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Nasal Obstruction with Hypertrophic Inferior Turbinate: Treatment with Non-ablative Erbium YAG laser – a Pilot Study with Randomized Placebo-Controlled Trial Design

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ABSTRACT

All surgical procedures used today for the treatment of hypertrophic inferior turbinate are more or less invasive. Erbium YAG laser in non-ablative, SMOOTH thermal mode is considered as a non-invasive treatment and could be a new and safe alternative. The aim of this study was to evaluate this laser treatment.

Materials and methods: 20 patients were included in this prospective, parallel group, single-blinded (patient), randomized placebo-controlled pilot study. The objectives were to evaluate the safety and performance of the laser during and after 3 sessions of treatment in one month. The primary objective was to evaluate the nasal obstruction both subjectively and objectively (by Visual Analogue Scale, VAS, and Nasal Peak Inspiratory Flow Meter, N-PIF). The secondary objective was to evaluate the nasal burden on quality of life according to a severity classification system (the modified Nasal Obstruction Symptom Evaluation Scale, or NOSE-scale).

Results: The active laser treatment showed high improvement during and after the procedure, both subjectively and objectively, regarding nasal obstruction, and decreased the nasal burden on quality of life. The placebo laser treatment showed no changes or improvements. The safety evaluation did not present any safety concerns.

Conclusion: This pilot study showed that Erbium YAG laser could be an effective, rapid, non-invasive, pain free, and safe alternative method for the treatment of nasal obstruction with inferior turbinate hypertrophy. Further and larger studies with longer evaluations could be recommended for stronger evidence.

Key words: Turbinate; Nasal obstruction; non-ablative laser, Erbium YAG.

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I. INTRODUCTION

Bilateral hypertrophic inferior turbinate (hypertrophic nasal concha or enlargement of the concha) is a common sign in subjective bilateral nasal obstruction in adults [1]. It affects the most important and narrow part of the upper airway [2]. The cause of the hypertrophy or enlargement can be of various reasons such as allergic rhinitis, hyperreactivity, hormonal causes, rhinitis medicamentosa, or a combination of known or unknown causes [3]. The treatment alternatives today are primarily long-term local nasal corticosteroids or secondary (when medical treatment is not sufficient) surgical techniques, primarily inferior turbinate reduction as a "turbinoplasty" (mostly submucosa resection) with cold knife, cauterization or microdebrider, or thermal ablation with radiofrequency, coblation or ablative laser (mainly CO2 or diode lasers) [4-8]. All surgical procedures used today are invasive, even if most modern alternatives are considered as minimally invasive, with the risk of bleeding and infection. They are painful and leave unwanted crusts and scar tissue and/or various degree of dysfunctional mucosa. All local nasal corticosteroids require daily compliance and can, long term, cause nose bleedings, nasal septum perforations, dry nose symptoms and may affect the natural human corticosteroid hormone axis even if this is rarely common. Therefore, it can be of value to find an optimized non-invasive but still effective enough treatment, preferably as a quick and convenient procedure. Erbium YAG laser (solid-state, wavelength 2940 nm) treatment is widely used in resurfacing, shrinkage, trimming and tightening of skin, as well as for vaginal and oral mucosa in various conditions [9-12]. This laser with its unique water absorption could therefore be an alternative method for the watery nasal mucosa and for turbinate shrinkage and tightening, but this has never been tried in a modern clinical study involving the nose. The aim of this pilot study was to evaluate a quick and easy laser session with a smooth non-ablative thermal protocol for patients with moderate or more subjective bilateral nasal obstruction due to enlargement of the inferior turbinate and without any other obstructions like deviated tip or deviated septum, or nasal polyps. The laser system itself is expensive but requires a minimum of consumables and service needed, and can be run at a low cost. The system

can also be used for different skin lesions and oral lesions as well as for palatal tightening for snorers, which makes it more cost beneficial for an ENT clinic.

