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Radiofrequency thermal ablation for patients with nasal symptoms: a systematic review of effectiveness and complications

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Abstract Radiofrequency ablation (RFA) is a relatively new method for the reduction of submucosal tissue. The method has gained increasing popularity in the treatment of snoring, tonsillar hypertrophy, tongue base hypertrophy, and nasal obstruction secondary to non-allergic or allergic rhinitis. We present a systematic literature review of current knowledge on the effectiveness, and complications of nasal radiofrequency thermal ablation (RFA) in the treatment of nasal obstruction. We performed a computerized literature search using several databases to select articles dealing with RFA treatment in the field of otorhinolaryngology. Selected articles were independently appraised by at least two of the authors. Thirty-five articles met the inclusion criteria. Twenty-six articles were reports on uncontrolled patient series. Of the nine included randomized controlled trials only one reported a double-blind comparison. Most of the studies reported an improvement in subjective symptoms after treatment and the number of serious side effects was small. However, the only placebo-controlled trial did not show effectiveness. Nasal-RFA appears to be a safe operative procedure and may reduce inferior turbinate submucosal tissue volume in patients having chronic nasal obstruction and who fail to respond to medical treatment. Based on current knowledge, RFA alters the nasal mucosa only slightly and causes only minor discomfort and risk of side effects for the patient. However, most of the published studies on nasal-RFA are observational and have a relatively short follow-up. Consequently, there is an urgent need for well-planned, double-blind, placebo-controlled randomized trials on nasal-RFA treatment.

Keywords Allergic rhinitis · Blockage · Health technology assessment · Nasal polyps · Nose · Obstruction · RFA · RFTA · Systematic literature review · Turbinate

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Introduction

Nasal obstruction is one of the most common reasons why patients visit an otorhinolaryngologist. Nasal obstruction can cause considerable discomfort and impair health-related quality of life. There are many different causes of nasal obstruction. Structural changes, such as septal deviation, can be operatively treated. Nasal obstruction caused by acute or chronic infection, hypersensivity, or nasal polyps can mostly be treated with systemic or local medication. However, there are many patients in whom nasal blockage remains despite medical treatment.

The inferior turbinate is in the anterior part of the nose and its hypertrophy or mucosal congestion is an important cause for nasal obstruction. If conservative treatment does not produce adequate relief of symptoms, operative treatment of the inferior turbinate is considered. The available methods include, for example, partial or total turbinectomy, electrocautery of the turbinate mucosa, laser vaporization/reduction/cauterization of the mucosa, mucosal or submucosal microdebrider-assisted turbinoplasty, and cryosurgery.

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However, these procedures often cause pain, bleeding and a need for nasal packing, and post-operative crusting, and dryness of the nasal mucosa.

Radiofrequency ablation (RFA) is a relatively new method for the reduction of submucosal tissue. RFA causes fibrosis of the underlying stroma leaving the surface epithelium intact [1]. RF energy creates an elliptical submucosal lesion in soft tissues. The targeted, finely controlled RF energy induced coagulative necrotic lesion leads to, following the general pattern of wound healing, scar formation and retraction of tissue, resulting in an overall reduction and stiffening of the treated area. Over time, partial resorption of the scar tissue causes further volume reduction. The RF generators have an output frequency varying from 100 to 4,000 kHz in the electromagnetic spectrum. So far, there is no knowledge whether frequency influences the created lesion in any way. The bipolar RF generators have a significantly shorter lesion creation time making the procedure controllable and easier for the patient. The applicators are mostly of the single-use type.

There are different devices available (Table 1). In this review the term RFA is used to cover all the different RFA methods, for example, temperature-controlled radiofrequency, radiofrequency induced thermotherapy, and radiofrequency tissue volume reduction. In otorhinolaryngology RFA has been used to treat snoring, tonsillar hypertrophy, tongue base hypertrophy, and nasal obstruction secondary to non-allergic or allergic rhinitis. The first article included in this review describing the treatment of hypertrophic inferior turbinate dates back to 1998 [2].

Any treatment can cause per- or postoperative sequelae. Kezirian et al. [3] have published a prospective study on complications after RFA treatment of the inferior turbinates, soft palate, and tongue. There were altogether 136 patients with a total of 470 lesion spots. The incidence of minor complications was 1.2% (6/470) and there were no moderate or major complications. Madani [4] reported retrospectively the complication rate of laser-assisted uvulopalatopharyngoplasty and RFA treatments in 5,600 patients treated for snoring and/or nasal obstruction. Twelve percent of the nasal-RFA patients had localized infection following nasal intervention and were treated with antibiotics.

