

Original Research Article

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Effect of radiofrequency vs other surgeries in the management of obstructive sleep apnoea

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ABSTRACT

Background: Snoring is an important social problem seen in both men and women. Snoring occurs as a result of soft tissue vibration caused by a partial upper airway collapse during sleep. The aim of the study was to analyse the morbidity and efficacy of radiofrequency thermal ablation of upper airway in patients suffering from OSA.

Methods: In the Department of ENT, Pondicherry, 40 patients between the age group of 20 to 60 years who were diagnosed to have OSA were operated according to the site of obstruction including RFVTR. Various parameters including ESS, partner scores, post-op pain, bleeding, pharyngeal dryness voice change were measured accordingly on the 1st day, 45th day, 90th day and 180th day postoperatively for the efficacy of treatment and also for assessing the morbidity of treatment provided.

Results: There is a statistically significant reduction in ESS scores and partner scores between pre-operative period and post operatively on the 45th day, 90th day and 180th day. Post-operative pain assessment also showed that patients who underwent RFVTR had lesser pain when compared to other surgeries like zeta-plasty, LAUP, etc.

Conclusions: Radiofrequency surgery should be considered as the treatment of choice for mild OSA and hypopneic snorers. The important advantage of these procedures is technically simple and minimally invasive. RFTA of the soft palate leaves the mucosa intact contrary to LAUP, hence the pain comparably less. Relatively cost effective when compared to LASER and Coblator.

Keywords: Radiofrequency thermal ablation, OSA, RFVTR, RAUP

INTRODUCTION

Snoring is an important social problem seen in both men and women. Snoring is part of the spectrum of sleep disordered breathing (SDB), from obstructive sleep apnoea hypopnea OSAHS at one end to simple snoring at the other. Snoring can occur as primary snoring or as part of a syndrome of the obstructive sleep apnoea.

A conservative estimate of the prevalence of OSAHS in middle aged men (30-65 years) is in the range of 0.34% with most studies giving a prevalence of 1-2% which is a simple prevalence to type 2 diabetes and approximately double that of severe asthma.¹ The prevalence of OSAHS

in middle-aged women has been less well studied but is probably about half that in males at around 0.51%.¹

Snoring occurs as a result of soft tissue vibration caused by a partial upper airway collapse during sleep. The most common site of obstruction during snoring is the soft palate; however, other regions of the upper airway tract also may cause snoring such as the nose, base of tongue, tonsils and the epiglottis.

OSA is clinically associated with obesity epidemic globally, and it is characterized by repetitive, partial or complete collapse of the upper airway during sleep, causing impaired gaseous exchange and sleep

disturbance. It is the most common form of sleep disordered breathing (SOB). There is increasing evidence that OSA is an independent risk factor for an adverse cardio-metabolic profile and it has been associated with increased cardiovascular and cerebrovascular morbidity and mortality.²

Other health consequences from OSA are also significant: excessive daytime sleepiness, cognitive dysfunction, impaired work performance, anxiety, difficulties in personal relations, and an increased risk of fatal and non-fatal automobile accidents which lead to loss of human life and huge economic burden in our modern world.³

Henceforth majority of this renewed interest within the otolaryngologists has been focused on sleep related breathing disorder OSA and this recognition has led to a multidisciplinary approach with a creation of new medical discipline - Sleep medicine; with a team made up of otolaryngologists, pulmonologists, neurologists, maxillofacial surgeons, and behavioral psychologists.

Radiofrequency thermal ablation 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.

Aims and objectives

- To estimate the role of radiofrequency thermal ablation in habitual snoring patients with multilevel obstruction.
- To analyze the morbidity and efficacy of Radiofrequency thermal ablation of upper airway in patients suffering from OSA.

METHODS

In this prospective study which was conducted in the Dept. of Otolaryngology, SMVMCH, Pondicherry between September 2016 to December 2018, 40 patients who presented to the our OPD with the complaints of snoring, frequent awakening at night, excessive day time sleepiness, hallucinations. Choking in sleep were further evaluated were included in the study after the approval of the institutional ethical committee and after the patients gave consent for the surgical management of OSA after they were explained about conservative management options also. The study population comprised of 10 females and 30 males who were randomly selected and belonged to the age group of 20 and 60 years (Mean age=40 years). All patients consented to participate in the study after being informed of the benefits, risks and complications of the procedures.

