Results of Temperature-Controlled Radiofrequency Tissue Volume Reduction for the Turbinate Hypertrophy

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Objectives : *To assess the efficacy of temperature-controlled radiofrequency tissue volume reduction (RFTVR) for the inferior turbinate.*
Research designs: *Prospective, single-blinded, experimental clinical trial.*
Method : *Twenty patients with nasal obstruction secondary to inferior turbinate hypertrophy were enrolled. Nasal obstruction was compared between before and after the treatment (at 1-3 days, 1 week and 6-8 weeks) of RFTVR using subjective symptom scores, physical findings and videotape images.*
Results : *Improvement of nasal symptoms was observed as early as 1 week after the operation. However, significant improvement was obtained at 6-8 weeks.*
Conclusion : *RFTVR for the turbinate may be useful as an alternative approach for the treatment of chronic turbinate hypertrophy.*

Keywords : *Radiofrequency, Nasal obstruction, Nasal turbinate hypertrophy*

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Hypertrophy of the inferior turbinate is a common cause of chronic nasal obstruction. Many cases have responded to conventional medical managements with topical steroids or nasal decongestants. In some patients, this therapy is not sufficient, and many surgical procedures such as laser turbinoplasty[1], cryosurgery, electrocautery, and turbinectomy[2] have been used to reduce the size of the inferior turbinates. However, these surgical treatment modalities tend to be invasive or painful and may cause postoperative complications such as pain, bleeding, crusting, sense of dryness, and adhesion, and the efficacy varies between surgeries. Recently, temperature-controlled RFTVR has been used for the treatment of hypertrophied turbinate. Radio-frequency energy delivered submucosally in the inferior turbinate creates a thermal lesion (60°-80°C) which preserves the mucosa. It uses heat generated from radiofrequency energy to create ionic agitation in the surrounding tissue, which induces submucosal inflammation. The circumscribed area of submucosal necrosis is replaced over time by fibroblasts as part of the normal wound repair process. Wound contraction results in turbinate volumetric reduction, leading to relief of nasal obstruction without causing damage to the overlying mucosa.

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Material and Method

Study Design

The present study is a prospective, experimental clinical trial to evaluate the efficacy of temperature-monitored and temperature-controlled RFTVR in achieving the reduction of nasal obstructive symptoms. The study was carried out from January 2000 to December 2000 at ENT department, King Chulalongkorn Memorial Hospital and Eye Ear Nose Throat Hospital. Every procedure was performed after obtaining informed consent.

Patients

Twenty patients with nasal obstruction secondary to inferior turbinate hypertrophy were enrolled in the present study. Volunteers willing to participate were informed of the nature of the study and its primary end-point. Each patient underwent a complete medical history and physical examination.

All patients were treated with RFTVR. All patients were over the age of 18 years and consisted of 15 men and 5 women with a mean age of 38 ± 9 years. Two patients were excluded from the study due to loss of follow-up. Subjective symptom changes were evaluated preoperatively for baseline and postoperatively at day 1-3, week 1, and week 6-8. Preoperative and postoperative (at week 6-8) videotape images of the nasal cavity were graded for obstruction in a blinded manner by another physician. Physical assessment of crusting, pain, bleeding, and infection on the operative site related to the treatment was recorded at postoperative day 1-3, week 1, and week 6-8.

Evaluation

Subjective symptoms including severity and frequency of nasal obstruction were measured by symptom scores. The patient's assessment of the degree and frequency of nasal obstruction was recorded. A score of 1 represented no obstruction, 2 = mild degree of obstruction, 3 = moderate degree of obstruction, 4 = severe but not complete obstruction, and a score of 5 indicated complete nasal obstruction and constant, unremitting nasal obstruction. Preoperative and postoperative (at week 6-8) videotape images of the nasal cavity were graded for obstruction in the same scoring method. The degree of obstruction was graded from 1-5. All images were labeled with a code and evaluated by the other ENT surgeon not involved in the treatment of these patients.

Procedure

Radiofrequency tissue volume reduction was performed as follows: A cotton pledget soaked with 4% lidocaine was placed on the anterior portion of the inferior turbinate for 10 minutes. Afterwards, a local anesthetic solution of 1% lidocaine without epinephrine was injected. The Somnoplasty handpiece for the turbinate (Somnus Medical Technologies, Inc., Sunnyvale, CA) consists of a 40-mm electrode with a distal 15-mm active portion and a proximal 25-mm insulated portion. The active portion of the electrode and 2 to 3 mm of the insulation were inserted into the inferior turbinate and the active electrode was placed below the surface of the nasal mucosa. A thermocouple at the needle tip and at the junction of the exposed and insulated portions of the needle provides temperature feedback to control power delivery. The procedure was performed on the anterior portion (+/- middle portion) of each inferior turbinate. An average of 1100 Joules per side radiofrequency energy was delivered by the Somnus S2 radiofrequency generator (Somnus Medical Technologies, Inc.) at a target temperature of 80°C. The procedure was then performed on the contralateral side.