II. MATERIALS AND METHODS

a) Study design, monitoring and ethics

This prospective, parallel group, single-blinded (patient), randomized placebo-controlled pilot study was approved by the Regional Ethical Review Board in Stockholm, Sweden and monitored independently, including a visiting report.

b) Investigational objects

Twenty patients (13 men, 7 women) suffering subjectively from obstructed or blocked nose were recruited from the clinic's database and local advertisement. They all received oral and written information about the study and signed informed consent. The mean age was 40.2 years for the active group and 43.3 years for the placebo group. Inclusion and exclusion criteria were as follows.

c) Inclusion criteria

- Male or female adults 18 years or more of age
- 4 weeks or more of subjective bilateral nasal obstruction with self-estimation on Visual Analogue Scale, VAS, 3 or more (VAS 0-10)
- Endoscopic finding at ENT (Ear, nose and throat) physician examination with moderate or more symmetrical bilateral hypertrophic inferior turbinate (grade 3 or more with scale 1-4, none-mild-moderate-severe hypertrophy, per validated Friedman scale [13, 14].
- Signed informed consent document indicating that the patients understand the purpose of and procedures required for the clinical investigation and are willing to participate in the clinical investigation

d) Exclusion criteria

- <18 year old
- Ongoing upper airway infection
- Mainly unilateral nasal obstruction caused by deviated septum or deviated nose tip, nasal obstruction caused by alar cartilage weakness or nasal obstruction caused by nasal polyps
- Epilepsy
- History of malignancy or other serious medical conditions within 3 years before screening
- Ongoing photosensitive treatment
- Pregnant or breast-feeding or planning to become pregnant or breast-feed during the clinical investigation
- Ongoing serious life event
- Simultaneous (or within 2 months prior to investigation) participation in a clinical investigation using experimental drugs or devices
- Patients who have started treatment or have made clinically significant changes in treatment with drugs or devices known to influence or treat nasal obstruction within 3 weeks before the start of investigation. Ongoing treatment longer than 3 weeks is not an exclusion criteria.
- Any condition that in the opinion of the investigator would make participation not in the best interest of the patient, or could prevent, limit, or confound the protocol-specified assessments.

e) Clinical investigation and treatment design

Day 1 included a clinic visit with standard ear, nose and throat investigation performed by a specialized ENT physician, a written standard health form, written forms rating the nasal congestion, nasal-related symptoms (including the VAS-rating and modified NOSE scale rating) and Nasal Peak Inspiratory Flow Meter (N-PIF) measuring the nasal flow capacity. After the inclusion criteria and signed informed consent, the study participant was then randomized in either the placebo (only guided laser without effect) or active laser treatment group by the study nurse, and the ENT physician performed the laser treatment.

Day 8 (+/-2 days) included a clinic visit and investigation of the nose, and collection of data from the written forms rating nasal congestion, nasal-related symptoms, eventual adverse events and N-PIF. The nasal laser procedure (active or placebo) was then repeated.

Day 15 (+/-2 days) included a clinic visit and investigation of the nose and collection of data from the written forms rating nasal congestion, nasal-related symptoms, eventual adverse events and N-PIF. The nasal laser procedure (active or placebo) was then repeated.

Day 30 (+/-2 days) included a clinic visit and investigation of the nose and collection of data from the written forms rating nasal congestion, nasal-related symptoms, eventual adverse events and N-PIF.

f) Nasal investigation

Nasal investigation was performed first by inspection of the outer part of the whole nose, including the vestibulum, with an anterior rhinoscope with speculum and light source and then the rest of the nasal cavity with a flexible nasal fibre endoscope carried out by an experienced ENT physician (the investigator and author) to elicit information relevant to the inclusion and exclusion criteria.

