Eur Arch Otorhinolaryngol
DOI 10.1007/s00405-010-1462-1

RHINOLOGY

Intranasal steroids or radiofrequency turbinoplasty in persistent allergic rhinitis: effects on quality of life and objective parameters

Kivanc Gunhan · Halis Unlu · Ali Vefa Yuceturk · Murat Songu

Received: 4 June 2010 / Accepted: 6 December 2010

Abstract Nasal congestion is a cardinal symptom of allergic rhinitis (AR). It is associated with decreased quality of life and difficult to treat as perceived by the patients. The purpose of this study is to evaluate the mid-term objective and subjective outcomes of management of nasal congestion using intranasal steroid (INS) therapy or radiofrequency turbinoplasty (RFT) in patients with persistent AR who have mucosal hypertrophy of the inferior turbinate. Fifty-five adult patients with AR, who claimed nasal congestion refractory to oral antihistamine (desloratadine) therapy, were randomized to INS (mometasone furoate) or temperature-controlled RFT treatment groups. Outcomes were determined by active anterior rhinomanometry, visual analog scale (VAS), and rhinoconjunctivitis quality of life questionnaire (RQLQ) at least 12 months after treatment. The median total nasal resistance decreased from 0.49 ± 0.17 to 0.39 ± 0.12 Pa/cm^3/s ($p = 0.42$), and from 0.51 ± 0.18 to 0.29 ± 0.07 Pa/cm^3/s ($p = 0.003$) with INS and RFT, respectively. RFT provided a better reduction in the perception of congestion in VAS scores. RQLQ scores improved significantly in both groups 1 year after treatment (mean follow-up 14.2 months) ($p < 0.05$). No adverse reactions were encountered in either group. Nasal congestion refractory to antihistamine appears to be improved by INS at some point, while reduced significantly by RFT in objective and subjective parameters. Both options are also effective in increasing the quality of life in patients with AR. RFT might be a safe and effective treatment of option in AR compared with INS.

Keywords Allergic rhinitis · Nasal congestion · Intranasal steroid · Radiofrequency turbinoplasty · Quality of life · Rhinomanometry

Introduction

Allergic rhinitis (AR) is the most prevalent chronic allergic disorder, affecting 10–30% of the adult population [1]. The symptoms of AR are not only bothersome, but also perceived by many affected patients as serious and debilitating [2]. Data from a large patient survey suggest that nasal congestion is the most bothersome symptom of this common form of chronic rhinitis, which also has a significant negative impact on quality of life [3].

Nasal breathing is essential in maintaining the physiology of the upper and lower airways via some of the nasal functions such as superior humidification, warming and filtration of the inhaled air, and production and distribution of aerocrine mediators [4]. Intractable nasal blockage due to inferior turbinate hypertrophy interferes with the nasal functions. A severe drug-resistant hypertrophy and increase in glandular structures of the inferior turbinate may develop in patients who suffer from persistent allergic rhinitis (PAR), which leads to constant nasal obstruction [5]. Continuous allergen exposure causes a persistent mucosal inflammation and thus persistent nasal congestion in nearly 70% of patients with PAR [6].

There is a need for therapies that are well tolerated and effective in relieving nasal congestion in AR. In a recent survey, it is reported that many AR patients claim that they

K. Gunhan (✉) · H. Unlu · A. V. Yuceturk
Department of Otorhinolaryngology and Head-Neck Surgery, Celal Bayar University, Manisa, Turkey
e-mail: kivanc.gunhan@bayar.edu.tr

M. Songu
Otorhinolaryngology and Head-Neck Surgery, Izmir Ataturk Research and Training Hospital, Izmir, Turkey

Published online: 28 December 2010

are "very interested" in finding a new medication and some are "constantly" trying different medications to find one that "works" [2]. Dissatisfaction leads to decreased compliance and an increased reliance on multiple agents [2].