The purpose of this review is to summarize the current knowledge of the effectiveness and complications of nasal-RFA.

Materials and methods

Selection of the articles for the review

Literature searches were performed using the MEDLINE, Cochrane Controlled Trials Register and Current Controlled Trial Register databases up to May 31st, 2008. The aim was to identify all scientific articles dealing with RFA treatment of nasal problems or snoring and the search strategy used is described in Table 2. Initial screening of the chosen articles was based on the information obtained from their abstracts. All abstracts were read independently by two of the authors (MH, RPR) and the selection of relevant articles dealing with nasal problems (articles dealing with snoring will be reported in a separate publication) agreed upon in discussion between the authors. When an abstract did not give sufficiently precise information about the study, or such information was not available at all, the article was obtained for further review. Full-text articles obtained for closer inspection were again evaluated independently by two of the authors, who then reached a consensus on whether an article should be included in the final review. Included were articles of any language that reported outcomes of nasal-RFA treatment in at least ten subjects.

Data extraction and management

One of the authors (RPR) extracted the basic data and results from the articles to pre-planned data collection tables, and another (MH) checked the data extraction. RPR also assessed the quality of the trials using criteria described by van Tulder et al. [7] for controlled trials and those described by Borghouts et al. [8] for observational studies. This assessment was checked by another author (AM). Initial disagreement between the evaluators regarding the quality of the studies (one item in one of the observational studies and one item in three of the controlled studies) was solved in a consensus

Table 1 Different radiofrequency generators and applicators used in the treatment of ENT-disorders

Name of generator	KHz	Applicators	Polarity	Firm
Celon	465	Single use	Bipolar	Celon AG medical instruments, Germany
Coblator	100	Single use	Bipolar	ArthroCare, TX, USA
Curis RFA	4,000	Multi use	Bipolar	Sutter Medizintechnik GmbH, Germany
ORL-set Marinescu	4,000	Multi use	Bipolar	Sutter Medizintechnik GmbH, Germany
Somnoplasty	465	Single use	Monopolar	Somnus Medical Technologies, CA, USA
Surgitron	4,000	Single use	Bipolar	Ellman International Inc, NY, USA

Table 2 Search strategy

Database: Ovid MEDLINE(R) <1950 to May 2008> Search Strategy:	
1	Snoring$.mp. Or exp snoring/(3192)
2	Sneezing$.mp. Or exp sneezing/(1719)
3	Nasal obstruction$.mp. Or exp nasal obstruction/(3593)
4	Exp Rhinitis/or rhinitis$.mp. (22171)
5	Exp Palate, Soft/or soft palate.mp. (4497)
6	Turbinate$.mp. Or exp turbinates/(3150)
7	1 or 2 or 3 or 4 or 5 or 6 (34633)
8	(Nasal adj block$).mp. [mp = title, original title, abstract, name of substance word, subject heading word] (271)
9	(Nasal adj congest$).mp. [mp = title, original title, abstract, name of substance word, subject heading word] (829)
10	(Nasal adj decongest$).mp. [mp = title, original title, abstract, name of substance word, subject heading word] (1258)
11	8 or 9 or 10 (2258)
12	7 or 11 (35743)
13	(Rfa or tcrfta or rfta or rfitt or coblation).mp. (1178)
14	Radiofrequen$.mp. [mp = title, original title, abstract, name of substance word, subject heading word] (9946)
15	13 or 14 (10424)
16	12 and 15 (125)

meeting. We were able to extract data from all included articles, but could not assess the methodological quality of the Chinese- and Japanese-language observational studies.

Results

Search results

From 125 articles identified by the systematic literature search, 35 dealing with nasal problems were judged to meet the selection criteria and were included in the review. Nine of the studies were randomized controlled trials (RCT) and 26 non-controlled follow-up studies.