Inclusion criteria

Inclusion criteria were age between 20 and 60 years; both sexes (male and female); apnoea/hypopnoea index <15; BMI <32.

Exclusion criteria

Exclusion criteria were allergy to local anaesthetics / anaesthesia drugs; bleeding disorders and other comorbidities; neuro-psychiatric disorder; pacemakers or other implants; previous palatal surgery; speech/swallowing disorders.

Investigations

- Routine haematological and biochemistry investigations
- Panendoscopy
- Polysomnography (PSG)
- Drug induced sleep endoscopy (DISE)

After the detailed clinical and endoscopic examination and appropriate hematologic and radiologic investigations for anaesthesiologist fitness for surgery, informed consent was taken from the patient for the necessary surgery. Patients and the bed partners were given questionnaires (ESS) regarding the severity of snoring.

Patients were subjected to various surgical procedures done for OSA, depending on the site of obstruction identified by DISE.

Patients who had antero-posterior collapse underwent uvulopalatopharyngoplasty (UPPP) while the patients who had circumferential collapse underwent zeta-plasty (ZP).

Patients with lateral collapse underwent lateral expansion procedures such as lateral expansion pharyngoplasty (LEP) and modified lateral expansion pharyngoplasty (mLEP).

Patients with fluttering of soft palate or uvula underwent Radiofrequency volumetric tissue reduction (RFVTR) of soft palate. An important advantage of sub-mucosal radiofrequency is delivering of energy to the muscle without injuring the mucosa.

Postoperatively

On 1st day: (a) Inspection of ablated site, any local infection or bleeding to be noted.

On 7th day: (a) Inspection of ablated site any local infection, hematoma to be noted; (b) Questionnaires were given regarding patient tolerance to the procedure, pain,

bleeding, crusting, pharyngeal dryness, globus sensation, voice change, nasal regurgitation.

On 45th day: (a) Inspection of the site; (b) Questionnaires were given to both patient and his/her bed partner for the assessment of snoring of the patient.^{4,5}

On 90th day: (a) Assessment of the site; (b) Questionnaires were given to the patient and his/her bed partner for the assessment of snoring of patient.

On 180th day: (a) Questionnaires were given to the patient and his/her partner for assessing overall satisfaction after the procedure and if they would recommend this procedure to others will be given at the 6th month review.

All the relevant data was collected and final statistical calculations were done with SPSS software version 21 and Chi square test and the results were compared to find out the efficacy of RFVTR in OSA.

Ethical committee approval

Institutional Ethical Committee reviewed the experimental design and protocol as well as the letter of information and consent form. Full approval of the board was granted. All patients were given information outlining the experimental protocol and all patients signed a consent form prior to entering the study.

RESULTS

Table 1 shows age distribution of the patients in our study. Maximum number (70%) of patients belong to age group of 40-60 years in our study.

Table 1: Distribution of patients according to age.

Age	No of patients	Percentage (%)	Cumulative percentage (%)
≤40	12	30	30
40 to 60	28	70	100
Total	40	100	

Table 2: Distribution of patients according to their gender.

Gender	No of patients	Percentage (%)	Cumulative percentage (%)
Male	30	75	75
Female	10	25	100
Total	40	100	

The above table depicts gender distribution of the patients. 75% of patients are males indicating the incidence of OSA to be more common in male population than their female counterparts.

Table 3: Distribution of patients according to Pre OP AHI.

	No of Patients(n)	Range	Minimum	Maximum	Mean	Std. Deviation
Preoperative AHI	40	8.00	7.00	15.00	11.6747	2.49555

Table 4: Distribution of patients according to their preoperative and postoperative BMI.

	No of patients	Min.	Max.	Mean
Preoperative BMI	40	27	34	28.00
Postoperative 4th day BMI	40	23	31	27.75
Postoperative 90th day BMI	38	22	31	27.29
Postoperative 180th day BMI	35	22	31	27.27
Total	35	22	31	27.59

Table 5: Distribution of patients according to the type of surgery they underwent.

