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Original Research

Radiofrequency Thermal Ablation: A Treatment Modality for Upper Airway Disorders

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ABSTRACT:
Background: Radiofrequency thermal ablation (RFTA) is a well-known treatment modality. The proposed advantages of RFTA over conventional procedures include less pain, faster healing and reduced postoperative care. **Objective**: To evaluate the feasibility of radiofrequency thermal ablation as treatment of pathological conditions of upper airway tissues. **Methods**: A total 25 healthy patients having sleep-disordered breathing were enrolled to the study. Radiofrequency energy was delivered to the soft palate Snoring Score, Epworth Sleepiness Scale, and cephalometric analysis, certain inflammatory laboratory parameters and visual analogue scale scores were measured related to the procedure. **Results**: reported that immediately post-treatment mild discomfort, swelling of the soft palate, mild Speech and swallowing difficulties, mucosal ulcerations and tissue loss which was majorly resolved within 2 days after treatment. Snoring in habitual snorers was reduced. Shrinkage in the length of the soft palate was observed. There were no notable changes in the laboratory parameters. The symptom visual analogue scores were low and transient, resolving within days. 5 cases of relapse were observed. **Conclusion**: RFTA might be regarded as a good minimally invasive alternative for the treatment of patients with habitual snoring and day time sleepiness but with no anatomical abnormalities. More studies with larger sample size are required to validate our results and to provide more emphasis on complications associated with this treatment.
Key words: Posterior Airway Space (PAS), Radiofrequency thermal ablation, snoring (RFTA), soft palate, upper airways, Visual Analogue Scale (VAS).

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INTRODUCTION:
Radiofrequency thermal ablation (RFTA) is a well-known treatment modality, which is characterized by a precise controllable lesion and has demonstrated, in other areas of medicine, acceptable efficacy, safety and reproducibility of treatment results. In soft tissues it has been studied extensively by specialists in cardiology, neurosurgery, urology and oncology.[1-4] It has demonstrated acceptable efficacy, safety, and reproducibility of treatment results. In otolaryngology, it is used in the Somnoplasty system for tongue base reduction for obstructive sleep apnoea, palatal reduction for snoring, and turbinate reduction for nasal obstruction.[5-7] Applied to reducing tonsil size, RFTVR has several significant advantages over current tonsillectomy procedures. The RFTA method is characterized by a precise controllable lesion. Following wound healing the delivered radiofrequency current leads to scar formation and retraction of tissue, resulting in a volume reduction.[8,9] The proposed advantages of RFTA over conventional procedures include less pain, faster healing and reduced postoperative care
The application of temperature-controlled radiofrequency (TCRF) for tissue ablation in the upper airway was first reported by Powell et al.[9] in the

in vitro bovine model and in vivo porcine model. Because of this investigation, there has been a keen interest in the investigation and application of radiofrequency to the soft tissues of the upper airway.

In radiofrequency (RF) needle ablation, the generators operate at a much lower frequency, which means that the impedance to current flow is four or five times greater than that associated with the use of conventional electro-surgery generators. Equally, the cutting action of needle ablation method is also achieved at lower temperature (65-100^{o} C) than with conventional electrosurgery devices (400-600 ^{o}C). The high current density in tissue within a few millimetres of needle electrode causes a rapid local temperature rise of 50 – 90 ^{o}C, within seconds to minutes resulting in thermal injury, coagulation, protein denaturation and irreversible tissue destruction. RF needle ablation uses frictional heating that is caused when ions in the tissue attempt to follow the changing directions of alternating currents. When the 100 ^{o}C threshold is reached, boiling at the electrode-tissue interface results in tissue coagulum adhering to and insulating the electrode and there is an abrupt drop in current density; tissue heating ceases as does lesion formation and tissuedamage.[4]In recent years, electrosurgical devices developed for RF needle ablation have incorporated sensors in the electrode to monitor local tissue temperature and impedance to prevent tissue near the electrode attaining 100^{o} C.

With the present ability to accurately deliver specific amounts of radiofrequency energy at relatively low temperatures (50°C-95°C) to submucosal target tissue, heat dissipation and damage to adjacent tissue structures are minimized. In contrast, Laser and electrocautery techniques, by contrast, deliver temperatures around 750°C to 900°C, which are far in excess of therapeutic needs, since tissue protein denatures at 47°C, thus extending collateral damage to surrounding structures. Therefore ideally the needle ablation method should produce less collateral tissue damage than conventional electrosurgery.