Various medical and surgical procedures have been employed to treat turbinate hypertrophy caused by various etiologies [6–9]. Clinical data have shown intranasal steroids (INS) to be the most potent medications available for symptom relief. Recently, antihistamines and INS have also been claimed to reduce nasal congestion [10, 11]. On the other hand, radiofrequency turbinoplasty (RFT) which is known to be very effective in reducing nasal obstruction due to turbinate hypertrophy might also reduce the other symptoms of PAR as well increase the AR-related quality of life.

It is often an uneasy decision both for the physician and the patient how to manage nasal congestion in PAR in long terms. Simultaneous objective evaluation and subjective patient perceptions of the management of nasal congestion in patients with PAR are not well compared. It might be useful to see the effects of INS and RFT on the symptoms of PAR in the similar group of patients. The purpose of this study is to evaluate the objective and subjective outcomes of two treatment options (INS and RFT) in patients with PAR focusing on nasal congestion and quality of life.

Materials and method

Our clinical approach to mild to moderate PAR is to advise environmental allergen avoidance and to prescribe newer antihistamines initially, following the diagnosis via medical history and skin prick test. Additional therapies are considered at the 3rd monthly visit if required. This prospective, single-sited study randomized 58 patients fulfilling the inclusion criteria with PAR who had nasal congestion refractory to antihistamine therapy into two groups of additional treatments to use INS (group A) or undergo RFT (group B).

Patients who claimed continued nasal congestion at the control visit despite initial antihistamine (desloratadine 5 mg/day) therapy during the preceding 3 months and fulfilling the following criteria were enrolled to the study. All patients were diagnosed by similar documented clinical histories of mild or moderate PAR and positive skin prick test of at least one member of the *Dermatophagoides* spp. Previously, they were not tested or treated for AR. Their nasal congestion was found to be due to the bilateral hypertrophy of the inferior turbinate via nasal endoscopic examination and topical decongestant test described earlier [12]. Patients with systemic disease, previous sinonasal or turbinate surgery, severe nasal septal deviation, nasal valve insufficiency, concomitant sinonasal disorders or who were smoking were excluded. Both groups continued their antihistamine therapy. All eligible patients fulfiling these inclusion criteria between May 2007 and April 2008 were offered to be enrolled in the study consecutively. Four of the 62 patients who declined to be randomized were excluded from the study.

The decision of INS or RFT was assigned randomly on a 1:1 ratio according to the date of application. These two groups of patients were fairly homogeneous regarding their clinical findings. The demographic data are shown in Table 1.

Patients in group A received mometasone furoate monohydrate nasal spray (MFMNS), two sprays per nostril, once daily with a total dose of 200 μg, and continued consistently until the last visit. Patients in group B underwent temperature-controlled radiofrequency inferior turbinate ablation (model S2 Somnoplasty, Gyrus ENT, Gyrus Medical, Inc., Maple Grove, MN). RFT was applied under local anesthesia with two or three punctures per turbinate on each site (one facing to the inferior meatus and parallel to the septum, the other facing the inferior meatus and parallel to the nasal floor, and when required the third one 2 cm posterior to the first two), total dose of 1580 ± 210 joule (350–400 joule per puncture), plateau temperature of 75°C and energy of 10 watt. All procedures were performed by the same surgeon (K. G.) in the same fashion. Each patient was discharged without any limitation of normal daily activities. No nasal packing was administered, and only topical decongestants (oxymetazoline) were prescribed for the first 5 days to be used if required. The outcomes for both groups were evaluated

