ORIGINAL REPORT

Radiofrequency Uvulopalatoplasty for Primary Snoring

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Abstract- Simple snoring is a social problem, one that can gravely affect the patient's married life. About 40% of men and 20% of women are affected, and it often goes along with sleep-disordered breathing. Up to now various surgical techniques have been defined such as UPPP(uvulopalatopharyngo plasty), and laser-assisted uvulopalatoplasty (LAUP). Among the surgical methods, RAUP (radiofrequency assisted uvulopalatoplasty) is a minimal invasive, an easy performed, and time and cost effective one. We designed a before and after a clinical trial. The inclusion criteria were age >18 years, complaint of nocturnal snoring, have a bed partner to assess snoring, AHI<5 events per hour in the polysomnography, malampathy score (soft palate position) I or II, an elongated uvula, grade I and II of pharyngeal webbing and patient consent was needed too. A 10-score visual analog scale (VAS) of snoring severity was completed by bed partner. All of 35 included patients underwent RAUP under local anesthesia by the same expert surgeon. After 3 months, 6 months and one year, subjective snoring decreased significantly compared to the preoperative period. The decline in VAS in 6 month compared to 3 months postoperatively, was not significant (P=0.223). When comparing 1 year and 6 months after treatment, the VAS scores were increased, but they were not significant (From 1.8 to 1.9, P=0.78). Three months after treatment minor complications consisted of: nasal regurgitation in 2 patients (5.7%), nasal speech in 2 (5.7%) and exacerbation of snoring in 2 (5.7%) patients.There was no major complication including mucosal laceration, uvular damage and obstruction of the airway. The rate of snoring decrease did not correlate with age, sex and BMI. Based on this study and literature review, it seems RAUP is a safe surgery, which may decrease symptoms of snoring, at least, in short-term follow-up.

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Introduction

The vibration of the pharyngeal soft tissues causes the sound of the snoring. About 40% of men and 20% of women are affected, and it often goes along with sleep-disordered breathing.However, it can happen in isolation. Habitual audible snoring, in the absence of OSA (Obstructive Sleep Apnea), with an apnea hypopnea index (AHI) of less than five events per hour without daytime somnolence is documented as primary snoring (PS) (1). In adults, the independent risk factors for self-reported snoring are such as age, obesity, smoking, asthma, nasal obstruction and male sex (2). Simple snoring is a social problem, one that can gravely affect the patient's married life (3). Although excessive daytime sleepiness does not occur in PS, but it seems, in adults, PS is linked to daytime functioning impairments and traffic disasters (2). Besides nonsurgical management, the most accepted surgical methods for snoring are velopharyngeal surgeries to decrease the soft palate vibration and to enlarge the velopharyngeal isthmus, so the collapse of the upper respiratory tract is prevented during sleep. Up to now various surgical techniques have been defined. In 1981, Fujita et al. Introduced UPPP (uvulopalatopharyngo plasty) and Kamami defined in 1990 CO2 Laser Vaporizations of the PalatoPharynx (LVPP), is a new technique, effective and safe, ambulant, by local anesthetic spray, performed

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for the treatment of snoring, which involves a successive "vaporizations" (or laser-strip carbonization) of the vibrating soft palate, wide posterior tonsil pillars and redundant posterior pharyngeal mucosa (4). More recently, in 1998, Powell et al. Used radio frequency (RF) as a mean for volumetric tissue reduction of the palate (5). Among the surgical methods, RAUP (radiofrequency assisted uvulopalatoplasty) is a minimal invasive, an easily performed, and time and cost effective one. It also causes a little pain and scar-induced contracture. In the field of RAUP, researchers for better methods to get better outcomes have been continued (6). In this study, our aim was to evaluate in a prospective trial the efficacy and morbidity of RAUP and the correlation the surgical success with age, sex and primary body mass index (BMI).

Materials and Methods

We designed a before and after a clinical trial . 35 out of 42 patients referred to the department of Otolaryngology-head and neck surgery of Shahid Sadooghi and Shahid Rahnamoon Hospitals of Yazd from May 2007 to February 2009 entered the study after a physical examination and performing a polysomnography. The inclusion criteria were age >18 years, complained of nocturnal snoring, has a bed partner to assess snoring, AHI<5 events per hour in the polysomnography, malampathy score (soft palate position) I or II, an elongated uvula, grade I and II of pharyngeal webbing, (according to clinical definition shown in Table 1) and patient consent was needed too. Polysomnography was done by means of SOMNOscreen ^{TM} PSG. The exclusion criteria were suffering from airway resistance syndrome or obstructive sleep apnea syndrome (AHI>=5), co-morbid diseases (psychiatric, respiratory or neurological diseases and mandibular skeletal defects). History of radiotherapy to the upper aerodigestive tract, morbid obesity (BMI>33 kg/m^2), previous surgery on the soft palate, hypopharyngeal collapse>75% at Muller maneuver, Clinical suspicion of obstruction at the base of tongue, tonsillar hypertrophy (grade III, IV) (according to clinical definition shown in Table 1). Nose breathing problems like septal deviation, and turbinates hypertrophy. Muller maneuver is done by inspiration against closed nose and mouth, for assessing hypopharyngeal collapse by means of fiber optic nasopharyngoscopy (1).