Snoring is a noisy inspiratory sound produced by vibrations and partial obstruction in the oropharynx. Although, in some cases it can be associated with structural abnormalities, the obstruction is mostly the consequence of a functional pharyngeal hypotonia. It becomes a medical entity when it is habitual and causes social or other disturbances, or when it is associated with symptoms of obstructive sleep apnoea syndrome (OSAS). Habitual snoring is a common condition affecting 9-35% of the general adult population and the prevalence is increasing up to the age of 60-65 years. Neuromuscular control is a contributory factor to upper airway collapse. It has been suggested that in patients with chronic snoring, vibrations lead to lesions in the afferent and efferent nerves innervating upper airway tissues.

The surgical interventions of the soft palate for treatment of snoring share a common goal; reduction, stiffening and stabilization of the soft palate. However, surgical procedures are associated with significant morbidity and complications.

The purpose of the present study was to evaluate the feasibility of radiofrequency thermal ablation as treatment of pathological conditions of upper airway tissues.

MATERIAL AND METHODS

This study was a prospective, nonrandomized study conducted in the department of Otorhinolaryngology, Dr. D. Y. Patil Medical College, Navi Mumbai (Maharashtra), in the year March 2008 to March 2009, over a period of one year. The study protocol was approved by the institutional Research Ethical Committee. An Informed consent was obtained from all patients. A total of Twenty five patients within age range of 18 to 60 years of both gender, with sleep disordered breathing (SDB) were enrolled to the present study. All the patients visited the ENT ward because of habitual snoring of at least 1 year's duration. In each case, snoring was associated with excessive daytime sleepiness that interfered with social or professional activities and they were scheduled for palatal surgery.

25 subjects of either sex were included in the study with age range of 18-60 years. Posterior Airway Space (PAS), Sella – Nasion point B (SNB) angle, Oxygen Desaturation Index (ODI) and Body Mass Index (BMI) was calculated.

A complete history and physical examination was done for each patient. The upper airway anatomy examination using cephalometric radiographs and fiberoptic naso-pharyngoscopy were performed to evaluate the level of obstruction. Patients whose major site of obstruction was located at the soft palate were primarily included in our study. A lateral radiographic cephalometric head film was taken prior to and three months after the RFTA-treatments (Radiofrequency thermal ablation).All radiographs were taken in the same anatomic head position that was assured by the use of a standardised, ridged, cephalometric head holder. The traditional bony and soft tissue measurements (PNS-P and PW) were measured both before and after treatments. Those patients in with micrognathia, with levels of obstruction within posterior airspace, patients with coagulopathy, psychiatric or neurologic disorder, or implanted pacemakers, history of previous palatal surgery, speech or swallowing disorders, were excluded from the study.

Procedure: In our study, Radiofrequency energy delivered was at 460 + 1 kHz using a RF generator with needle electrodes (VidaMed® generator, model nr. 7200, double-needle electrode, Tuna 3, model 6193).The soft palate was sprayed with Xylocaine 10 mg/dose as a topical anesthetic. A 24-gauge needle was used to inject lidocaine 10 mg/mL with epinephrine 4 to 6 mL at the mid part of the soft palate. To eliminate surface damage, a protective

thermal cheat (5 mm) was used on the proximal portion of both needle electrodes, which had an active length of 10 mm. The needle electrodes were penetrated into the palatal mucosa from beneath, between the palatal arches on both sides of the uvula (Fig. 2). The patients were treated with a single lesiontwice with 1-week interval with energy of 5 W resulting in an energy delivery of 600 J to the first lesion and 300 J to the second. No medications were prescribed postoperatively when patient leaves, but the patients were advised to use ibuprofen or ketoprofen if needed.