Table 1 Descriptive data obtained in the study

	Group A ($n = 27$)	Group B ($n = 28$)	All groups ($n = 55$)
Sex			
Male	12 (44.4%)	15 (53.5%)	27 (49%)
Female	15 (55.5%)	13 (46.4%)	28 (51%)
Age (years)			
Mean	35.4 ± 9.4	33.2 ± 8.9	34.8 ± 9.1
Range	21–51	22–48	21–51
Follow up (months)			
Mean ± SD	14.1 ± 1.3	14.4 ± 1.6	14.2 ± 2.1
Range	13–16	14–16	13–16
Nasal congestion VAS score			
Pretreatment	7.7 ± 2.1	7.9 ± 1.8	
Posttreatment	4.8 ± 1.6	3.6 ± 1.6	
Total nasal resistance ($Pa/cm^3/s$)			
Pretreatment	0.49 ± 0.17	0.51 ± 0.18	
Posttreatment	0.39 ± 0.12	0.29 ± 0.07	

before and after treatment period with respect to two distinct objective and subjective parameters. All patients were evaluated prior to the study and at least 12 months after treatment.

Objective outcomes were evaluated by total nasal resistance measurements obtained by active anterior rhinomanometry (SRE 2000, Rhinomanometrics A/S, Lynge, Denmark). All measurements were performed and analyzed by the same specialist (K. G) in a standard fashion that has been described previously and in the non-decongested state [13]. The 150 Pa reference pressured "*R*" value obtained from active anterior rhinomanometry curves was determined by 2.6 version of Rhinoscan programme and the total nasal resistance was evaluated.

Quality of life was investigated using the Turkish validated form of rhinoconjunctivitis quality of life questionnaire (RQLQ) consisting of 28 questions in 7 domains: activities, sleep, non-hay fever symptoms, practical problems, nasal symptoms, eye symptoms, and emotions [14]. Each item is rated on a scale of 0 (not bothersome) to 6 (extremely bothersome). The scores of the domains were expressed as the mean score for each item. A change in score greater than 0.5 was considered clinically important as reported earlier [15]. Subjective outcome of severity of nasal congestion was assessed with a standard visual analogue scale (VAS) with an anchor (ranging from 0 to 10, with 0 representing no symptoms and 10 representing the most severe symptoms).

All outcomes were analyzed using paired *t* test for statistical significance using SPSS 9.0 (SPSS Inc, Chicago, IL). The applicable data were expressed as the mean ± SD. Statistical significance was determined as $p < 0.05$.

Our institutional review board approved the study. The study was carried out according to the principles of Declaration of Helsinki. All participants gave their written consent after being informed about the procedures.

Results

One patient from group A and two patients from group B did not complete the study because they moved to another city. The study included 27 (12 male) and 28 (15 male) adult patients in group A and B respectively. Their mean ages were not different (35.4 ± 9.4 and 33.2 ± 8.9 years, respectively; $p > 0.05$). The final evaluations were done at least 12 months after the initial assessments (14.2 ± 2.1 months). The demographic characteristics are shown in Table 1.

None of the patients reported obvious discomfort in either group. No patients in group A who have used INS for over 12 months reported any adverse events including nasal bleeding, burning, stinging and irritation as well as altered taste and smell. In group B postprocedure bleeding, crusting, mucosal damage or synechia were not seen at any follow-up examination after RFT. Topical decongestants were required by 18 patients (64%) for no more than the first 5 days. No analgesics were requested by any of the patients. The inferior turbinate was appreciably smaller at the endoscopic examination in 24 of the patients (85%) in this group at the 3rd week visit as found by the non-blinded examiner, but this was not measured objectively.

The mean total nasal resistance in group A patients decreased from 0.49 ± 0.17 to 0.39 ± 0.12 Pa/cm3/s ($p = 0.42$), and 0.51 ± 0.18 to 0.29 ± 0.07 Pa/cm3/s in group B patients ($p = 0.003$) at the end of 1 year (Fig. 1). INS treatment reduced the hypertrophy of the inferior turbinate, but this effect did not reach the statistical significance. RFT treatment was significantly better in reducing the total nasal resistance and nasal congestion 1 year after the application.

