A) and the response to the vasoconstrictor agent (B) evaluated with rhinomanometry related to the submucosal bipolar radiofrequency thermal ablations of the inferior turbinates (box plot). Pretreat = evaluation visit preoperatively; operation day = the morning before the procedure; 3, 6, and 12 months = 3, 6, and 12 months after the treatments (postoperatively).

and leading to necrosis and fibrosis with contracture of tissue without actual removal.¹⁴ In the present study, a group of patients with chronic nasal obstruction resistant to earlier therapies was treated with bRFTA. This treatment led to sustained subjective and objective improvement of nasal obstruction with minimal morbidity. Bipolar RFTA was performed using local anesthesia on an outpatient basis, and nasal packing was not needed. The procedure is simple, and the efficacy is comparable with other surgical procedures.

Our results are in accordance with previous reports on RFTA of inferior turbinates.^{6–8} Our results are based on long-term subjective and objective assessment, which has not been reported previously. The procedure is effective, it can be repeated if necessary, and there were no significant relapses. The results indicate that in treating this patient group a 6-month follow-up is needed before you can determine whether the intervention is effective.

Laser cautery, cryocautery, and electrocautery submucosal reductions are not well tolerated by patients under local anesthesia and can cause prolonged rhinorrhea, worsening of nasal obstruction secondary to edema, and crusting. This is probably due to the depth of tissue injury, which is unpredictable with laser cautery, cryocautery, and electrocautery, in contrast with bRFTA. In addition,

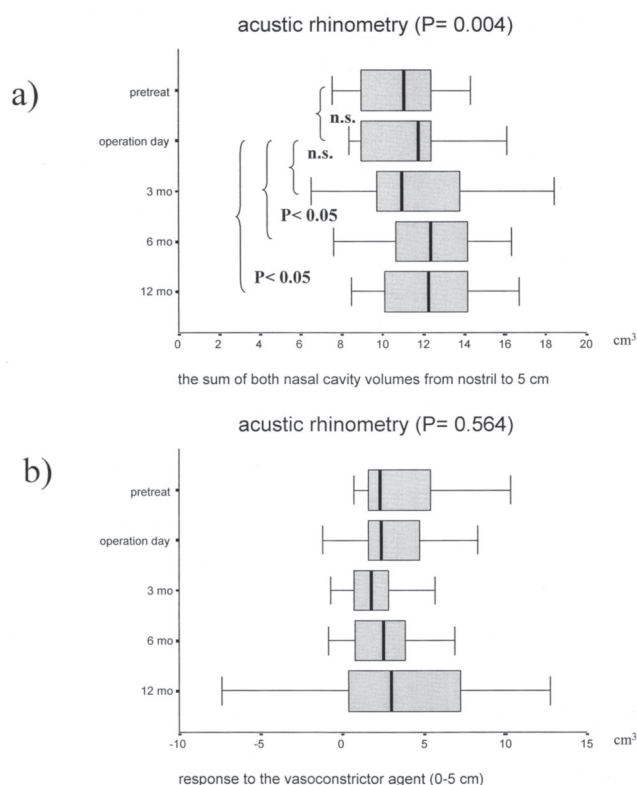


Fig. 5. The sum of both nasal cavity volumes from nostril to 5 cm (A) the response to the vasoconstrictor agent (B) evaluated with acoustic rhinometry related to the submucosal bipolar radiofrequency thermal ablations of the inferior turbinates (box plot). Pretreat = evaluation visit preoperatively; operation day = the morning before the procedure; 3, 6, and 12 months = 3, 6, and 12 months after the treatments (postoperatively).

radiofrequency equipment avoids potential laser hazards. In our study, VAS scores of subjective long-term nasal complaints in our follow-up decreased statistically significantly, indicating the procedure having a symptom-controlling effect.

The application of bRFTA to the anterior part of inferior turbinates was used to minimize any potential adverse effect to the physiological function of the turbinate. In addition, the anterior end of the inferior turbinate was selected as the treatment site because the swelling of the erectile tissue in this location significantly increases nasal resistance leading to nasal airway obstruction.¹⁵ Previous turbinate procedures were not exclusion criteria because the patients were still unsatisfied with the present situation. The small number of subjects, the diversity of the study group, and lack of control group are the major limitations of the present study.

