Clinical Feasibility Trial of 1,940-nm Diode Laser in Korean Patients with Inferior Turbinate Hypertrophy

Sung Hoon Kang

Saehee Lim

Dongju Oh

Karam Kang

Kwang Jin Jung

Ha Kyun Kim

Sang Hag Lee

Seung-Kuk Baek

Tae Hoon Kim

*Department of Otorhinolaryngology-Head & Neck
Surgery, College of Medicine, Korea University,
Seoul, Korea*

Received November 24, 2015

Revised November 30, 2015

Accepted November 30, 2015

Correspondence

Seung-Kuk Baek, Tae Hoon Kim
Department of Otorhinolaryngology-Head & Neck
Surgery, College of Medicine, Korea University,
126-1, 5 ga, Anam-dong, Sungbuk-gu,
Seoul 02841, Korea
Tel: +82-2-920-5486
Fax: +82-2-925-5233
E-mail: doctorth@korea.ac.kr; mdskbaek@gmail.com

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Background and Objectives

The purpose of this clinical feasibility trial was to evaluate the preliminary results regarding postoperative outcomes of inferior turbinate reduction using a 1,940-nm thulium laser system.

Materials and Methods

This clinical feasibility trial included eight patients with inferior turbinate hypertrophy. The inferior turbinate reduction was performed using a 1,940-nm thulium laser with 4.5 W of output power. Intraoperative scoring was performed by a surgeon rating the ablative capacity of the apparatus [5-point scale, 1-5], as well as intraoperative bleeding [3-point scale, 0-2]. Patient questionnaires on pain and the surgeon's reports on postoperative changes in the surgical field [11-point scale, 0-10] were also analyzed on postoperative days 1, 7, and 14.

Results

No complications were observed in this study. The surgeon's mean rating on the ablative capacity of the laser was 4.13 ± 0.35 . Postoperative pain decreased prominently (4.13 ± 2.10 , 1.38 ± 1.19 , 0.25 ± 0.46 on postoperative day one, week one, and week two, respectively) with a statistically significant difference observed between postoperative day one and week two [$p=0.0005$]. Swelling on postoperative day one had decreased significantly by postoperative week one [$p=0.001$]. Scar contraction score on postoperative day one had decreased significantly by postoperative week one [$p=0.003$].

Conclusion

The 1,940-nm Thulium fiber laser system is an efficient alternative to conventional laser systems in the treatment of nasal congestion due to hypertrophied nasal turbinates. Further randomized comparative clinical trials are needed to confirm these results and to extend the 1,940-nm laser-energy application in the clinics.

Key words

1,940-nm thulium laser system; Inferior turbinate hypertrophy; Feasibility trial

INTRODUCTION

Inferior turbinate hypertrophy is one of the most common causes of nasal congestion.¹ The common causes of inferior turbinate hypertrophy are chronic hypertrophic rhinitis, chronic infectious rhinitis, and vasomotor rhinitis.² The first-line treatment of these conditions is the medication. However, patients with the abuse of topical nasal decongestants suffer from more severe nasal congestion such as rhinitis medicamentosa.³ Surgical treatment is considered for patients who are unresponsive to conservative medication.¹ Over the years, several surgical techniques such as total/partial turbinectomy, submucosal turbinectomy, laser submucosal turbinectomy, electrocauterization and radiofrequency ablation has been introduced, but there is no consensus of optimal procedure of inferior turbinate surgery.⁴

The major complications of inferior turbinate surgery are bleeding, crusting, and atrophic rhinitis by high thermal damages and excessive resection.¹ Recently, 1,940-nm thulium fiber laser system was developed and now clinical trials using 1,940-nm laser are actively being conducted.⁵ 1,940-nm laser has a high water absorption rate of the tissue and it enables the 1,940-nm laser to handle tissues more precise with low thermal damage.⁶⁻¹⁰ However, there is no report about the clinical trial in Korean patients with inferior turbinate hypertrophy using 1,940-nm thulium fiber laser system. Therefore, this study is conducted prospectively to evaluate the clinical feasibility of 1,940-nm laser in the treatment of Korean patients with inferior turbinate hypertrophy.