Study characteristics

The most common indication (28/35 studies) for the RFA treatment was chronic nasal obstruction due to hypertrophic turbinates, which had not responded to systemic or local medical treatment (Tables 3 and 5) [1, 2, 5, 9–33]. In one study the patients were children [23]. Allergic rhinitis unresponsive to medical treatment was an inclusion criterion in six studies (Table 4) [34–39]. RFA treatment for nasal polyps was reported in one study [40]. In six studies RFA was compared to some other operative method and in one study the bipolar- and monopolar-RFA were compared (Table 5) [27–33]. Patients with systemic disease, severe septal deviation, nasal polyps, respiratory tract infection, or radiation therapy had been excluded in most of the studies. RFA had been applied bilaterally exclusively into the lower inferior turbinate in most studies. In three studies RFA had been applied also to areas of the nasal mucosa other than the inferior turbinate [34, 35, 38].

Methodological quality of the studies

Methodological quality of the controlled trials was mostly poor as only four trials scored at least 6 points out of the 11 possible (Table 6). The main shortcomings were in reporting of randomization, concealment of allocation, and baseline comparability of the patients.

Methodological quality of the non-controlled follow-up studies is shown in Table 7. The main shortcomings were in reporting selection of patients, description of baseline characteristics, small number of patients, short follow-up and description of drop-outs.

The devices used

Several different RFA devices had been used in the 35 included studies. Somnoplasty devices were used in 15, Coblator in five, Surgitron in five, Celon in four and SHP-1 in three studies. SHP-1 is no more available; it has been replaced by SHP-II (http://med9334.b2b.hc360.com). In one study both Coblator and Somnoplasty were used [31]. The RFA device was not mentioned in two studies.

Table 3 RFA studies, in which the inclusion criterion was nasal blockage

Study		*N*	Follow-up	Outcome												
				Pt VAS	Phyc VAS	Symp	Quest	QoL	Status	Video	RMM	ARM	STT/ MCT	EM	Smell	MRI	P-G plate
RCT	Powell et al. [9]	17 + 5	4 weeks	ns	ns, SS			ns									
RCT	Nease and Krempl [10]	16 + 16	6 months	SS, SS													
UNC	Li et al. [2]	22	8 weeks	SS					SS								
UNC	Elwany et al. [1]	50	12 months			SS						SS		ns			
UNC	Smith et al. [12]	11	12 months	SS	SS												
UNC	Utley et al. [13]	10	8 weeks	SS	SS					SS							
UNC	Fischer et al. [14]	22	3 months			SS					ns	SS					
UNC	Coste et al. [15]	14	2 months	SS					SS			SS	SS	ns, SS			
UNC	Back et al. [5]	20	12 months	SS							ns	SS	ns		ns		
UNC	Bhattacharyy and Kepnes [16]	26	6 months				SS										
UNC	Bruno et al. [19]	60	24 months			SS					SS						
UNC	Li et al. [18]	18	3 months	SS													
UNC	Seeger et al. [17]	38	20 months	SS			SS				SS						
UNC	Harsten [20]	158	3–30 months			SS											
UNC	Hirunwiwatkul et al. [11]	20	6–8 weeks			SS			SS	SS							
UNC	Yue and Zhang [21]	82	10 months	SS							SS						
UNC	Atef et al. [22]	102	12 months	SS								SS					
UNC	O'Connor-Reina et al. [23]	93	12 months				SS										SS
UNC	Porter et al. [24]	19	24 months	SS													
UNC	Yilmaz et al. [25]	22	24 weeks	SS													
UNC	Sapci et al. [26]	21	10 weeks	SS	SS											ns, SS	

RCT randomized controlled trial, *UNC* uncontrolled retrospective or prospective study, *N* number of patients, *Follow-up* follow-up time, *Pt VAS* visual analog scale assessed by the patient, *Phyc VAS* visual analog scale assessed by the physician, *Symp* nasal symptoms, *Quest* questionnaire, *Qol* Quality of life, *Status* nasal status, *Video* videotape images, *RMM* rhinomanometry, *ARM* acoustic rhinometry, *STT* saccharine transit time, *MCT* mean clearance time, *EM* electron microscopy, *Smell* sense of smell test. *MRI* magnetic resonance imaging, *P-G plate* Gertner-Podoshin plate. *SS* statistically significant change in the parameter, *ns* non-significant change

Table 4 RFA studies, in which the inclusion criteria was allergic rhinitis

Study		*N*	Follow-up	Outcome		
				Pt VAS	Symp	RMM
UNC	Liang et al. [34]	73	12 months		SS	
UNC	Lu et al. [35]	58	12 months		SS	
UNC	Lin et al. [36]	108	12 months	SS		
UNC	Oyake et al. [37]	16	2 months	SS		SS
UNC	Fang and Zhen [38]	63	12 months		SS	
UNC	Kong et al. [39]	35	6 months		SS	

