

EVALUATION OF THE FEASIBILITY OF RTA (RADIOFREQUENCY THERMAL ABLATION) IN TREATMENT OF PATHOLOGIES OF THE UPPER AIRWAY: A COMPREHENSIVE CLINICAL STUDY

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ABSTRACT

Background: RFTA (Radiofrequency thermal ablation) is a modality that has recently gained popularity as a treatment approach. It has advantages over conventional procedures including reduced postoperative care, less pain, and faster healing.

Objective: The present study was conducted to assess the feasibility of radiofrequency thermal ablation in treating the pathological conditions of upper airway tissues.

Methods: A total of 28 healthy subjects with sleep-disordered breathing were included in the present study. Radiofrequency energy was delivered to the soft palate of included subjects. Cephalometric analysis, Epworth Sleepiness Scale, Snoring Score, visual analog scale (VAS) scores, and inflammatory laboratory parameters were evaluated in all subjects.

Results: Within 2 days of RFTA, tissue loss, mucosal ulcerations, mild swallowing difficulties, mild speech problems, swelling of the soft palate, and immediately post-treatment mild discomfort was resolved. In habitual snorers, snoring was reduced with soft palate length shrinkage. No significant change in any assessed laboratory parameter was seen. VAS scores were transient and low. Relapse was observed in 6 subjects.

Conclusion: The present study concludes that RFTA can be considered as an acceptable and minimally invasive substitute for treating subjects of habitual snoring and daytime sleepiness having no associated anatomical abnormalities.

Keywords: Posterior Airway Space (PAS), Radiofrequency thermal ablation, snoring (RFTA), soft palate, upper airways, Visual Analogue Scale (VAS).

INTRODUCTION:

RFTA (Radiofrequency thermal ablation) is a globally prevalent treatment method identified by an accurate controllable session in different areas of medicine with reproducibility of treatment results, safety, and efficacy. It is widely researched in the specialties of oncology, urology, neurosurgery, and cardiology. Concerning Otolaryngology, it is used in subjects with obstructive sleep apnoea under the Somnoplasty system for tongue base reduction, turbinate reduction for nasal obstruction, and palatal reduction for snoring.¹ Compared to conventional tonsillectomy procedure, RFTVR has significant advantages as it leads to reduced tonsillar size. It is characterized by a precisely controllable lesion. During wound healing, tissue retraction and scar formation are seen due to radiofrequency delivered leading to a reduction in volume.²

RTA has various advantages over conventional procedures like reduced postoperative care, faster healing, and less pain. Power et al first described TCRF (temperature-controlled radiofrequency) for tissue ablation in the upper airway in vitro as well as in vivo. This led to focus on the investigation and application of radiofrequency to the soft tissues of the upper airway.³

Compared to conventional electrosurgery, radiofrequency needle ablation works at a lower temperature (65-100° C) and operates at greater current flow with equal cutting efficacy. This high current flow rapidly raises the tissue temperature locally leading to irreversible tissue destruction, protein denaturation, coagulation, and thermal injury by using frictional heating resulting from ion flow changing directions of alternating currents.⁴ On reaching the 100° C threshold, due to boiling, tissue coagulum adheres to the electrode and insulates it with abrupt current density drop with stoppage of tissue damage, lesion formation, and tissue healing. Recently, electrosurgical devices are added with electrode sensors to prevent near electrode-tissue reaching 100° C and to monitor local tissue temperature. On the contrary, electrocautery techniques and LASER reach temperatures of 750°C to 900°C in the tissues, which is significantly higher than what is needed for therapeutics leading to tissue damage and collateral damage to surrounding structures. Hence, the needle ablation method should produce less collateral tissue damage compared to electrosurgery.⁵

Snoring is a noisy inspiratory sound produced by vibrations and partial obstruction in the oropharynx. Snoring in the majority of the cases is seen secondary to structural abnormalities with obstruction mainly resulting from functional pharyngeal hypotonia. Snoring when associated with obstructive sleep apnoea syndrome (OSAS), or leads to social disturbances, medical intervention is needed. Habitual snoring affects 9-35% of the general adult population with a higher prevalence in the age group of 60-65 years.⁶ Upper airway collapse is largely governed by neuromuscular control. In chronic snoring subjects, vibrations lead to lesions in the afferent and efferent nerves innervating upper airway tissues. Surgical management done of soft palate tissues in subjects with snoring is aimed at stabilization, stiffening, and reduction of the soft palate. However, surgical interventions are associated with significant complications and morbidity.⁷ Hence, the present study was conducted to assess the feasibility of radiofrequency thermal ablation in treating the pathological conditions of upper airway tissues.