The subjective assessment of the severity of nasal congestion in VAS scores diminished in both groups. While this amelioration was statistically significant only in group B ($p = 0.032$) (Fig. 2). RFT treatment resulted in satisfactory nasal congestion control.

The RQLQ scores of the two groups were not significantly different at baseline ($p > 0.05$). The RQLQ measures revealed that both treatments were effective in improving the quality of life overall and in seven separate domains ($p < 0.05$) (Fig. 3). Patients in group B revealed better results in nasal symptoms and sleep domains.

Discussion

Nasal congestion affects most patients with AR, and has been reported to be one of the main reasons in patients who seek medical advice. Nasal congestion has a complex

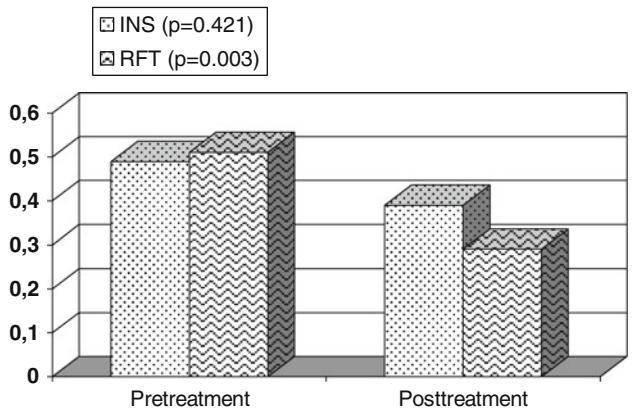


Fig. 1 Average of mean total nasal resistance measurements

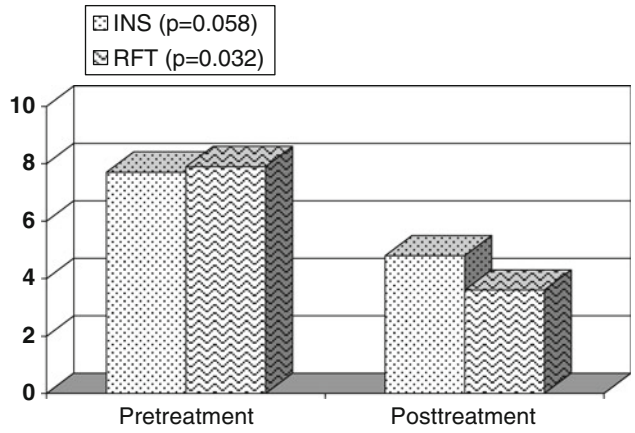


Fig. 2 Comparison of mean VAS scores for the severity of nasal congestion

pathophysiology that involves neural, vascular, and inflammatory elements. Its complexity poses challenges in the medical treatment of AR and may partially explain patients' dissatisfaction with the ability of currently available treatments to relieve nasal congestion associated with AR. The high prevalence and undesirable effects of nasal congestion, and the limited therapeutic efficacy of existing therapies point out that there remains a need for new and/or improved treatment options for nasal congestion associated with AR.

Most of the clinical trials that are reported on the control of AR symptoms have not evaluated efficacy in relieving nasal congestion per se, but instead have examined efficacy against total AR symptoms or nasal symptoms. In addition, most of the clinical trials that presented data on efficacy in relieving nasal congestion included only subjective measures of efficacy (i.e., patients' rating of the severity of nasal congestion) [1]. The lack of an objective measure of nasal congestion in these trials makes it difficult to assess the true efficacy of some therapies.