Type of surgery	Frequency	Percentage (%)	Cumulative percent (%)
LEP	9	22.5	22.5
mLEP	8	20	42.5
RFVTR	11	27.5	70
ZP	12	30	100
Total	40	100	

From Table 3 it is evident the preoperative AHI of the patients in our study ranged from 7.00-15.00 with a mean Pre-op AHI of 11.67.

From the Table 4 it is evident the BMI of the patients have decreased after the procedure but the mean BMI preoperatively was 28 and post operatively at 180th day

was 27.59 indicating not a significant reduction in BMI post operatively in the long term follow up

Among the study population, most of the patients underwent Zetaplasty (30%) followed by RFVTR (27.5%), LEP (22.5%) and least being mLEP (20%) (Table 5).

During successive post-operative follow-ups some patients were lost. From the Table 6 we can see the changes in the ESSS between pre-operative period and postoperative periods at various intervals showing the reduction in the ESSS in the postoperative period than before procedure.

Table 6: Changes in the Epworth sleepiness scale scoring (ESSS) during preoperative and postoperative periods.

Day of assessment	N	Range	Min.	Max.	Mean	SD
Preoperative ESSS	40	13	10	23	17.00	3.295
45 days ESSS	40	10	8	18	13.03	3.019
90 days ESSS	38	9	4	13	7.82	2.081
180 days ESSS	35	7	4	11	8.12	1.654
Valid N (listwise)	35					

Table 7: Change in the partner scoring (PS) during pre-operative and post-operative periods.

Day of assessment	N	Range	Min.	Max.	Mean	SD
Preoperative PS	40	5	5	10	8.28	1.632
45 days PS	40	5	3	8	5.64	1.376
90 days PS	38	5	1	6	2.71	1.404
180 days PS	35	4	2	6	3.39	1.248
Valid N (listwise)	35					

Table 8: Frequency of surgical complications in patients after various surgeries.

Complication		Type of surgery			
		LEP (9)	mLEP (8)	RFVTR (11)	ZP (12)
Pain Score (VAS)	Mild	0	3	10	0
	Moderate	6	4	1	3
	Severe	3	1	0	9
Pharyngeal dryness		8	7	0	11
Globus sensation		8	7	10	11
Voice change		0	0	0	0
Nasal regurgitation		0	0	0	0
Bleeding		0	0	0	0
Crusting		0	0	0	0

During successive postoperative follow-ups some patients were lost. From the Table 7 the Partner Scoring has reduced comparatively in the postoperative period at various times showing relief from snoring post operatively as assessed by the partners.

From the Table 8 pain was the most common complication followed by pharyngeal dryness and globus like sensation. Pain was severe post zetaplasty and mild post RFVTR and also patients post zetaplasty suffered from pharyngeal dryness and globus like sensation whereas patients post RFVTR had only Globus like sensation but no dryness.

DISCUSSION

This study was done with the aim of estimating the efficacy of RF surgery in patients with snoring. In our

study, a total of 40 patients were included in the study comprising of 10 females and 30 males. This eventually shows that 75% are males and 25% are females, hence relying on the fact that OSA is more predominant in males which was similar to a study by Yoruk et al and Lim et al.^{6,7}

The mean pre-op AHI in our study group is 11.67 ± 2.49 . The mean pre-op BMI is 28.00 and at 6 months postop is 27.27. There was no statistically significant difference in mean BMI between the groups ($p > 0.05$), indicating that BMI remained unchanged during the study.

Out of the 40 patients in our study, 9 patients (22.5%) underwent LEP, 8 patients (20%) underwent mLEP, 11 patients (27.5%) underwent RFVTR and the rest 12(30%) had undergone zetaplasty.