For each patient, a questionnaire was completed by a trained physician, including the personal information about the patient, disease history, physical examination (mouth and pharynx according to the clinical definition (Table 1). To determine the grading for each part, nose and Muller maneuver by flexible endoscopy), and a 10-score visual analog scale (VAS) of snoring severity was completed by a bed partner. All of the included patients underwent RAUP by the same expert surgeon and Celon AG/Pro sleep machine.

The patients were asked to sit in a comfortable position. Local anesthesia was used with lidocaine spray and injection of 2% lidocaine and epinephrine 1/100000, according to patient weight, in 5 points of the soft palate (2 points beneath the border between hard and soft palate and 3 other points above the palatal arcs, with injection one of this three pointer at the midline, near the base of uvula). After about 5 minutes**,** radiofrequency probe was entered in 2 points in the soft palate in modeling with the power of 10 ^{w} and 2 points in lateral with the power of 13^{w} for tissue coagulation, then we cut the long uvula with the power of 20^{w} (Table 2).

Table 1. Mouth and pharynx according to the clinical definition.

Size Of The Tonsils	Grade 0 Tonsil in Palatine fossa Grade 1 Tonsil occupying less than 25% of oropharynx Grade 2 Tonsil occupying less than 25-50% of oropharynx Grade 3 Tonsil occupying less than 25-75% of oropharynx Grade 4 Tonsil occupying more than 75% of oropharynx
Mallampati score (Soft Palate Position)	The score was determined with mouth open completely without protrusion of the tongue. In • Class I: Soft palate, uvula, fauces, pillars visible. • Class II: Soft palate, uvula, fauces visible. • Class III: Soft palate, base of uvula visible. • Class IV: Only hard palate visible

As provided by the manufacturer, in vivo application of the power setting of 10W in about 4.2 seconds leads to a diameter of coagulation, slightly smaller than 4.30 mm (the machine is programmed to alarm acoustically for termination the energy delivery). The power setting of 13W and 20 W, respectively, in about 2.8 seconds and 1.3 seconds make coagulation diameters slightly smaller than 3.90 mm and 3.35 mm. Lower powers setting cause larger coagulation.

The Patients had taken Diclofenac 1-2 tablets (50mg) preoperatively and a single dose of dexamethasone 8 mg/IV, Cephalexin one capsule (500 mg) four times a day, Diclofenac if needed, and mouth washes for 1 week postoperatively.

We visited the patients and their bed partners 3, 6 and 12 months after surgery and reassessed the improvement of snoring with the 10-score VAS and considered possible complication, such as exacerbation of snoring, nasal speech, and nasal regurgitation. We analyzed the data by Wilcoxon Signed-Rank, Mann Whitney and Freidman tests.

Results

The study group consisted of 35 subjects, with an age range between 20 and 65 years (mean of 37.8 years). We included 7 males (20%) and 28 females (80%). The range of body mass index (BMI) was between 18 and 32 kg/m^{2,} and the mean BMI was 25.9 kg/m^2 (Table 3).

After 3 months, subjective snoring decreased significantly (from 9.3 to 2.1, P<0.0001). This decline considered maximum if the difference of pre-treatment and post-treatment scores were at least 5 points. In 25 (71.5%) patients we had maximal response. Minimal response occurred when the difference of pre-treatment and post-treatment scores were less than 5 points. In 7 patients, we had minimal success and 1 patient (2.8%) without response and 2 patients (5.7%) with exacerbation of snoring. These 3 patients did not accept a second RAUP. Two of 35 patients were not available to continue the follow up period.

After 6 months, in comparison with the preoperative period, snoring was significantly decreased (from 9.3 to 1.8, P<0.0001). In 33 patients who returned for a second visit, 24 (73%) had maximal, 8 (24%) had a minimal decrease including one of the cases with exacerbation at our first postoperative visit, and the score of 1 (3%) patient, the same case which did not respond at the first visit, remained unchanged.