g) Nasal symptom questionnaire and visual analogue scale

For subjective evaluation of nasal symptoms, a questionnaire using standard visual analogue scale was used to assess the severity of the patient's nasal blockage, the possibility to breathe freely through the nose and the self-experience of crust formations, runny nose and sneezing. The visual analogue scale (VAS) was defined by scores from 0 (equal to no symptoms) to 10 (equal to maximum symptoms), self-rated by the study patient.

h) NOSE scale (modified)

The NOSE scale is a standardized questionnaire for measuring quality of life related to nasal obstruction for the last 4 weeks [15]. This scale is easy to understand and answer, validated and reliable, and has been used in many studies. In its original form, it consists of five questions that have as possible answers a series of values from 0 to 4, where a low value indicates lesser symptoms and a high value means more severe symptoms. Due to translation matters the investigator chose to merge the two first questions into one in the Swedish language, referring to patients' self-estimation of "nasal blockage". Although this minor translation modification has not yet been validated in studies, it was chosen by the investigator for the overall advantage of an easy and rapid questionnaire.

i) Nasal Peak Inspiratory Flow Meter

The Nasal Peak Inspiratory Flow Meter (N-PIF) measures the air flow through both nasal cavities during forced inspiration, expressed in litres per minute. The measurement summarizes the bilateral flow from both nostrils at the same time. It is the most validated technique for the evaluation of nasal flow through the nose [16]. Nasal inspiration correlates most closely with the subjective feeling of obstruction and is the most validated technique for monitoring nasal flow in clinical trials [17].

j) Randomization and blinding

Due to the obvious reason that the active laser shows immediate signs on the turbinate, it was not possible to have the procedure double-blinded, however, the patient was blinded. The study participant was randomized by the study nurse to either placebo (only guided laser without any effect) or active laser treatment by blindly choosing a card showing either "O" meaning active for the physician or "X" meaning placebo. Only the study nurse and the physician knew the meaning of the symbol. There were ten cards of each symbol and twenty cards in total.

k) Description and mode of action of the laser

The Erbium YAG laser treatment is used for shrinkage and tightening of the skin and for vaginal and oral mucosa in various conditions (9-12). These kinds of treatments are usually rapid, non-invasive, pain free and safe. It could therefore be an alternative method for the nasal mucosa. In non-ablative, thermal mode it is considered as non-invasive treatment and it will leave no obvious scar in the tissue.

l) Treatment protocol

The LightWalker® (Fotona D.D., Ljubljana, Slovenia) Erbium YAG laser system was used in a non-ablative thermal mode with the Very Long Pulse (VPL) protocol, 1.5 J/cm², 0.20 W and 2 Hz. The hand piece "R15" used with a 3 mm round spot size with a total of 200-300 laser shots in a brushstroke manner for each nasal cavity, covering the anterior part of the inferior turbinate on both sides. This protocol means a pain-free, smooth warming and shrinkage of watery tissue like the turbinate. The treatment takes about 15 min.

m) Safety assessment

The safety was assessed based on the incidence and severity of potential and eventual adverse events (AEs), symptoms and nasal investigations checked at the clinic visits. The AEs were monitored during the treatment and follow-up period. The causal relationships between all the AEs and the treatment were categorized by the investigator as probable, possible, unlikely, or unrelated.

n) Statistical analysis

Analysis between the groups was performed with Student's t-test with set alpha=0.05.

The statistical program package SAS (Statistical Analysis System) version 9.3 was used for the statistical analysis.

III. RESULTS

a) Baseline characteristics

9 out of 10 in the active group and 7 out of 10 in the placebo group had tried nasal steroid before without subjectively sufficient effect. None of the patients had taken any nasal steroid or other treatment known to influence or treat nasal obstruction within 3 weeks before their screening and inclusion visit or during the study. This was considered as a sufficient wash out time. In the active group, 4 had seasonal allergic rhinitis and 2 had a history of rhinitis medicamentosa before. In the placebo group 7 had seasonal allergic rhinitis. The study was performed off-season regarding their allergy, so no medication was necessary. There was no significant difference between the active and the placebo group prior to treatment regarding the objective hypertrophic grade, the Nasal

symptom questionnaire (VAS), or the modified NOSE score and Nasal Peak Inspiratory Flow Meter results.