Evaluation of post-operative morbidity: VAS was used for evaluation of the morbidity of the procedures. Patients were asked to grade their symptoms from score 0 was as no symptoms to 100 representing intensive symptoms. The symptoms evaluated were pain, swelling sensation of the oropharynx, difficulty in drinking, difficulty in eating, difficulty in opening the mouth, and in difficulty in speaking. Epworth Sleepiness Scale (ESS) and Snoring Score (SS) questionnaires were completed before the treatments and 3 and 12 months after the treatments. (Table 1 &2)

Table 1: Snoring score assessed by the patients in study

Characteristics of snoring	Points
No snoring	0
Soft snoring, which does not interrupt the bed partners sleep	1-3
Loud snoring, enough to be bothersome to bed partner	4-6
Very intense, snoring is annoying to anyone nearby	7-9
Bed partner leaves the room	10

Table 2: Epworth sleepiness scale (ESS) used in study
How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? Use the following scale to choose the most appropriate number for each situation.

Characteristics of dozing	Points
Never	0
slight change	1
moderate change	2
high change	3

Situations	**Chance of dozing**
Sitting and reading	
Watching TV	
Sitting inactive in a public place (e.g. a theatre or a meeting)	
As a passenger in a car for an hour without break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	
	Total score: ____

Haematological evaluation: C-reactive protein, blood hemoglobin, leukocyte counts, and creatine kinase levels, were measured before each treatment session, and postoperatively also on the day 2 and 1 week after the last treatment to evaluate the inflammatory host response induced by the procedure.

Statistical Analysis: Mean and standard deviations were recorded for variables and sent for statistical analysis using SPSS version 20. Paired Wilcoxon test and Mann Whitney test were applied. P value <0.5 was regarded as significant.

RESULTS
A total of 25 patients were included in our study. Mean age in our study came to be 29.4±1.8 years of age (min age: 18 years and maximum of 42 years of age). Male population formed 84% (n=21) and females were 16% (n=4) of the study population. The most common diagnosis in our study population was habitual snoring accounting for 64% cases (n=16) and 36% (n=9) patients had obstructive sleep apnoea syndrome (OSAS). (table 3)

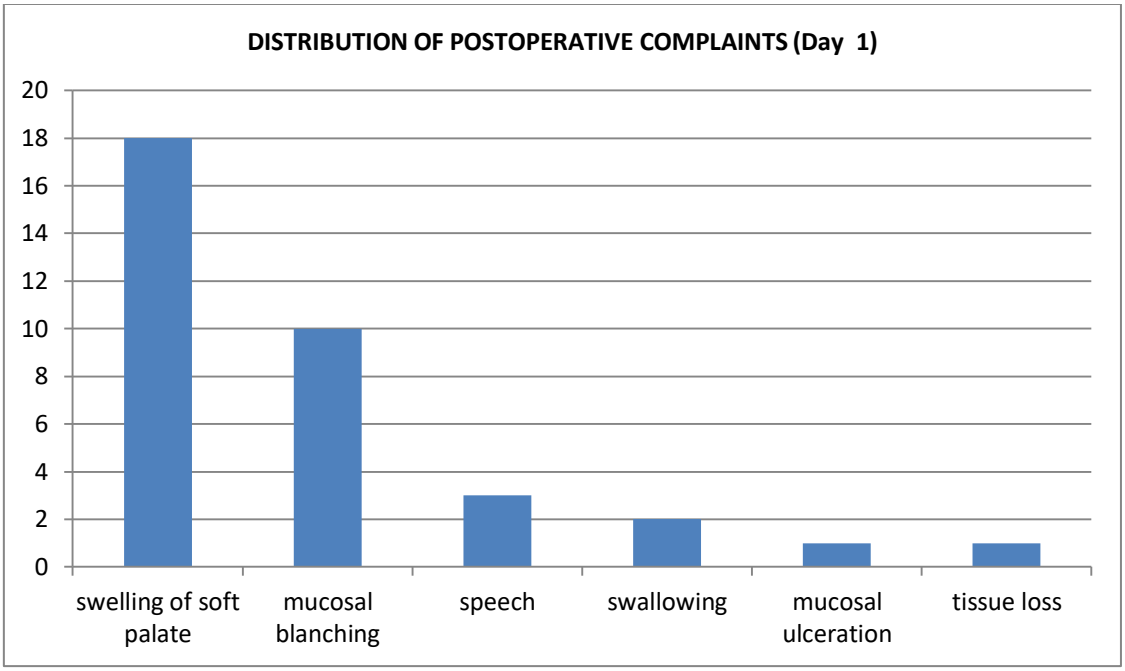
Table 3: Study characteristics of patients included in present study