The decline in VAS in 6 months compared to 3 months postoperatively, was not significant (P=0.223). 17 (51.5%) of the patients were unchanged, 10 (30%) decreased, and 6 (18.5%) relapsed. Relapse is defined as an increase in the score of snoring after 6 months compared to 3-month score, but this score never returned to the pre-operative one.

Table 2. Treatment points and powers.

Position of the probe	Power
1. Median - 15mm above height of palatal arcs	10 W
2. Medium - 8 to 10 mm above point 1	10W
3. Lateral - 5mm left, 4mm above point 1	13 W
4. Lateral - 5mm right, 4 mm above point 1	13 W
5. Cutting the excess of the Uvula	20W

Table 3. Demographic data about patients.

		Frequency	Percent%
Age	<40	16	45
	>40	19	55
Sex	Male	28	80
	Female	7	20
BMI*	18-25	7	20
	25-32	28	80
Total		35	100

*Body Mass Index

After one year the mean score of snoring decreased significantly compared to the preoperative period (From 9.3 to 1.9, *P*=0.0001). In 33 patients 26 (78.7%) had maximal decrease, 6 patients (18.1%) had minimal decrease, and one patient, the same case which did not respond at first and second visit, remained unchanged.

When comparing 1 year and 6 months after treatment, the VAS scores were increased, but they were not significant (From 1.8 to 1.9, *P*=0.78). 22 patients (66.6%) had no change, 4 patients were decreasing scores and 7 (21.2%) relapsed, but never returned to pre-operative score. The decrease in VAS along the time was signed by Freidman test. (*P*=0.0001)

Comparing 1 year and 3 months after the surgery, the changes in the VAS was not significant (From 2.1 to 1.9, *P*=0.634). The VAS score in 13 patients (39.3%) decreased, in 11 patients (33.3%) was unchanged, and in 9 patients (27.2%) was increased (Table 4).

3 months after treatment minor complications consisted of: nasal regurgitation in 4 patients (11.4%), 2 of them had a transient problem and the others had a persistent but mild and occasional compliant, nasal speech in 2 (5.7%) and exacerbation of snoring in 2 (5.7%) patients.There was no major complication including mucosal laceration, uvular damage and obstruction of the airway (Table 5).

Table 4. Snoring reduction values in patients treated with RF palatoplasty.

VAS*	Number of patients	Mean	Median
Preoperative	35	9.3	10±1.3
3 months postoperative	35	2.1	2±2.2
6 months postoperative	33	1.8	2±2
1 year postoperative	33	1.9	2±2.1

P=0.0001, pre versus 3 months postoperative
P=0.0001, pre versus 6 months postoperative
P=0.223, 3 months versus 6 months postoperative
P=0.0001, pre versus 1 year post operative
P=0.634, 3months versus 1 year post operative
P=0.78, 6 months versus 1 year post operative
*Visual Analog Scale

Table 5. Frequency of surgical complications after RF palatoplasty.

Complication	Frequency	Percent%
Persistent nasal reflux	2	5.7
Exacerbation of snoring	2	5.7
Nasal speech	2	5.7
Total complication	8	17.1
Without complication	27	82.9
Total patients	35	100

Table 6. The correlation between snoring reduction and age of patients.

		VAS* reduction	
		Frequency	Mean
Age	<40	16	7.7±2.1
	>40	19	6.1±3.1

*Visual analog scale, *P*=0.237

Table 7. The correlation between snoring reduction and sex of patients.

		VAS* reduction	
		Frequency	Mean
Sex	Male	28	6.9±2.6
	Female	7	6.5±3.4

*Visual analog scale *P*=0.559

Table 8. The correlation between snoring reduction and primary BMI of patients.

		VAS* reduction	
		Frequency	**Mean**
BMI**	18-25	7	6±3.3
	25-32	28	7.1±2.6

*Visual analog scale *P*=O. 55

**Body Mass Index

The rate of snoring decrease did not correlate with age, sex and BMI (*P*=0.237, *P*=0.559, *P*=0.55 respectively) (Tables 6-8).