When the RMM and ARM measurements before and after bRFTA are compared in the same patient, whose obstruction is caused by mucosal disorders, they provide an objective measurement of the nasal mucosal change.¹⁶ The reproducibility of both methods of nasal patency assessment, if performed by an experienced operator under controlled circumstances, compared favorably with many widely accepted clinical tests.^{17,18} However, ARM and RMM results are sometimes inconsistent with the pa-

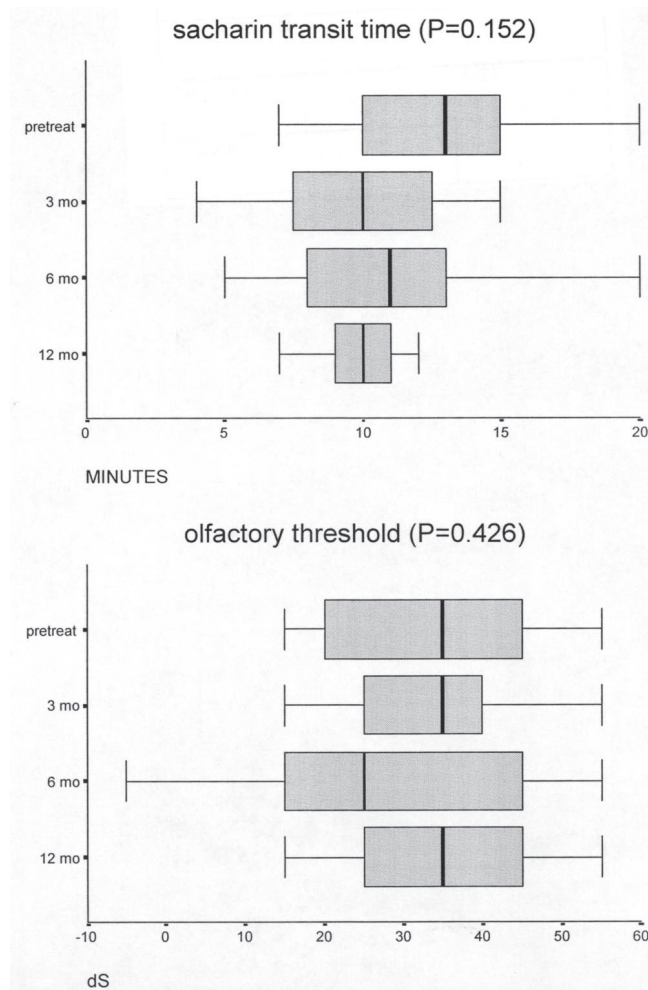


Fig. 6. Saccharine transit time (STT) and olfactory threshold determination (OTH) related to the submucosal bipolar radiofrequency thermal ablations of the inferior turbinates (box plot). Pretreat = before the treatments; 3, 6, and 12 months = 3, 6, and 12 months after the treatments (postoperatively). In rhinomanometry the nasal resistance was measured on each side of a Brooms 200-unit circle and was calculated. In acoustic rhinometry the nasal mucosa was decongested by inhalation of 0.5% xylometazoline hydrochloride nasal spray in each nasal cavity for 15 minutes before the measurements.

tient's subjective assessment of nasal obstruction.¹⁹ The VAS has been used in previous studies as an effective method to quantify the condition of the subject.^{20,21} Ultimate success in treating patients with nasal obstruction should include each patient's perception of nasal obstruction, highlighting the significance of patient-assessment data such as VAS.²²

One indication for a successful soft tissue reduction in chronic hypertrophied turbinates is a decreased response to the vasoconstrictor agent postoperatively. The induced fibrosis fixes the epithelium to the underlying tissues, resulting in decreased congestion of the turbinate in response to noxious and other stimuli.⁷ The effect of topical vasoconstrictors in the present study did not change significantly, even though the tendency was clear. A repeated treatment at 6 months after the first procedure

in patients with partial response must be further investigated.

Radiofrequency tissue ablation of the inferior turbinate is an outpatient procedure, which is simple for the doctor, and for the patient is accompanied by a high repeat-treatment acceptance and minimal patient discomfort. The ideal treatment modality of obstructive hypertrophied turbinates is unclear. The number of treatment sites, optimal energy per treatment site, and value of repeated treatment sessions while maintaining satisfactory tolerance must be evaluated.

CONCLUSION

Radiofrequency is a safe, minimally invasive surgical procedure capable of reducing turbinate volume without altering the nasal mucosa and causing only minimal discomfort for the patient. The long-term radiofrequency results are comparable with other surgical treatment modalities. The results are based on subjective and objective outcomes. The promising results must be confirmed in a placebo-controlled study with a larger sample size.

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