MATERIALS AND METHODS

The present study was conducted to assess the feasibility of radiofrequency thermal ablation in treating the pathological conditions of upper airway tissues. The study was conducted at Shyam Shah Medical College And Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradesh after obtaining clearance from the concerned Ethical committee. The study population was comprised of the subjects from the Department of Otorhinolaryngology of the Institute. After explaining the detailed study design, informed consent, both written and verbal, was taken from all study subjects.

A total of 28 subjects from both genders within the age range of 18-62 years having SDB (sleep-disordered breathing) were included in the study. The subjects were seeking treatment for snoring for a minimum of 1 year, and snoring was affecting their social life with excessive daytime sleepiness, and all the subjects had to undergo soft-palate surgery. In all the included 28 subjects, Body Mass Index (BMI), Oxygen Desaturation Index (ODI), Sella – Nasion point B (SNB) angle, and Posterior Airway Space (PAS), was calculated.

For all the subjects detailed history recording and physical examination were conducted. To assess the obstruction level, fiberoptic Naso-pharyngoscopy, and to examine upper airway anatomy, cephalometric radiographs were utilized. Primarily, the subjects with major obstruction sites located at the soft-palate were included i

n the study. All subjects were managed with Radiofrequency thermal ablation (RTFA). Before RTFA and 3 months following RTFA, lateral cephalometric radiographs were taken for all the subjects in the same anatomic position which was confirmed by a cephalometric head holder. All conventional soft-tissue and bony landmarks were evaluated before and following RTFA (PNS-P and PW).

The exclusion criteria were subjects having speech or swallowing disorders, history of previous palatal surgery, implanted pacemakers, psychiatric or neurologic disorder, coagulopathy, levels of obstruction within posterior airspace, and/or micrognathia.

After anesthetizing the soft palate with Xylocaine 10mg/dose as a topical anesthetic, 10mg/ml Lidocaine with epinephrine was administered with a 24-gauge needle in the soft palate (mid-part). Radiofrequency energy delivered was at 460 + 1 kHz using an RF generator with needle electrodes (VidaMed® generator, model no. 7200, double-needle electrode, Tuna 3, model 6193). To avoid surface damage, a protective thermal heat, 10mm long, was placed on both needle electrodes proximally. Between palatal arches, on both sides of the uvula, needle electrodes were penetrated the palatal mucosa from beneath. The single lesion was treated twice at a 1-week interval using the energy of 5 W delivering energies of 600 J and 300 J respectively to the two lesions. No postoperative medication was given to any subjects. However, they were advised to take ibuprofen or ketoprofen as and when needed.

To assess postoperative morbidity, VAS was used where patients graded their symptoms on a scale of 0-100 assessing no symptom to intensive symptoms. Symptoms assessed were difficulty in speaking, difficulty in opening the mouth, difficulty in eating, difficulty in drinking, the swelling sensation of the oropharynx, and/or pain. Snoring Score (SS) and Epworth Sleepiness Scale (ESS) questionnaires were recorded before treatment, and 3 months and 12 months following the treatment. Hematological parameters assessed were creatine kinase levels, leukocyte counts, blood hemoglobin, and C-reactive protein. They were

assessed before each session, and postoperatively on the 2nd day and week 1 following the last session to assess inflammatory host response following treatment.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p < 0.05$.

RESULTS

The present study was conducted to assess the feasibility of radiofrequency thermal ablation in treating the pathological conditions of upper airway tissues. A total of 28 subjects from both genders within the age range of 18-62 years having SDB (sleep-disordered breathing) were included in the study. The demographic characteristics of the study subjects are depicted in Table 1. It was seen that the mean age of the study subjects was 29.6 ± 1.6 years. There were 82.14% (n=23) males and 17.85% (n=5) females in the present study. The mean BMI of the study subjects was 28.4 ± 2.36 . ODI 4% was 0.7, PW was 12 mm, PNS-P was 44.4 mm, and mean PAS was 14 mm in the subjects of the present study.

The present study also assessed the postoperative complications reported by the study subjects. It was seen that the most common postoperative complaint was soft-tissue swelling reported by 64.28% (n=18) of study subjects followed by blanching of the soft palate in 35.71% (n=10) of study subjects. Other reported complications were speech difficulty in 10.71% (n=3) study subjects, swallowing difficulty in 7.14% (n=2) study subjects, mucosal ulceration in 3.57% (n=1) study subject, and tissue loss in 3.57% (n=1) study subject as shown in Table 2. All the reported postoperative complications were decreased gradually in 2-weeks follow-up time.