b) Nasal symptom questionnaire and visual analogue scale

The active laser showed a mean value decrease of -3.5 for rated blockage (dropped from 6.9 to 3.4, VAS 0-10) compared to a slight non-significant increase of mean value +0.65 for the placebo group at the day 30 follow-ups. The improvement for the active laser group was statistically significant with $p<0.001$ (Figure 1). The other symptoms such as self-experience of crust formations, runny nose and sneezing did not show any significant changes between the groups, and such changes were not noticed during the study.

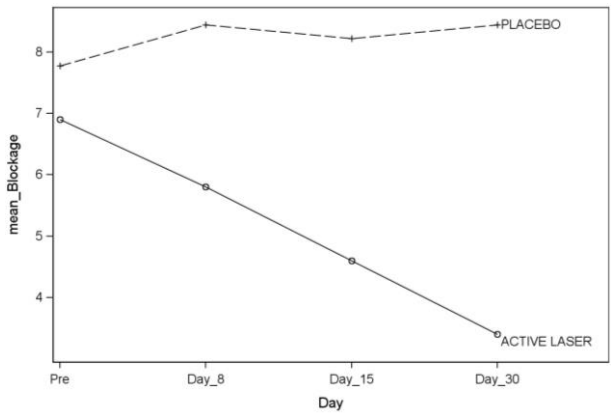


Fig. 1: The improvement for the active laser group was statistically significant with $p<0.001$

c) NOSE scale (modified)

The modified NOSE score improved by mean value 5.4 (dropped from 10.7 to 5.3) for the active laser group compared to no difference for the placebo group at day 30 follow-ups. This was significant with $p=0.0003$ (Figure 2).

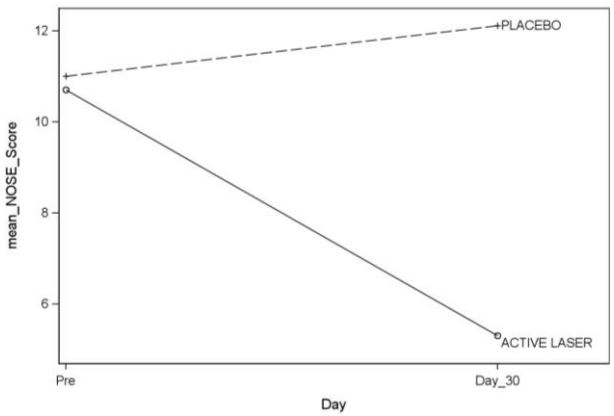
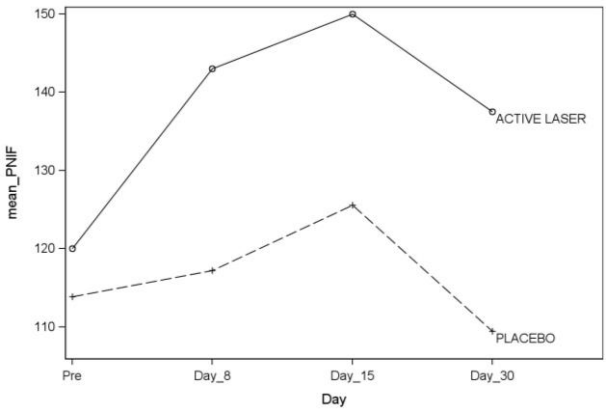


Fig. 2: The modified NOSE score improved by mean value 5.4 (dropped from 10.7 to 5.3) for the active laser group compared to no difference for the placebo group at day 30 follow-ups. This was significant with $p=0.0003$

d) Nasal Peak Inspiratory Flow Meter

N-PIF showed an improvement with mean value 18 L/min (from 120 to 138) for the active group and no significant difference for the placebo group at day 30 and with significance $p=0.043$ (Figure 3).



e) Endoscopic findings

The turbinate showed a significant visual shrinkage with a reduction of hypertrophy grading mean from 3.5 to 2.5 in the active laser group, from baseline to the day 30 follow-up. No significant changes in the placebo group were seen.