The abbreviations in the Table 3

Table 5 RFA studies, in which for RFA was compared to some other method to reduce the inferior turbinate volume

Study	Methods	*N*	Follow-up	Outcome measurements	Results	
					Effect	Side effects
Rhee et al. [27]	RFA, laser vaporizing turbinoplasty	16 + 8	8 weeks	VAS, ARM, RMM, STT, EM, Smell	RFA = laser	RFA < laser
Sapci et al. [28]	RFA, laser ablation, control group	45 + 45 + 45	3 months	RMM, MCT	RFA = laser	RFA < laser
Cavaliere et al. [29]	RFA, turbinoplasty, control group	75 + 75 + 75	3 months	VAS, RMM, STT, endoscopy	RFA = TP	RFA < TP
Lee and Lee [30]	RFA, microdebrider	30 + 30	12 months	VAS, ARM	RFA < MD	RFA < MD
Cavaliere et al. [31]	Monopolar-RFA, bipolar-RFA	150	20 months	VAS, endoscopy, RMM, ARM, STT	monoRFA = biRFA	monoRFA = biRFA
Harrill et al. [32]	RFA, RFA + septoplasty	77	6 months	Questionnaire	RFA = RFA + SP	
Kizilkaya et al. [33]	RFA, microdebrider l dx/l sin	30	6 (12) months	VAS, ARM, STT, CBF	RFA = MD	

The abbreviations in the Table 3 CBF = ciliary beat frequency

Effect on relieving symptoms or signs of nasal obstruction

There is great variability in the methods used for measuring the subjective relief of the nasal blockage after RFA (Table 3). For example, patient-visual analog scale (VAS), physician-VAS, symptom- and QoL-questionnaires have been used. The mean nasal obstruction decreased statistically significantly (SS, $P < 0.05$) in all but one study when the effect of RFA was measured by patient-VAS or symptom questionnaires. However, in the only placebo-controlled, double-blind study there was no significant difference in the nasal obstruction outcome as measured with VAS [9]. In the studies where physicians' non-blinded assessment of the change in the nasal status was used, the change after the treatment was considered statistically significant.

Effect on relieving objectively measured nasal obstruction

Rhinomanometry (RMM) was used in nine out of the 21 RFA studies performed in patients with nasal blockage (Tables 3 and 5). The mean nasal resistance decrease after the RFA-treatment was statistically significant in seven and non-statistically significant in two studies. Acoustic rhinometry (ARM) was used in eight studies (Tables 3 and 5). The ARM measurements demonstrated a SS mean increase in the nasal volume in all of those eight studies.

Allergic rhinitis and nasal polyposis

The effect of RFA on allergic rhinitis was studied in six uncontrolled studies (Table 4). In all but one study the effect was estimated subjectively by the patient. They all showed a statistically significant effect on allergic rhinitis symptoms. In the study by Oyake [37] also RMM measurement showed a SS improvement. One study on RFA applied to nasal polyps reported a statistically significant improvement in nasal discharge, postnasal drip and RMM during the 4-week follow-up [40]. However, the change in subjective nasal obstruction, nasal status or smell was not statistically significant.

Effect on nasal mucosa

In several nasal-RFA studies the effect of RFA on nasal mucosa was studied by saccharine transit time (STT), ciliary beat frequency (CBF) or sense of smell tests (Tables 3 and 5). The results showed either no change, tendency to a better status, or SS improved values. CBF

Table 6 Quality of the randomized or controlled trials according to a criteria list by van Tulder et al. [7]

Study	1	2	3	4	5	6	7	8	9	10	11	Total
Powell et al. [9]	0	1	0	1	1	1	1	1	1	1	1	9
Rhee et al. [27]	0	0	0	0	0	0	0	1	0	1	1	3
Sapci et al. [28]	1	0	0	0	0	0	0	1	1	0	1	4
Nease and Krempl [10]	0	0	0	1	0	0	1	1	1	1	1	6
Cavaliere et al. [29]	1	0	0	0	0	0	0	1	0	1	1	4
Lee and Lee [30]	0	0	1	0	0	0	0	1	1	1	1	5
Cavaliere et al. [31]	1	0	1	0	0	0	1	1	0	1	1	6
Harrill et al. [32]	0	0	0	0	0	0	1	1	0	1	0	3
Kizilkaya et al. [33]	0	0	1	1	0	0	1	1	0	1	1	6