N	25
Age Range	18-60 Years (Mean 29.4±1.8 years)
Gender	MALE: 84% FEMALE: 16%
Mean PAS (Mm)	14
PNS-P (Mm)	44.2 mm
PW (Mm)	10
ODI 4%	0.7
Mean BMI	28.6

Pain scores were the maximum at 1st day following the first treatment session, and it gradually decreased following the 2-week period. Almost majority of 16 patients took pain medications only on the day of treatment and on the following 2 days. 7 patients used pain medications for up to 7 days while only 3 patients reported not to take any medication. Cephalometric analysis in study with RFTA of the soft palate showed a significant shrinkage of the PNS-P, but not in the PW.

Most common postoperative complaint was swelling of the soft palate seen in 18 patients, followed by mucosal blanching which was observed on 10 patients. 3 patients also developed minor changes in speech and swallowing due to soreness, mucosal ulceration (1 patient), tissue loss (1 patient). These symptoms gradually decreased during the 2 week of follow-up time.

Figure 1: Distribution of patients on basis of postopertative complaints on day 1.



VAS score were high for the patients with both swelling of the soft palate and blanching. For swelling in soft palate mean VAS score on day 1 was 69 and reduced gradually to mean score 5 by day 21. Similarly for blanching mean VAS score on day 1 was 65 and reduced gradually to mean score 4 by day 21

Table 4: Mean Vas Score For Swelling And Blanching Of The Soft Palate On Day 1 Till Day 21.

Follow up days	**Mean VAS score for swelling of the soft palate**	**Mean VAS score for blanching**
Day 1	69 (48-89)	65 (24-78)
Day 2	28 (4-65)	38 (2-65)
Day 7	17 (1-52)	18(0-60)
Day 21	5 (0-40)	4(0-35)

Figure 2: VAS score for swelling of the soft palate on day 1 till day 21.

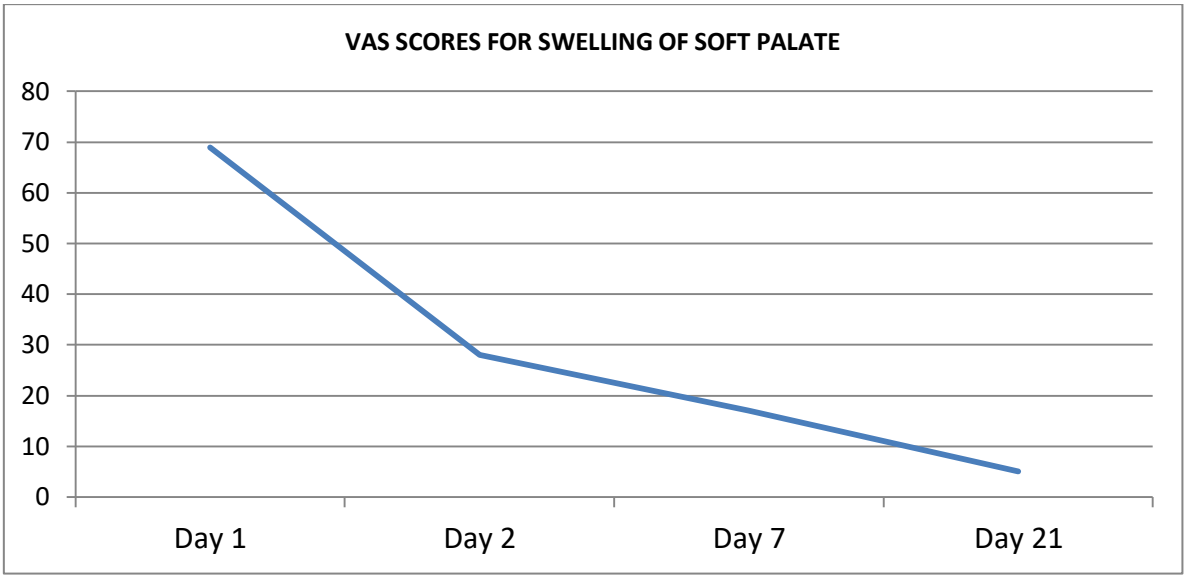
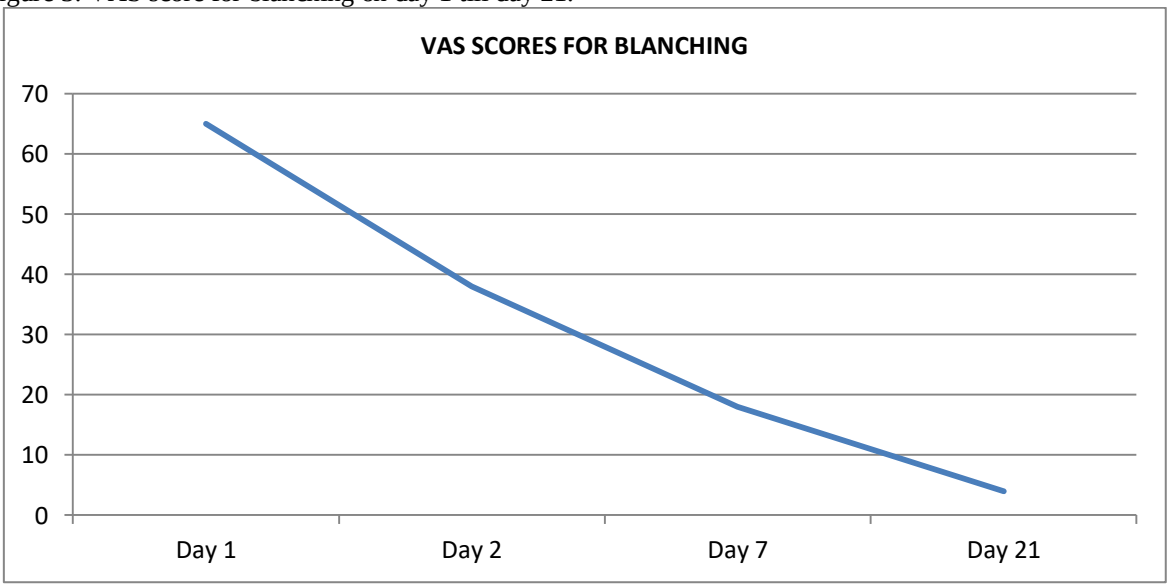