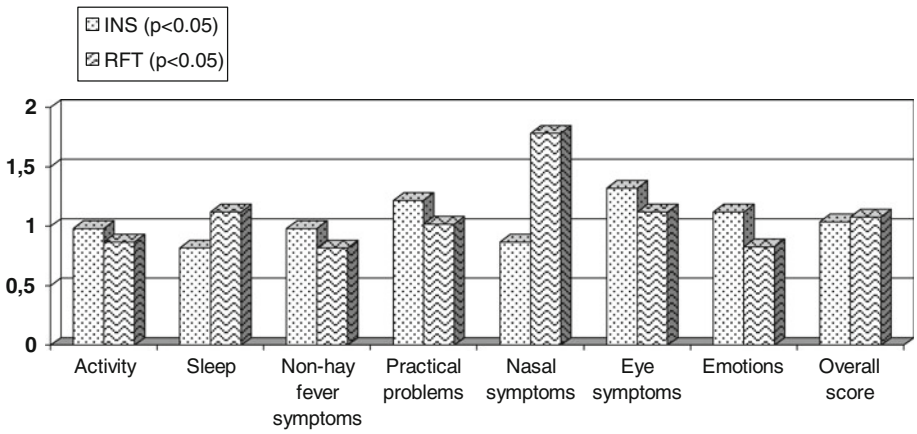
All eligible patients who comprehend the inclusion criteria were offered to be enrolled in our study. Only 4 patients out of 62 were declined, since they did not know what to be randomized. Three patients were lost during the follow-up period. The data obtained from 55 patients were analyzed. The study population was quite uniform to provide accurate information and minimize the confounding factors. The patients were randomized 1:1 into the groups, and results were evaluated with strongly recommended objective and subjective measures [15].

Although some mild benefit in the treatment of nasal congestion has been noted with newer antihistamines, such as desloratadine and levocetirizine, no oral antihistamines have significant effects on reducing nasal congestion [10]. Our study group were consisted of patients with continuous nasal congestion after a 3 month antihistamin (desloratadine) therapy.

INS are accepted as the most effective pharmacologic treatment of AR. The superior efficacy of INS in AR may be due to the multiple effects these agents have at suppressing the underlying pathophysiological processes. In particular, the beneficial effects of INS on nasal congestion may be a direct consequence of the suppressed release of many of the inflammatory mediators involved in the late phase of the nasal allergic reaction. However it should be noted that nasal congestion may limit the penetration of INS to nasal mucosa.

In this setting, addition of INS to sole antihistamine therapy significantly improved the quality of life, including the nasal symptoms while reducing the volume of inferior turbinate. Nasal congestion showed a tendency towards a decrease in the subjective perception of the severity at VAS and in the objective measures at rhinomanometry, but did not reach the statistical significance. The reasons of this insignificance might be the relatively small study size and the long duration of the study. Compliance with medication is essential in the long-term treatment of AR. Patients frequently may fail to perceive the need for regular use of medication, particularly because INS therapy does not provide immediate symptomatic relief. Therefore, patient

Fig. 3 Change of scores from baseline of the RQLQ domains



involvement and education should be an integral component of any INS treatment plan. Most of the studies that focus on the efficacy of INS and nasal congestion are for shorter periods with subjective evaluations and include patients with seasonal AR [16]. On the other hand, SAR and PAR have some differences in the pathophysiology of nasal congestion [4].

No complications or discomfort were reported after using INS for over a year. Patients were distinctly advised and taught to direct the spray towards the head of the inferior turbinate and away from the septum. This might have been useful in avoiding the local adverse events.

The results of this study point out that additional RFT to antihistamine therapy is an effective treatment option in reducing the nasal congestion, which is lasting for at least one year. RFT was more effective than INS at this point. There was a good correlation between active anterior rhinomanometry and VAS results.

The hypertrophied inferior turbinate shows dilated, engorged thin walled venous sinusoids, marked subepithelial inflammatory cell infiltrate beneath the basement membrane and fibrosis of the lamina propria, suggesting a progressive and irreversible course and representing the end point of inflammation unresponsive to sympathetic nervous system stimulation or medical treatment [17]. At this point of persistent symptoms, medical management usually fails and the grounds for surgical reduction are laid down [9].