On assessing the mean VAS scores in the study subjects, it was seen that for soft palate blanching, at postoperative days 1, 2, 7, and 21 the VAS score was 64 (23-77), 37 (2-64), 17 (0-58), and 3 (0-34) respectively. Concerning the soft palate swelling, it was seen that the mean VAS scores at day 1, day 2, day 7, and day 21 postoperatively were 68 (47-88), 27 (4-64), 16 (1-48), and 4 (0-40) respectively in the study subjects (Table 3). It was seen that the mean VAS scores were higher in all the study subjects for both soft palate swelling and blanching. However, the mean VAS scores decreased significantly in all the subjects by day 21.

DISCUSSION

The present study was conducted to assess the feasibility of radiofrequency thermal ablation in treating the pathological conditions of upper airway tissues. A total of 28 subjects from both genders within the age range of 18-62 years having SDB (sleep-disordered breathing) were included in the study. It was seen that the mean age of the study subjects was 29.6 ± 1.6 years. There were 82.14% (n=23) males and 17.85% (n=5) females in the present study. The mean BMI of the study subjects was 28.4 ± 2.36 . ODI 4% was 0.7, PW was 12 mm, PNS-P was 44.4 mm, and mean PAS was 14 mm in the subjects of the present study. These demographics were comparable to the studies of Robinson S et al⁸ in 2003 and Pazos G et al⁹ in 2001 where authors assessed the subjects with characteristics comparable to the present study.

Postoperative complications are usually seen associated with the RTFA procedure. The present study also assessed the postoperative complications reported by the study subjects. It

was seen that the most common postoperative complaint was soft-tissue swelling reported by 64.28% (n=18) of study subjects followed by blanching of the soft palate in 35.71% (n=10) of study subjects. Other reported complications were speech difficulty in 10.71% (n=3) study subjects, swallowing difficulty in 7.14% (n=2) study subjects, mucosal ulceration in 3.57% (n=1) study subject, and tissue loss in 3.57% (n=1) study subject. All the reported postoperative complications were decreased gradually in 2-weeks follow-up time. These results were comparable to the results by the studies of Baack L et al¹⁰ in 2001 and Erik JK et al¹¹ in 2005 where authors reported similar complications following RTFA with soft palate swelling being the most common complication in their studies also.

VAS scores in the present study assessed the success of RTFA. On assessing the mean VAS scores in the study subjects, it was seen that for soft palate blanching, at postoperative day 1, 2, 7, and 21 the VAS score was 64 (23-77), 37 (2-64), 17 (0-58), and 3 (0-34) respectively. Concerning the soft palate swelling, it was seen that the mean VAS scores at day 1, day 2, day 7, and day 21 postoperatively were 68 (47-88), 27 (4-64), 16 (1-48), and 4 (0-40) respectively in the study subjects. It was seen that the mean VAS scores were higher in all the study subjects for both soft palate swelling and blanching. However, the mean VAS scores decreased significantly in all the subjects by day 21. These results were consistent with the findings of Blume MB et al¹² in 2002 where VAS scores were comparable to the present study.

CONCLUSION

Within its limitations, the present study concludes that RFTA can be considered as an acceptable and minimally invasive substitute for treating subjects of habitual snoring and daytime sleepiness having no associated anatomical abnormalities. However, the present study had a few limitations including a small sample size, short study duration, and geographical area biases. Hence, more longitudinal studies with a larger sample size and longer monitoring period will help reach a definitive conclusion.

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TABLES

Characteristics	Value (Mean±S. D) n (%)
Mean age (years)	29.6±1.6
Age range (years)	18-62
Gender	
Males	23 (82.14)
Females	5 (17.85)
Mean BMI	28.4±2.36
ODI 4%	0.7
PW (Mm)	12
PNS-P (Mm)	44.4
Mean PAS (Mm)	14

Table 1: Demographic characteristics of the study subjects

Complications	n	%
Swelling of the soft palate	18	64.28
Mucosal blanching	10	35.71
Speech difficulty	3	10.71
Swallowing difficulty	2	7.14
MucosalUlceration	1	3.57
Tissue Loss	1	3.57

Table 2: Complications following RTFA in the study subjects

Follow up duration (days)	VAS score for soft palate blanching	VAS score for soft palate swelling
1	64 (23-77)	68 (47-88)
2	37 (2-64)	27 (4-64)

7	17 (0-58)	16 (1-48)
21	3 (0-34)	4 (-40)

Table 3: Mean VAS scores from day 1 to day 21 in the study subjects