Figure 3: VAS score for blanching on day 1 till day 21.



No statistically significant relationship was observed of postoperative morbidity with presenting symptoms. Also, there were no significant changes in any of the laboratory parameters noted in relation to the procedure. Further, ESS and SS questionnaires of all the patients showed a statistically significant reduction in snoring and daytime sleeping in the habitual snorers. We observed a significant shrinkage of soft palate (1–5 mm) in 18 patients (72%). The changes in the length of the soft palate indicated volume reduction of the soft palate. Five cases of relapse were observed during the follow-up in our study.

DISCUSSION

Since the advent of RFTA, there has been a keen interest in the investigation and application of radiofrequency to the soft tissues of the upper airway. The peer-reviewed literature on the use of radiofrequency to the upper airway in humans and animals includes publications from all over world now.

RFTA has been shown by most authors to be safe and effective in treatment of the inferior turbinates, soft palate, and tongue in patients with snoring, sleep-disordered breathing (SDB) or nasal obstruction secondary to turbinate hypertrophy. Thus the primary goal in using RFTA in the upper airway is to achieve maximal efficacy while maintaining a minimal risk of complications.

Site of obstruction can be assessed by several means, such as fiberoptic awake endoscopy with or without Muller maneuver, airway manometry, asleep endoscopy with or without continuous positive airway pressure, or imaging. There is no universally validated method to determine precisely the site of obstruction.