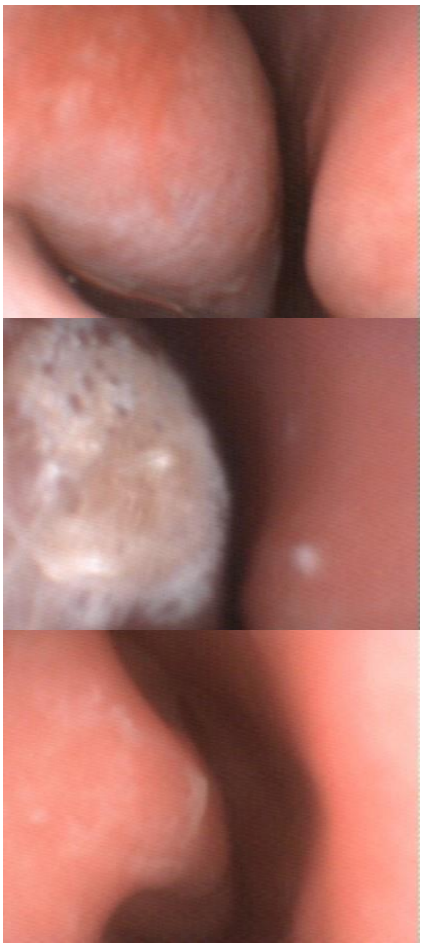


Fig. 4: The turbinate showed a significant visual shrinkage. Pre-laser, directly after laser and post-laser.

f) Safety

19 of the recruited 20 study participants completed all visits. One patient from the placebo group dropped out after the first visit without known reason or causes. The active laser made a slight warming sensation in the nose and some smell during the procedure but this did not concern any of the patients. The study participants reported no complaints during or after the procedure. There were no reports of any laser-related adverse advents. No bleeding, oedema or crust formations were noticed..

IV. DISCUSSION

Even if nasal corticosteroid is the treatment of choice for most patients with nasal blockage due to enlargement of the turbinate, there are still many that seek a quicker and more persistent but preferably harmless alternative to the daily (requiring compliance) local treatment that we have today. Surgical reduction, microdebrider, thermal ablation and coblation are all common alternatives, but they are more or less invasive and not always harmless. To our knowledge this was the first study to investigate with randomized placebo-controlled trial design the effect of repetitive Erbium YAG laser in SMOOTH thermal non-ablative mode on hypertrophic inferior turbinate and its palette of associated symptoms. For the clinic, the laser system is still an expensive investment but it requires no consumables and just ordinary ENT instruments and equipment. It can be done as a suggested 15 min office walk-in-walk-out procedure with no pre-laser preparations, no local anaesthetics, and no convalescence or injunctions for the patient. However, with this laser protocol the patient needs to come 3 times weekly to the clinic, which might affect the compliance. Other limitations are that symptoms like crusts, sneezing and runny nose seem not to be affected with this laser protocol and we do not know if patients with allergy could benefit from the treatment during season.

V. CONCLUSIONS

The Erbium YAG laser in non-ablative mode as a "turbino-tightener" showed significant positive effect on all nasal obstruction symptoms, both subjectively and objectively, over placebo treatment. The treatment was simple and quick to perform, easily tolerated by the patients and showed no significant negative side effects. However, this was a small pilot study with a rather short follow-up time. Larger studies with longer follow-ups, preferable at least 6 months, are encouraged. We also do not know if there are sub-groups of different cause of the hypertrophy that might be more, or less, responsive to the treatment.

DISCLOSURE OF INTEREST

The author declares no competing interest.

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