Patients were evaluated at day 1-3, week 1, and week 6-8. At each visit, the patient's assessment of the degree and frequency of nasal obstruction was recorded. The degree of nasal obstruction was also graded by the primary surgeon in the same manner. The adverse reactions such as pain, bleeding, crusting and infection were graded (no, mild, moderate, severe). Videotape images of the nasal cavities were acquired on pre-op and post-op week 6-8.

Paired T-Test was used for statistical analysis for assessment of efficacy of the procedure, and p value less than.05 was considered to be statistically significant.

Results

Twenty patients were enrolled in the present study. Two patients were excluded from the study due to loss of follow-up.

Mean nasal obstruction as graded by the patients improved on the left side from 3.00 (preoperatively) to 2.89 (at day 1-3), to 2.44 (at week 1) and to 2.11 (at week 6-8) and on the right side from 3.11 (preoperatively) to 2.33 (at day 1-3), to 2.17 (at week 1) and to 2.06 (at week 6-8). For the frequency of nasal obstruction, statistical significance was observed between the baseline and at 1-3 days ($p = 0.623$), 1 week ($p = 0.054$) and 6-8 weeks ($p = 0.004$) on the left side and $p = 0.010$, $p = 0.007$, $p = 0.010$ respectively on the right side.

Mean nasal obstruction as graded by the physician (unblinded examiner) decreased on the left side from 3.28 (preoperatively) to 3.11 (at day 1-3; $p = 0.317$), to 2.50 (at week 1; $p = 0.007$) and to 1.94 (at week 6-8; $p < 0.000$) and on the right side from 3.17 (preoperatively) to 3.06 (at day 1-3; $p = 0.480$), to 2.22 (at week 1; $p = 0.002$) and to 1.72 (at week 6-8; $p < 0.000$).

Mean nasal obstruction as graded from VDO recording at baseline and week 6-8 by the physician (blinded examiner) decreased on the left side from 3.78 to 3.44 ($p = 0.014$) and on the right side from 3.94 to 3.28 ($p = 0.001$).

One patient had a moderate degree of bleeding at the site of needle insertion after the procedure. However, no packing was required. Five patients reported moderate pain and six patients reported mild pain during the procedure. No patient required postoperative pain medication. One patient had a moderate degree of crusting at week 1. No adverse effects were observed at week 6-8.

Table 1. Shows the degree of nasal obstruction graded by the patients

	Pre-op	Post-op Day 1-3	p-value	Post-op Week 1	p-value	Post-op Week 6-8	p-value
Patient's assessment: Lt nose	3.0000	2.8889	0.623	2.4444	0.054	2.1111	0.004
Patient's assessment: Rt nose	3.1111	2.3333	0.010	2.1667	0.007	2.0556	0.010

1 = no obstruction, 2 = mild degree of obstruction, 3 = moderate degree of obstruction, 4 = severe but not complete obstruction, 5 = complete nasal obstruction and constant, unremitting nasal obstruction

Table 2. Shows the degree of nasal obstruction graded by the physician (unblinded examiner)

	Pre-op	Post-op Day 1-3	p-value	Post-op Week 1	p-value	Post-op Week 6-8	p-value
Physician's assessment: Lt nose	3.2778	3.1111	0.317	2.5000	0.007	1.9444	0.000
Physician's assessment: Rt nose	3.1667	3.0556	0.480	2.2222	0.002	1.7222	0.000

1 = no obstruction, 2 = mild degree of obstruction, 3 = moderate degree of obstruction, 4 = severe but not complete obstruction, 5 = complete nasal obstruction and constant, unremitting nasal obstruction

Table 3. Shows the degree of nasal obstruction graded by the physician (blinded examiner)

	Pre-op	Post-op Week 6-8	p-value
VDO assessment: Lt nose	3.7778	3.4444	0.014
VDO assessment: Rt nose	3.9444	3.2778	0.001

1 = no obstruction, 2 = mild degree of obstruction, 3 = moderate degree of obstruction, 4 = severe but not complete obstruction, 5 = complete nasal obstruction and constant, unremitting nasal obstruction