The ideal turbinate surgery should effectively reduce the volume of the submucosal stromal tissue while preserving the overlying respiratory epithelium and averting complications. RFT is a minimally invasive procedure. It has similar, if not better, long-term symptom relief than other common surgical treatments such as turbinectomy, submucosal turbinectomy, microdebrider submucosal resection, cryotherapy, submucous electrosurgery, and laser turbinectomy [7]. There were no significant complications and minimal morbidity (rebound congestion for shorter than 5 days in 64% of the patients) in our study as compatible with the published series to date [7–9].

The cause and degree of turbinate enlargement need to be assessed before choosing a particular technique. We evaluated all patients with endoscopic nasal examination and decongestant test before randomization. The treating physician could not be blinded as to the treatment, but the effect of this bias was minimized by not including any subjective outcome measures by the treating physician. Although there was not a sole surgeon doing RFT, our technique was standard.

It has been reported that submucosal turbinectomy is an excellent procedure for reducing not only nasal congestion but also sneezing and rhinorrhea in patient with PAR [18]. RFT has been found effective in patient with AR subjectively [19]. This study confirmed the safety and efficacy of RFT for the treatment of nasal congestion due to inferior turbinate hypertrophy in patients with PAR both objectively and subjectively. Furthermore these data demonstrated statistically significant improvement was achieved with RFT combined to antihistamine therapy in some other symptoms of PAR that are related to the quality of life such as sleep, and emotional functions after 12 months. RFT, when combined with an oral antihistamine, might be a treatment of option in patients with PAR who do not want to use INS.

Aside from volume and allergen contact surface reduction, the additional effect of RFT might be due to the switch between the inflammatory cells and the fibrotic tissue, obliteration of submucosal vessels, and destruction of submucosal glands. Postcapillary venules that are particularly well developed in the inferior turbinate play an important role in vascular permeability changes [20]. RFT might also cause a reaction that inhibits passage of mediators causing the late phase of the allergic inflammation.

AR has a notable negative impact on quality of life, sleep, emotional function, productivity, and the ability to perform daily activities. RQLQ has strong discriminative and evaluative properties for measuring rhinoconjunctivitis-specific quality of life, and offers a better registration of changes in disease related problems compared to generic quality of life questionnaires [21]. The beneficial effects of RFT on RQLQ (other than nasal congestion) may be the result of a halo effect as improvement in nasal congestion may improve patients' overall sense of well-being and reduce their perception of the severity of other AR symptoms.

This study points out that RFT added on antihistamine therapy has been significantly more effective than INS and antihistamine treatment in reducing nasal congestion in patients with PAR 1 year after treatment with objective and subjective measures.

Conclusion

The judicious use of pharmacotherapy remains a necessary adjunct in the treatment of AR. Rational therapy and the physician's appropriate recommendation of safe and effective medications are critical elements in the treatment of nasal congestion. These results suggest that additional INS reduces (not significantly) the volume of inferior turbinate obtaining a relief from nasal congestion at some point while improving the quality of life significantly. On the other hand RFT, which is a minimally invasive procedure, seems to be a safe and effective alternative in the management of PAR. It has some encouraging mid-term results that reveal nasal congestion significantly and also

improves quality of life measurements compared with INS, especially on nasal symptoms and sleep in selected patients with PAR who have nasal congestion refractory to antihistamines.

Conflict of interest None of the authors have any conflict of interest.