Maximum 11 points: 1 = Yes; 0 = No/Not reported

1. Was the method of randomization adequate?
2. Was the treatment allocation concealed?
3. Were the groups similar at baseline regarding the most important prognostic indicators?
4. Was the patient blinded to the intervention?
5. Was the care provider blinded to the intervention?
6. Was the outcome assessor blinded to the intervention?
7. Were co-interventions avoided or similar?
8. Was the compliance acceptable in all groups?
9. Was the drop-out rate described and acceptable?
10. Was the timing of the outcome assessment in all groups similar?
11. Did the analysis include an intention-to-treat analysis?

significantly decreased on day 7 and returned to preoperative values on day 60 [15]. In five out of 14 patients a moderate number of squamous cells were detected on either day 7 or 60 after treatment, and a small area of necrosis was seen on day 7 on one turbinate but it had disappeared on day 60 control visit [15]. Elwany [1] found no atrophic changes or adhesions 1 year after RFA-intervention.

Side effects

There were no major complications reported in the reviewed 35 studies. Also among pediatric patients no adverse effects were encountered [23]. The most common complaint was pain during and after the RFA treatment. In the study by Coste et al. [15] three patients out of 14 had pain during the procedure, and in two of them treatment had to be stopped because of the pain. Postoperative pain was reported to be non-existent or minimal and controlled by occasional analgesics [15, 16]. Repeat-treatment acceptance was 17/19 (89%) [5]. Epistaxis was seen in two out of 24 cases, the other one needing nasal packing [16]. Patients usually have an initial edematous response after RFA and nasal obstruction increases during the early postoperative period for an average of 1 week. Subjective improvement of nasal patency was seen 2–3 weeks postoperatively [14]. Prolonged crust formation for as long as 2–4 weeks was sometimes observed [1, 14].

Nasal-RFA compared to other treatment methods

In six studies RFA was compared to some other operative method and in one study bipolar- and monopolar-RFA was compared (Table 5). Rhee et al. [27] compared RFA and laser vaporizing turbinoplasty, Sapci et al. [28] RFA, CO_2 laser ablation, and partial turbinectomy, Cavaliere et al. [29] RFA and partial turbinectomy, Lee and Lee [30] and Kizilkaya et al. [33] RFA and microdebrider-assisted partial turbinoplasty, and Harrill et al. [32] RFA and RFA in combination with septoplasty. RFA, laser vaporizing turbinoplasty, laser ablation and turbinoplasty all decreased nasal blockage in a statistically significant manner. Trimming of the hypertrophied mucosa with a microdebrider was SS more effective in reducing nasal volume and nasal blockage than RFA. In the comparative studies RFA caused fewer side effects than the other methods used.

Can additional relief of nasal obstruction be achieved by repeated RFA treatments?

Three (3/16) patients still had nasal obstruction 8 weeks after the turbinate-RFA treatment. Two patients received one extra treatment and one patient two additional turbinate-RFAs. In all cases the additional treatment gave relief [27]. Atef et al. [22] found improving nasal volumes after five RFA treatments.

Table 7 Quality of the prospective non-controlled studies according to criteria modified from Borghouts et al. [8]

Study	1	2	3	4	5	6	7	8	9	10	Total
Li et al. [2]	0	1	1	0	0	1	1	1	1	1	7
Elwany et al. [1]	1	1	0	1	1	1	1	1	1	0	8
Smith et al. [12]	0	1	1	0	1	1	0	1	1	1	7
Utley et al. [13]	0	1	0	0	0	1	1	1	1	1	6
Fischer et al. [14]	1	1	0	0	0	1	1	1	1	0	6
Coste et al. [15]	0	1	1	0	0	1	1	1	1	1	7
Back et al. [6]	1	1	0	0	1	1	0	1	1	1	7
Bhattacharyya and Kepnes [16]	0	1	0	0	0	1	0	1	1	1	5
Bruno et al. [19]	0	0	0	0	0	0	0	1	0	0	1
Lin et al. [36]	1	1	0	1	1	1	0	1	1	1	8
Seeger et al. [17]	0	0	0	1	1	1	0	1	1	1	6
Harsten [20]	0	1	0	1	0	0	0	1	1	0	4
Hirunwiwatkul et al. [11]	0	0	0	0	0	1	0	1	1	0	3
Fischer et al. [14]	0	1	1	0	0	1	0	1	1	1	6
Atef et al. [22]	1	1	0	1	1	1	0	1	1	1	8
Porter et al. [24]	1	1	0	1	1	0	0	1	1	1	7
Yilmaz et al. [25]	1	1	1	0	0	0	0	1	1	1	6
O'Connor-Reina et al. [23]	1	0	0	1	1	1	1	1	0	0	6
Sapci et al. [26]	1	1	1	0	0	0	0	1	1	1	6