MATERIALS AND METHODS

Patients and study design

A prospective and non-blinded clinical study was con-

ducted from January to August 2015, at the Otorhinolaryngology department, Korea University Hospital. The study was approved by the Institutional Review Board of Korea University Hospital (IRB No. MD15001). The inclusion criteria were as follows: (1) patients with chronic nasal congestion caused by inferior turbinate hypertrophy, (2) patients who are refractory to medical treatment. Exclusion criteria were as follows: (1) patients with a history of previous oral/nasal surgery, (2) patients with nasal polyps, (3) patients with chronic rhinosinusitis, (4) patients who are pregnant. Informed consent was obtained from all of the patients. Laser apparatus (Xlender-Y; Wontech, Daejeon, South Korea) using 1,940-nm Thulium fiber laser was used for the operation. The diode module of laser system offers up to 12 W of output through a 600 µm diameter optical fiber with a 0.22 numerical aperture.

Clinical procedure

The operation was performed by a single surgeon under general anesthesia. During pre-operation, nasal packing was done with gauze soaked with 10% lidocaine plus epinephrine solution. Both inferior turbinates were infiltrated with 3 ml of 1:100,000 epinephrine in 1% lidocaine solution, preoperatively. The laser system mode was set to 3-6 W of power, 1,000 Hz. During operation, the laser was applied from posterior to anterior edge of the inferior turbinate under endoscope. The laser spot was applied four or five times more at the head of the inferior turbinate in cases where the head of the inferior turbinate is large. Following surgery, the nasal packing was done with NASOPORE® (Polyganics, The Netherlands). The nasal packing was removed post-operative Day 1. The patients were then followed up at postoperative day 1, 7, and 14.

Clinical parameters

The intraoperative grading was done by a single sur-

Table 1. Demographics and intraoperative findings

Number	Sex	Age	Operation time (min)	Ablative capacity*	Intraoperative bleeding†	Amount of bleeding	Number of bipolar electrocauterization
1	M	44	1	5	1	0.5	0
2	M	24	2	4	1	0	0
3	M	33	2	4	1	0	0
4	M	30	2	4	1	1	0
5	M	21	2	4	1	0	0
6	M	65	2	4	0	0	0
7	M	37	2	4	0	0	0
8	M	24	2	4	1	0	0

*1 = insufficient, 2 = poor, 3 = moderate, 4 = good, 5 = very good.

†0 = no bleeding, 1 = slight bleeding requiring additional laser application for bleeding control, 2 = bleeding requiring other additional intervention for bleeding control.

geon, mean and standard deviations were derived from all documented values (Table 1). 5-point grading scale was used for ablative ability, where 1 = insufficient, 2 = poor, 3 = moderate, 4 = good, and 5 = very good. 3-point grading scale was used for intraoperative bleeding, where 0 = no bleeding, 1 = slight bleeding requiring additional laser application for bleeding control, 2 = bleeding requiring other additional intervention for bleeding control. Visual Analog Scale using 11-point grading was used to evaluate patient's postoperative pain. The surgeon's ratings of swelling and scar contraction used an 11-point grading scale with endoscopic inspection. Student's t-test using

SPSS was used for statistical analysis.