Discussion

Primary snoring is a disorder that results in emotional and social malfunction at school or in the occupation of the patients. One of the proposed treatment options is the RF reduction of the soft palate or RF palatoplasty. In this study, we found a success rate of 71.5% and a failure rate of 8.5% after 3 months postoperatively. Back LJ evaluated the efficacy of one session RAUP on 74 patients with primary snoring after 3 months of follow up time and found a significant decrease in snoring VAS and success rate of 28.6%. He did only RF reduction without uvular surgery in all patients (even those with uvular elongation). He reported that the higher grade of uvula has a negative effect on surgery outcome (9)In 2009, a systematic review demonstrated that no generally accepted objective airway assessment is available, and the decision to select the patients for interstitial soft palate RF surgery depends on the physician's subjective clinical assessment (10). So we tried to use the clinical definitions, to select the patients suitable for RF surgery. Some reasons for the inadequate efficacy of interstitial RF surgery are an excessive soft tissue of the uvula and the posterior pillar (pharyngeal webbing) (10). In order to increase the success rate we also considered the long uvula treatment. In a combined approach, we used interstitial RF surgery and RF-assisted resection of excessive soft tissue of the uvula, which showed a significant effect on snoring reduction.Although, the morbidity increased compared to interstitial RF surgery alone (10). In our study, snoring relapsed in 18.5% of the patients after 6 months and in 21.2% after one year. The recurrence of symptoms is the main limitation of the surgery. According to the Back et al. Systematic review in 2009, the follow-up period in the different studies was from 6 weeks to 26 months. Only four of the seven articles with the mean follow-up time more than one year evaluated the possible relapse rate. Blumen *et al.* showed up to 50% of the patients had an aggravation of their snoring level at a mean follow-up time of 13.2 months. The other three studies reported relapse rates of 20%, 30%, and 41%. Li *et al.* Demonstrated that all the relapsed patients (41% of total) that underwent operation, had improved scores (11). RF induced scar in the soft palate during the natural course of wound healing. When the post-treatment assessment of snoring is limited to 6 weeks to 8 weeks after the treatment, the treatment results have less value because there is a possibility that the scar is still immature. Up to 2008, in 10 studies the follow-up time was only 2 months or less.To evaluate the long-term results, one should notice that absorption of the scar and possible further reduction of the soft palate is a process lasting for more than 1 year (10). The number of lesions created by RF and the treatment sessions differed in various studies from a single midline ablation to several ablations, and two treatment sessions repeated for up to five times, none of these different protocols had a significant impact on the treatment outcomes (10). It seems that besides the RF surgery on the soft palate , the other surgical protocols for snoring have also relapsing results; a relapsing score in tongue base radio frequency volume reduction (RFVR) and in lingual suspension for patients with mild OSAS, (respectively, a success rate of 75% and 67% after demonstrated decreasing success rate from 87% to 46% in patients treated by 6 months decreased to 33% and 42% after 2 years) (12). Levin and Waering reported decreased efficacy of LAUP (Laser assisted upper airway procedure) and UPPP (uvulopalatopharyngoplasty) between 18 and 24 months (13,14).

Several various RF devices had been used in the studies. A Somnus device (Somnus Medical Technologies, Sunnyvale, CA) was the most popular. We used Celon device (Celon AG medical instruments, Germany) which is used less frequently. Blumen *et al.* Had revealed in a multicenter randomized comparative study of four different RF generators that all devices decreased the snoring severity and the different devices had a comparable efficacy (10).

The description of the RAUP method and mention the details of the procedure are important for evaluating its effectiveness which is less covered in different studies. So we tried to explain as precisely as possible with three points and different steps of our surgery. In our study, Minor Complication included persistent nasal reflux (5.7%), exacerbation of snoring (5.7%) and nasal speech (5.7%). In our study, there was no major complication.

Lim DJ compared RF palatoplasty with LAUP in a randomly selected group of patients and found the same improvement in VAS scores but lower postoperative pain and complication including foreign body sensation and scar contracture in the RF group (15). The effect of RF surgery on voice, swallowing and velopharyngeal sufficiency is not significant (3,16). These low complication rates are comparable with the risk of dysphasia of 29% in UPPP and 40% in LAUP (13, 14).RF palatoplasty in Beisch's study had no complication as well (17). We found no correlation between the rate of VAS decrease with age, sex, and primary BMI (statistically insignificant). Stuck found the same results, but Hassan D´sausa had a better improvement in lower BMI also Kiani found higher decreasing scores in women (18-20). May be exclusion the patients with morbid obesity in this study, resulting in relatively few differences between BMI and VAS decrease. Based on this study and literature review, it seems RAUP is a safe surgery, which may decrease symptoms of snoring, at least, in short-term follow-up. It causes only minor complications for the patient. But most of the studies in this issue, as is ours, are uncontrolled clinical trials. So to make a final conclusion, we need well-planned, double-blind, placebo-controlled, randomized clinical trials which use subjective and objective outcome measures and compare different existed RF devices. Longer term follow up (at least 2 years) may show the ultimate outcomes more precisely.

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