Maximum 10 points: 1 = Yes; 0 = No/Not reported

Study population

1. Selection of study population. Positive if patients were identified at a uniform point of disease
2. Description of inclusion and exclusion criteria
3. Description and analysis of potential prognostic factors
4. Study size (at least 20 patient-years for every reported group)

Follow-up

5. Follow-up ≥12 months
6. Drop-outs/loss to follow-up <20%
7. Information provided for loss to follow-up/drop-outs (or there were no drop-outs/loss to follow-up = less than 5%)
8. Outcome measures used concords with the aim of the intervention in methods

Data presentation and analysis

9. Presentation of outcome measures concords with the aim of the intervention in results
10. Appropriate analysis techniques

The persistence of treatment effect

The mean follow-up time in the articles varied from four weeks to 24 months. In nine out of the 35 studies the follow-up time was less than 3 months. In 12 studies the follow-up time was between 3 and 10 months, and in 14 studies 1 year or more. In six of the 14 studies with a follow-up of at least 1 year the results were based on subjective symptoms only and in eight of them on symptom questionnaires, status evaluation, VAS, ARM, RMM, smell test and/or STT. In all those studies the mean effect of turbinate-RFA was maintained in a statistically significant manner in one or more of the follow-up parameters [1, 5, 17, 19, 22, 23, 30, 31]. In two studies a slight but not statistically significant decrease was seen in nasal patency measured by VAS [5, 30].

Discussion

Radiofrequency ablation is a relatively new method for the reduction of submucosal tissue of the nasal mucous membrane, mainly that of the inferior turbinate. According to our knowledge, and based on the literature search, the method is used in many different countries although the number of nasal-RFA studies, especially randomized controlled trials (RCTs), is relatively small. We found only one double-blind RCT [9].

The purpose of this article is to review, in a systematic manner, the effectiveness and complications of nasal-RFA and to summarize current gaps regarding scientific knowledge of RFA treatment outcomes. We did not use any language restrictions and all studies that had at least ten patients were included. Most of the selected articles had distinct handicaps. In many cases the patients and the degree of their symptoms were poorly described. A common description of the inclusion criteria in the articles was: "patients complaining of chronic nasal obstruction and failing to respond to medical treatment". A demographic categorizing of the symptoms was seen in only one article [10]. In one study, although a control group was mentioned in the methods, the follow-up results of the control group were not provided [29]. Publication bias and the fact that in these studies nasal-RFA treatment has probably been performed by experienced physicians on selected patients can also cause some bias on the conclusions of this review. The description of the RFA procedure also varied a lot. In some articles it was very carefully explained and in some mentioned only shortly. As the method is relatively new it should be a requirement that the procedure is described in detail. Most of the nasal-RFA studies published have been performed utilizing Somnus Medical Technologies devices. We did not find any study where two or more devices would have been compared although this kind of a comparison would be very useful for clinical practice, especially as the prices of the different devices and applicators vary.

In nasal-RFA studies, subjective symptoms are the most common outcome measure. However, irrespective of whether the evaluation of an invasive procedure is done by the patient or the physician, it is prone to be biased by the placebo effect. This is especially true when good results from a new method are sought. We included both controlled trials and uncontrolled studies in our review. The uncontrolled study design may provide valid information on outcomes that remain stable or progress in the absence of an intervention [41]. In case of nasal disorders, the symptoms usually fluctuate, diminishing the power of uncontrolled studies to distinguish the natural course of the disease from the treatment effect. Particularly in such instances, the value of controlled trials is much greater than that of uncontrolled studies in determining the effectiveness of an intervention.

Two controlled trials assessed the effectiveness of RFA in comparison with the natural course of the disease. The only double-blind RCT did not show effectiveness of RFA in patient VAS or quality of life, and had only a 4-week follow-up. The other controlled trial showed some effectiveness, but both two had a small number of patients.