We found difference in ESS scores after surgery, at a regular follow up of 45 days, 3 months and 6 months in the postoperative period. It was found that there was a statistically significant difference in ESS scoring overall ($p<0.001$). Median ESS scores from the pre-op, 45 days, 3 months and 6 months postop were 16, 12, 8 and 9.7 respectively. There was no significant difference between 3 months ESS and 6 months ESS ($Z=-1.676$, $p=0.094$). There is statistically significant reduction in ESS scores between pre-op and 45th day ESS ($z=-2.636$, $p=0.008$) pre-op to 3 months, pre-op to 6 months, 45 days to 3 months ESS and 45 days to 6 months ESS. Similarly, Lim et al noted in their study for OSA which included 44 patients with snoring who were divided randomly into two groups where RAUP was applied to 24 patients and conventional LAUP to 20 patients that the ESS score decreased from 12.21 ± 2.78 before the procedure to 5.13 ± 3.75 after the procedure in the RAUP group, and from 12.10 ± 2.85 to 5.35 ± 2.85 in the LAUP group, with the changes being statistically significant in both groups ($p<0.05$).⁷ Also Yoruk et al, in their study for the treatment of snoring using mRAUP, snoring was evaluated preoperatively, and at intervals of day 1, day 3, first and six months postoperatively using standard 10 cm VAS.⁶ It was found that snoring score evaluated from day 1 to 6 month after surgery was significantly better in mRAUP group.

In our study partner scoring was assessed preoperatively and post operatively at the 45th, 90th and 180th days and was found that there is a statistically significant improvement in partner scoring overall ($p<0.001$). Similarly Stuck et al did a placebo-controlled study with Radiofrequency surgery of soft palate for snoring in which in one group of patients received 2 sessions of Radiofrequency on the soft palate whereas the placebo group had just the device needle inserted into the soft palate but the RF energy was not delivered.⁸ They found that RF surgery was significantly better than placebo, although reduction in the snoring was only moderate in the study group of patients.

Stuck et al had performed a literature review of 22 studies on the Radiofrequency surgery of the soft palate in the treatment of snoring and concluded that according to all of the published material RF surgery of the soft palate led to significant reduction in the subjective snoring which again is reduced to a tolerable level.⁹

Morbidities associated with UPPP include haemorrhage, severe pain, velopharyngeal insufficiency, and nasopharyngeal stenosis, as well as complications of general anaesthesia.¹⁰ In our study patients operated with RF had no other significant symptoms except mild pain.

Pain after palate surgery was due to irritation of open nerve endings, pharyngeal and palatal muscle spasm and inflammation. Our study shows that among the patients who underwent zeta-plasty, 75% experienced severe pain and 25% patients had moderate pain and 58.9% of

patients who underwent Lateral expansion procedures experienced moderate pain, 23.52% severe and the remaining 17.64% had mild pain. Among the patients who underwent RFVTR, 91% of the patients had mild pain rest 9% had moderate pain.

Yoruk et al found in their study that out of 60 patients (30 in mRAUP and 30 in RAUP) patients in mRAUP group were associated with lower VAS score for pain especially in the first 5 days' post operatively.⁶

Similarly, Troell et al did a comparison of postoperative pain between LAUP, UPPP and RFVTR in their study and concluded that RFVTR of the soft palate produced less pain post operatively than LAUP or UPPP.¹¹ Cinciket al in a study in 2005 compared UPPP, LAUP and CAUP in the treatment of snoring observed that post-operative pain was mostly seen in LAUP and UPPP cases.¹² The CAUP procedures were easy and less painful. Rombaux et al compared the side-effects and complications of the LAUP and CAUP and RFVTR in snoring and concluded that RFVTR is a safer and less painful procedure than other procedures.¹³

Also Lim et al observed that the postoperative pain on days 1 and 7 after the operation was 7.75 ± 1.21 and 6.15 ± 0.83 , respectively, in the LAUP group, and 6.18 ± 0.97 and 2.84 ± 1.45 , respectively, in the RAUP group.⁷ It was significantly lower in the RAUP group at these time points ($p<0.05$), but it did not differ significantly between the two groups at 2 weeks after the operation ($p>0.05$).