RESULTS

Procedure-related results

This study included eight males with a median age of 31.5 ± 14.4 years. The average laser application time was 1.88 ± 0.35 minutes. The median laser power is 4.5 W. The total applied energy of laser was 11.25 ± 2.12 J. The surgeon's mean rating on the ablative capacity of the laser was 4.13 ± 0.35 . During operation, the number of bipolar cauterization in all cases was zero. The intraoperative

Fig. 1. Endoscopic findings before and after 1,940-nm Tm: fiber laser-assisted tissue reduction of hyperplastic turbinates in left and right nasal cavity. (A) In-situ nasal finding before reduction without decongestion. (B) Nasal finding of day 7 after reduction without decongestion. (C) Nasal finding of day 14 after reduction without decongestion, which shows reduced turbinate volume.

bleeding has occurred in six patients and the mean volume of bleeding was 0.19 ± 0.37 ml.

Statistical analysis of clinical parameters

All patients were able to be inspected at every follow-up day (postoperative day 1, 7, and 14), as scheduled (Fig. 1). There was no postoperative bleeding or re-admission into this study.

Postoperative pain decreased prominently (4.13 ± 2.10 , 1.38 ± 1.19 , 0.25 ± 0.46 on postoperative day 1, 7, and 14, respectively) with a statistically significant difference observed between postoperative day 1 and day 7 ($p=0.0005$; Fig. 2A). Swelling at postoperative day 1 decreased prominently by day 7 ($p=0.001$; Fig. 2B). Scar contraction score at postoperative day 1 decreased significantly by postoperative day 7 ($p=0.003$; Fig. 2C).

DISCUSSION

The inferior turbinate surgery is one of the common surgical procedures in clinical rhinology.² The main purpose of this surgery is the reduction of inferior turbinate bulk.¹ To reduce complications, the maintenance of optimum size of the inferior turbinates is crucial in the surgery.¹ Many surgical modalities have been introduced: submucosal turbinectomy, inferior turbinate outfracture, electrocauterization, and radiofrequency ablation.² The thermonecrosis of inferior turbinate tissue is the main principle of inferior turbinate surgeries using thermal technique.¹¹ Thermal technique was proven to be effective, but the excessive thermal damage to adjacent tissue could make irrevocable complications such as atrophic

turbinate.² New laser system being used in many clinical fields has been known to have a good accuracy and proper thermal energy delivery to ablating tissues.⁶

Diode laser system is one of the surgical instruments that is widely applied in many clinical departments. Recently, 1,940-nm laser system has been developed and the first was used in prostate surgery.¹²⁻¹³ Comparing with 940-nm, 1470-nm laser system, Ronald Sroka et al.⁵ reported that the operation time of 1,940-nm laser was shorter and total energy of 1,940-nm laser was lesser. Many studies have proven that a 1,940-nm emission wavelength overlaps with one of the water absorption peaks.⁶⁻¹⁰ The absorption coefficient of 1,940-nm laser is very high and this enables the 1,940-nm laser to ablate tissue more precise with less thermal damage.⁶

Guney et al.⁶ reported that hemostatic effect of 1,940-nm is superior to other types of inferior turbinate surgery. In our study, bleeding during surgery was very rare and there was no postoperative bleeding. The short operation time using low total energy was also an advantage of 1,940-nm thulium laser system.¹⁴ A tissue reduction with 1,940-nm laser was sufficient to reduce nasal obstructive symptoms as well. Moreover, easy and light-weighted handling was another advantage of 1,940-nm thulium laser fiber and accurate procedures during surgery were possible.

The major limitation of the present study is a small sample size. As the clinical application of 1,940-nm diode laser began recently, there was no clinical study of a large population. Lack of long-term follow-up is also a limitation of our study. Further study with large sample size and long-term follow-up period will be needed to compare

Fig. 2. Postoperative change of pain (A), swelling (B), and scar contraction (C).

1,940-nm laser with other methods.

ACKNOWLEDGMENTS

This research was supported by the Clinical Trial Center of Korea University Anam Hospital (I1500931), the Korea Health Technology R&D Project (HI14C0748) through the Korea Health Industry Development Institute (KHIDI) by the Ministry of Health & Welfare, and the Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education, Science and Technology and the Ministry of Science, ICT & Future Planning [2011-0014068, 2014R1A1A1002131].

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