The development of measurements for the nasal cavity such as RMM and ARM has given more objective tools to evaluate pre- and postoperative nasal function and anatomy than the rather subjective nasoscopy [42, 43]. RMM was used in eight and ARM in six out of the 21 RFA studies on nasal blockage (Tables 3 and 5). The RMM change was Statistically significant in six out of the eight studies and the ARM change in all six. This high number of positive results indicates that RFA has a measurable effect in diminishing the volume of the nasal mucosa.

The effect of nasal-RFA on nasal polyps has been studied in only one published article. Thus, it is too early to say whether RFA is useful in this indication. On allergic rhinitis six articles have been published (Table 4). Although the mean follow-up time in them is relatively long, the outcome is mainly (5/6) based on subjective evaluation. More RCTs are clearly needed to demonstrate the usefulness of RFA in allergic rhinitis patients who have failed to respond to medical treatment.

One well-defined advantage of nasal-RFA is that it is well tolerated. In all four studies in which RFA was compared with other methods, RFA caused fewer side effects (Table 5). RFA also decreased the symptoms in a statistically significant manner and only microdebrider-based reduction of the mucosa of the inferior turbinate achieved a better outcome [30]. The most common side effects of RFA are pain during the procedure, bleeding, crusting, and postoperative edema of the mucosa causing blockage of the nose for up to four weeks. The high number of localized infections after nasal-RFA, 12%, found by Madani (2004) was not seen in the studies included in this review [4]. The most easily avoidable of the side effects caused by nasal-RFA is probably pain during the procedure. It can sometimes be severe enough to prevent continuation of the treatment [15]. Therefore, it is of utmost importance that local anesthesia is well planned and performed as nasal-RFA is often given in outpatient departments having busy schedules.

RFA is well tolerated by the patient and also, so it seems, by the nasal mucous membrane. The changes in the mucosa seem to be few, momentary or non-existing depending on whether they are measured by status, video images, STT, MCT, electron microscopy, or sense of smell tests. However, one must pay attention to the fact that in one study five out of 14 patients showed a moderate number of squamous cells on either day 7 or day 60 after the treatment [15]. It has to be remembered that our knowledge of the long-term action of nasal-RFA on the mucosa is still limited.

Based on the published studies there is some evidence that nasal-RFA may decrease subjective symptoms and nasal blockage. However, as this evidence is mainly based on observational studies of symptoms with great natural variation, and we know that all invasive treatments have a significant placebo effect, there is an obvious need for well-planned, double-blind, placebo-controlled randomized trials of nasal-RFA. Also, the mean follow up times of the 35

studies selected for this review were short, and there clearly is a need for longer follow-up of subjective and objective outcomes as well as the mucosal changes observed after RFA treatment. Furthermore, as the market prices of the devices vary, it would be advisable to perform a study in which the effects and the adverse effects of the different priced devices would be compared. We recommend that a RFA study should include (1) the study is double-blind, placebo-controlled randomized trial, (2) change of the nasal mucosal oedema is objectively measured for example with acoustic rhinometry and/or MRI, (3) disease-specific and generic quality of life questionnaires are used, and (4) the follow-up time after RFA is at least 1 year.

Conclusion

Based on the results of the 35 studies included in this review, nasal-RFA is a safe operative procedure, reduces inferior turbinate mucous membrane volume in patients having chronic nasal obstruction failing to respond to medical treatment, and may thus decrease subjective symptoms and nasal blockage. Based on current knowledge RFA alters the nasal mucosa only slightly and causes only minor discomfort and risk of side effects for the patient. However, as most of the included studies are observational and have a relatively short follow-up, there is an urgent need for well-planned, double-blind, placebo-controlled randomized trials on nasal-RFA treatment.

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Conflict of interest statement AM and RPR have no clinical or commercial connections with RFA device producers. MH and LB use RFA devices in their clinical and research work. LB used in his studies RFA generators and applicators provided by the VidaMed Inc, USA (Bäck 2001) and Arthrocare Company, USA (Bäck 2002). MH was a co-author in the study of Bäck et al. (2002). LB and MH have no other connections with any of the device producers. Dr Hytönen has used a RFA device supplied by Arthrocare, USA, in one study [5]. Dr Bäck has used a RFA devices supplied by VidaMed (Bäck 2001) and Arthrocare, in two studies [5, 6].

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