References

1. Bousquet J, Khaltaev N, Cruz AA, Denburg J, Fokkens WJ et al (2008) Allergic rhinitis and its impact on asthma (ARIA) 2008 update. Allergy 63:S8–S160
2. Marple BF, Fornadley JA, Patel AA, Fineman SM, Fromer L, Krouse JH, Lanier BQ, Penna P (2007) American Academy of Otolaryngic Allergy Working Group on Allergic Rhinitis. Keys to successful management of patients with allergic rhinitis: focus on patient confidence, compliance, and satisfaction. Otolaryngol Head Neck Surg 136:S107–S124
3. Shedden A (2005) Impact of nasal congestion on quality of life and work productivity in allergic rhinitis: findings from a large online survey. Treat Respir Med 4:439–446
4. Nathan RA (2008) The pathophysiology, clinical impact, and management of nasal congestion in allergic rhinitis. Clin Ther 30:573–586
5. Berger G, Bernheim J, Ophir D (2007) Epithelial shedding of the inferior turbinate in perennial allergic and nonallergic rhinitis: a riddle to solve. Arch Otolaryngol Head Neck Surg 133:78–82
6. Wang DY, Raza R, Gordon BR (2004) Control of nasal obstruction in perennial allergic rhinitis. Curr Opin Allergy Clin Immunol 4:165–170
7. Sapci T, Sahin B, Karavus A et al (2003) Comparison of the effects of radiofrequency tissue ablation, CO_2 laser ablation and partial turbinectomy applications on nasal mucociliary functions. Laryngoscope 113:514–519
8. Porter MW, Hales NW, Nease CJ et al (2006) Long-term results of inferior turbinate hypertrophy with radiofrequency treatment: a new standard of care? Laryngoscope 116:554–557
9. Willatt D (2009) The evidence for reducing inferior turbinates. Rhinology 47:227–236
10. Canonica GW, Tarentini F, Compalati E et al (2007) Efficacy of desloratadine in the treatment of allergic rhinitis: a meta-analysis of randomized, double-blind, controlled trials. Allergy 62:359–366
11. Gurevich F, Glass C, Davies M, Wei W, McCann J et al (2005) The effect of intranasal steroid budesonide on the congestion-related sleep disturbance and daytime somnolence in patients with perennial allergic rhinitis. Allergy Asthma Proc 26:268–274
12. Yilmaz M, Kemaloğlu YK, Baysal E, Tutar H (2006) Radiofrequency for inferior turbinate hypertrophy: could its long-term effect be predicted with a preoperative topical vasoconstrictor drop test? Am J Rhinol 20:32–35
13. Clement PA, Gordts F (2005) Standardisation Committee on Objective Assessment of the Nasal Airway, IRS, and ERS. Consensus report on acoustic rhinometry and rhinomanometry. Rhinology 43:169–179
14. Yuksel H, Yilmaz O, Alkan S, Degirmenci P, Kirmaz C (2009) Validity and reliability of Turkish version of rhinitis and mini-rhinitis quality of life questionnaires. Allergol Immunopathol 37:293–297
15. van Spronsen E, Ingels KJ, Jansen AH, Graamans K, Fokkens WJ (2008) Evidence-based recommendations regarding the differential diagnosis and assessment of nasal congestion: using the new GRADE system. Allergy 63:820–833
16. Berger WE, Nayak AS, Staudinger HW (2005) Mometasone furoate improves congestion in patients with moderate-to-severe seasonal allergic rhinitis. Ann Pharmacother 39:1984–1989
17. Berger G, Gass S, Ophir D (2006) The histopathology of the hypertrophic inferior turbinate. Arch Otolaryngol Head Neck Surg 132:588–594
18. Mori S, Fujieda S, Yamada T, Kimura Y, Takahashi N (2002) Long-term effect of submucous turbinectomy in patients with perennial allergic rhinitis. Laryngoscope 112:865–869
19. Lin HC, Lin PW, Su SY et al (2003) Radiofrequency for the treatment of allergic rhinitis refractory to medical therapy. Laryngoscope 113:673–678
20. Salib RJ, Harries PG, Nair SB, Howarth PH (2008) Mechanisms and mediators of nasal symptoms in non-allergic rhinitis. Clin Exp Allergy 38:393–404
21. Juniper EF, Thompson AK, Roberts JN (2002) Can the standard gamble and rating scale be used to measure quality of life in rhinoconjunctivitis? Comparison with the RQLQ and SF-36. Allergy 57:201–207