The methods recommended by Sher et al. are fiberoptic endoscopy and lateral cephalometry.[10]
We aimed a study to evaluate the feasibility of radiofrequency thermal ablation as treatment of pathological conditions of upper airway tissues. Overall, 15 patients reported to have satisfying results. We observed that reduction in snoring was better in the habitual snorers.
In our study we used Questionnaires to gather data on the subjective variables such as pain, swelling sensation of the soft palate, swallowing, and speech. We reported that immediately post-treatment mild discomfort, swelling of the soft palate, mild Speech and swallowing difficulties, mucosal ulcerations and tissue loss which majorly resolved within 2 days after treatment. Thus, overall postoperative symptoms were present but there was no significant relationship observed.
We observed a significant shrinkage of soft palate 72% patients. The changes in the length of the soft palate indicated volume reduction of the soft palateIn our study Cephalometric analysis of the soft palate showed a significant shrinkage of the PNS-P, but not in the PW. This change in the volume may be attributed to increased stability of the soft palate mainly due to increased rigidity of the soft palate caused by the tissue scarring. Leif Back et al reported thatsoft tissue resolution capability is superior with MRI compared with other radiological methods available; it avoids radiation exposure and yields both transverse and sagittal sections of the upper airways. They thus hypothesized that MRI would be the only radiological way to find possible objective changes caused by RF energy.
The incidence to date of moderate and major complications after RFTA of the upper airway has been low, supporting the safety of this technology. However, there have been a few authors that have reported an unacceptably high number of moderate and major complications after application of TCRF.[11,12]
Several factors may influence the rate of complications, including a learning curve associated with the use of this technology, the amount of energy delivered per lesion, the temperature selection, the number and location of lesions created during each treatment session, and perioperative management of patients with special emphasis on airway control.
Kezirian et al reported that tissue bulk and consistency should be evaluated carefully, and one of the most important variables for palatal treatment is thickness. The midline palate is the safest region to treat because the musculus uvulae provide greatest bulk of the palate. The thickness of the palate decreases rapidly as one moves away from the median and paramedian region. Palate is thin, the total energy delivery must be limited or damage to the mucosa will occur more frequently. Treatment to the lateral region of the palate should be undertaken only when it is established that the tissue thickness is appropriate. Lateral cephalograms can be used to measure the palate thickness in the midline, and the lateral regions of the soft palate are thinner to varying degrees and must be evaluated clinically.[13]
In the present study soft palate showed shrinkage. Similar results were also observed by Back et al. in their study.[14] They justified saying that although there was some shrinkage of the soft palate, they presumed that the advantageous outcome regarding snoring and daytime somnolence was mainly attributable to increased rigidity of the palate caused by the tissue scarring. This speculation is supported by the fact that the shrinkage of the PNS-P did not correlate with the subjective outcome measures. The measurement of the palate length may not be a good parameter in determining the outcome in future studies. They concluded that RFTA is best suited, and may be the method of choice, for patients with loud snoring but normal palatal and mesopharyngeal anatomy.
Even Blumen et al.[15] in their study reported that the shrinkage in soft palate may be attributed to the scarring process, which is thought to rigidify the soft palate and decreases excessive compliance. Reduction of volume by necrosis may only be obtained using higher levels of energies. This may not be possible because of potential side effects such as postoperative edema, which may compromise the airway, and mucosa necrosis, which may lead to perforation or uvula destruction. Therefore, using lower energies may provide only a non-significant volume reduction by necrosis, a probable volume reduction by retraction, and a decrease in compliance.
Further, in our study questionnaires of all the patients showed, a statistically significant reduction in snoring and daytime sleeping in the habitual snorers.Snoring is first and foremost a subjective perception by a listener. Several methods of treatment for snoring have been developed but most studies really on subjective assessment methods. Previous literature shows that Snoring is not the best method to determine when to stop treatment because is limited because persons naturally are unaware of their behavior during sleep, therefore only bed partner may verify the patient symptoms. But some bed partners may be satisfied by snoring level even though the patients were not cured of their disease; on another hand, some patients, who did not have any significant residual apnoea or hypopnea, continued to snore and remained somnolent. Ambulatory oxygen saturation, because of it lower cost and its ease of use, could be one possible tool for evaluation of when to stop the treatment.[15]
In our study we observed 5 cases with relapses after RFTA treatment. The treatment failures as described in literature may have also been due to residual excessive tissue in the soft palate. On the human soft palate, using a mean total energy level of 2377 J in one to several sites, a reduction of volume was shown by Powell et al.[5]Our results are in agreement with the results previously reported by Li et al.[6]

CONCLUSION

Thus we conclude that, RFTA might be regarded as a good minimally invasive alternative for the treatment of patients with habitual snoring and day time sleepiness but with no anatomical abnormalities. More studies with larger sample size are required to validate our results and to provide more emphasis on complications associated with this treatment.

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