In our study, more than 90% of patients who underwent Zeta-plasty and LAUP and mLAUP respectively had experienced pharyngeal dryness and globus sensation whereas the patients in the RFVTR group had only globus sensation which relieved on successive follow-ups. Similarly, the postoperative complications of a foreign body sensation and pharyngeal dryness were observed in 7 out of 20 patients in LAUP group and in 2 of 24 patients in RAUP group in a study done by Lim et al.⁷

In our study 27.8% of patients who had underwent RFVTR received two sessions of RFVTR at day 1 and day 45. ESS Score was recorded preoperatively & postoperatively at 45 days, 3 months and 6 months had a statistically significant difference $p<0.001$. 10 patients who had received 2 sessions of RFVTR at day 1 and 45th day, there were statistically significant reduction in partner scores overall. Similarly, in a study done by Baisch et al for combined RF procedures in the treatment of snoring, patients received two sessions of combined RF procedures at the soft palate, consisting of interstitial bipolar RF-surgery and RF-assisted resection of excessive soft tissue observed that Daytime sleepiness (ESS) improved from baseline to the first follow-up and to the second follow-up (6.3 ± 3.5 to 4.8 ± 2.6 and to 4.2 ± 2.5).¹⁴ Between the baseline and the last visit, the

ESS improved statistically significant ($p < 0.05$). Thus he concluded that combined radiofrequency assisted uvulopalatoplasty (RF- UPP) is highly effective in the treatment of snoring. Snoring scores were reduced after the first session ($8.5 \pm 1.5 - 4.6 \pm 2.5$) and showed further improvement after the second session ($4.6 \pm 2.5 - 2.0 \pm 2.1$, the difference between baseline and the first session, as well as between the first and second session, was statistically significant ($p < 0.001$). Also in a study done by Back et al, twenty-one healthy men with sleep-disordered breathing received radiofrequency energy ablation to the soft palate in two sittings at the interval of 7 days and observed that the radiofrequency thermal ablation of the soft palate in patients with sleep-disordered breathing seems to be effective, safe and associated with low morbidity.¹⁵

In surgeries for the treatment for snoring scar tissue matures and softens over 12-18 months, which might explain the relapses. However, the relapses after RF treatments can be improved with additional sittings as concluded in their study by Powel et al.¹⁶

In a prospective study by Stuck et al on radiofrequency assisted UPP for snoring; it was demonstrated that on long term follow up, 21 patients with snoring had received two sessions of RFUPP at the soft palate.¹⁷ Snoring scores were initially reduced from 8.6-1.5 at inclusion to 2.0-2.1 after treatment ($p < 0.05$) at long term follow up. This increase in snoring score was statistically significant ($p < 0.006$). Hence he concluded that after UPP of soft palate relapse in snoring has to be expected at a long term follow up. Berger et al, in their 24-month follow-up, found a short-term success rate of 79% but in the long- term follow-up, the rate declined to 57%. Osman et al. found a success rate of 82.8% in the postoperative period and this rate declined to 75.9% in the long-term.^{18,19} Paulsen et al found structural changes in mucosa of the uvula with scanning electron microscopy and immunohistochemistry of patients with different degrees of SDB indicating increased collapsibility induced by the trauma of snoring.²⁰

Since the follow up period in our study is six months, the long term relapse could not be assessed. This is the limitation of our study, however 27.8% patients who underwent RFVTR, were willing to undergo the same procedure and they would recommend the same procedure as per the questionnaire given at 6 months. Out of 40 patients 5 patients didn't complete the six months follow up. Apart from the patients who had severe pain, remaining 26 patients were satisfied with the procedure. The minimal invasiveness of this treatment modality provides a high acceptance of re-treatment.

CONCLUSION

The important advantage of RFVTR procedure is they are technically simple and minimally invasive and can be performed at an outpatient setting under local anaesthesia

with a low complication rate and generally good therapeutic results. Relatively cost effective when compared to LASER and coblator which have more incidence of dysphonia, dysphagia and nasal regurgitation as post-op complications as per literature. Radiofrequency surgery should be considered as the treatment of choice for mild OSA and hypopneic snorers. The necessity of repeated treatment sessions should be kept in mind as a disadvantage of this technique.

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