Discussion

Radiofrequency energy has been used extensively in a variety of medical and surgical fields. It has been applied for the treatment of benign prostatic hypertrophy[3], correcting ligamentous laxity in chronic joint sublaxation[4], endometrial ablation for dysfunctional uterine bleeding [5] and aberrant conduction pathways such as in Wolf-Parkinson-White syndrome and other arrhythmias[6]. In otorhinolaryngology, it can be applied for the treatment of nasal obstruction by reducing the volume of the turbinates[2, 7-13], sleep-disordered breathing by reducing the soft palate[14] and base of the tongue [15, 16]. Temperature-controlled radiofrequency energy causes a high-frequency alternating current to flow from the tip of the electrode to the surrounding tissue, causing ionic agitation and frictional heating of the tissue around the electrode and resulting in local coagulation and destruction. The target tissue temperature can be maintained between 60° and 80°C with relatively low energy, avoiding damage to the surrounding tissue. The intent of tissue volume reduction is to induce submucosal fibrosis of the turbinate, which will adhere the mucosa to the turbinate periosteum and reduce the blood flow to the turbinate, rendering it less prone to swelling and edema. Another concern was that vasoconstriction would cause difficulty with insertion of the needle electrode, since there is less soft tissue thickness after vasoconstriction.

Utley[11] et al reported that the subjective symptoms began to improve at 1 week and gradually improved until 8 weeks. The present study was consistent with previous studies because RFTVR resulted in marked improvement of subjective nasal symptoms at 1 week or later. However, the authors demonstrated that the subjective symptoms began to improve in the very early postoperative days (day 1-3). In cases of inferior turbinate hypertrophy associated with mild to moderate septal deviation or septal ridges, the symptom relief obtained by RFTVR may reduce invasive procedures such as septoplasty. In other studies, RFTVR did not result in deterioration of the mucociliary transport mechanism. In the present study the authors demonstrated that RFTVR for the turbinate is effective in the improvement of nasal obstruction. The only disadvantage of this procedure in Thailand may be the high cost of the disposable needle tip compared with other procedures. Thus, research on cost-effectiveness is

needed for the future. The limitations of the present study are the small number of patients, lack of a control/placebo group, and short duration of follow-up. Therefore, a further follow-up study is needed for evaluation of long-term improvement of symptoms and maintenance of nasal function.

Conclusion

Temperature-controlled RFTVR for the turbinate reduces nasal obstruction with minimal complications. These results suggest that RFTVR for the turbinate may be a useful alternative method for the treatment of chronic turbinate hypertrophy.

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ผลการรักษาเพื่อลดขนาดของเยื่อบุกระดูกเทอร์บิเนทชิ้นล่างโดยใช้คลื่นวิทยุ

ประกอบเกียรติ หิรัญวิวัฒน์กุล, ทรงกลด เอี่ยมจตุรภัทร,พรชัย อรพินท์

วัตถุประสงค์ *: เพื่อประเมินประสิทธิผลของการลดขนาดเยื่อบุกระดูกเทอร์บิเนทชิ้นล่างที่หนาโดยใช้คลื่นวิทยุชนิดควบคุมอุณหภูมิได้*

รูปแบบการวิจัย *: การศึกษาไปข้างหน้า แบบการทดลองทางคลินิก แบบผู้ทดลองไม่ทราบผล*

วิธีการศึกษา-วัดผล *: คัดเลือก ผู้ป่วยที่มีภาวะจมูกอุดตันจากเยื่อบุกระดูกเทอร์บิเนทชิ้นล่างบวมโต จำนวน 20 คน และเปรียบเทียบภาวะจมูกอุดตันก่อนและหลังการรักษา โดยใช้แบบสอบถามอาการผู้ป่วย การตรวจร่างกาย และภาพถ่ายวิดิทัศน์*

ผลการศึกษา *: ภาวะจมูกอุดตันดีขึ้นหลังการรักษา เริ่มตั้งแต่สัปดาห์ที่ 1 แต่จะดีขึ้นอย่างมีนัยสำคัญเมื่อประมาณ สัปดาห์ที่ 6-8*

สรุป *: การรักษาโดยใช้คลื่นวิทยุเป็นวิธีที่ได้ผลและเป็นอีกทางเลือกในการรักษาภาวะจมูกอุดตันเนื่องจากเยื่อบุกระดูกเทอร์บิเนทชิ้นล่างบวมโต*
