

Original Research Article

Coblation Palatoplasty, A Treatment for Snoring: Our Experience

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Received: 04/03/2016

Revised: 14/03/2016

Accepted: 15/03/2016

ABSTRACT

Background: Snoring is the sound produced during sleep by vibration of respiratory structures due to obstructed air movement during breathing. It may be a sign or first warning of obstructive sleep apnea (OSA). Usually the commonly involved structures are uvula and soft palate. The suspicion of Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) is required to be confirmed along with location of obstruction and grade severity. Sleep study is done to determine this and guide the therapeutic choices available for these patients. Surgical procedures like Uvulopalatopharyngoplasty (UPPP), Coblation Palatoplasty and Uvulectomy have been tried for treatment. Coblation Palatoplasty is performed and preferred nowadays to reduce snoring and alleviate sleep apnoea. This operation involves trimming of tissues causing airway obstruction at the back of soft palate, resulting in improvement of the airflow and thus reduction in snoring. The minimally invasive nature of the procedure is its biggest advantage. The main objective of this study was to assess and evaluate the efficacy of plasma-mediated radiofrequency based ablation (*Coblation*) palatoplasty (PRAP) in the treatment of snoring.

Material & Methods: This prospective study included 32 cases between 30 and 60 years of age with no gender bias reporting to a tertiary care ENT centre with history of snoring and probable sleep disorders. Study was for two years including a one year follow up period. Clinical evaluation, drug induced sleep evaluation and Polysomnography was done for all subjects. A Perceptual Score for Snoring (PSS), Epworth Sleepiness Scale and Snoring Outcome Survey was done for snoring, daytime somnolence and quality of life index prior to and after intervention respectively.

Results: Plasma Mediated Radiofrequency Based Ablation (*Coblation*) Palatoplasty (PRAP) is a safe procedure having minimal morbidity and adverse symptoms. Efficacy of the procedure was established as evidenced by the improvement in outcome scores of Apnoea-Hypopnea Index, Snoring Outcome Survey and Epworth Sleepiness Scale in the initial phase and lasting for 06 months after the procedure. Long term efficacy of the procedure is doubtful as assessed after 06 weeks till 06 months.

Conclusion: The results of this study indicate that patients who undergo PRAP for treatment of snoring obtain a satisfactory response when assessed subjectively and objectively by pre intervention and post intervention. While perceptual scores significantly improved in the immediate post intervention period lasting till 06 months, there was a reversal of the status by twelve months. All these point to the fact that volumetric reduction of palate has a temporary influence on snoring. Despite this poor subjective efficacy, significant improvements were noted in indices of quality of life and sleepiness. This raises a significant question whether it is rational to repeat the procedure at intervals of six months. It is likely that the outcome results will be much longer lasting if the procedure is repeated. These results raise several concerns about the continued use of PRAP as a treatment for snoring and mild sleep apnoea.

Keywords: Snoring, Coblation, Apnoea-Hypopnea Index, Palatoplasty.

INTRODUCTION

Snoring is the sound produced during sleep by vibration of respiratory

structures due to obstructed air movement during breathing. Snoring is known to cause sleep deprivation to snorers and those

around them, irritability, daytime drowsiness, lack of focus and decreased libido. ⁽¹⁾ It has been suggested that it can cause significant social and psychological damage to sufferers. ⁽²⁾ Various studies reveal positive correlation between loud snoring and risk of heart attack (about +34% chances) and stroke. (about +67% chance) ^(3,4) A plethora of management options exist today. Of these, pharmacological agents have not been found to be useful, dental appliances and positive pressure devices face the problem of poor compliance. In this scenario, a one-time surgical procedure without significant morbidity which arrests the problem permanently would be the ideal choice of treatment. It is in this context that plasma mediated coblation palatoplasty which reduces the volume of palatal soft tissues must be reviewed. This study is designed to evaluate the efficacy of plasma mediated coblation palatoplasty in snoring with or without mild sleep apnoea.

Aim

The primary aim of the study was to assess the efficacy of plasma-mediated radiofrequency based ablation (Coblation) palatoplasty (PRAP) in the treatment of snoring.

Objectives

The objectives of the study were

- a) To perform volumetric reduction of soft palate using plasma-mediated radiofrequency based ablation (*Coblation*) palatoplasty.
- b) To assess objectively and subjectively the improvement in snoring following the procedure.
- c) To assess the improvement in the quality of life after the procedure.
- d) To analyse the morbidity data regarding the procedure.

MATERIALS AND METHODS

This prospective study was conducted at a tertiary care centre in otorhinolaryngology for a period of one year with a follow up period of one year.

CASE SELECTION

Screening

The cohort for the study was screened from adult human subjects between 30 and 60 years of age selected without gender bias who attended or were referred to the out-patient clinic of the Department of ENT. The patients were screened with a history of snoring and probable sleep disorders.

Inclusion Criteria

The following inclusion criteria were applied for the selection of cases for the study:-

- a) Subjects with socially unacceptable snoring.
- b) Subjects with mild sleep apnoea with Apnoea-hypopnoea score (AHI) equal to or less than 15 in one hour as measured with multi channel polysomnography.
- c) Drug Induced Sleep Endoscopic evaluation (DISE) showing palate as a probable site of obstruction.

Exclusion Criteria

The following exclusion criteria were used to select the cases for inclusion in the study:-

- a) Any concurrent nasal or nasopharyngeal pathology.
- b) History of surgical treatment for snoring or sleep apnoea.
- c) Medical contra-indications for surgery.
- d) Diagnosed as multiple level obstruction on DISE.
- e) AHI greater than 15.

EVALUATION

History

A detailed history was taken with specific emphasis on otorhinolaryngological, endocrinological and pulmonology related complaints. During the first visit, attendance of the subject's bed partner was mandatory. A Perceptual Score for Snoring (PSS) from 0 (no snoring) to 10 ('heroic' snoring) was used by the partner to rate the previous night's snoring subjectively. The term 'heroic' was represented as snoring which could be heard in an adjacent room separated by a wall from where the patient

was sleeping. In addition, degree of daytime somnolence was measured using Epworth Sleepiness Scale. The subjects rated themselves on a questionnaire based on numerical scale with a range of scores from 0 to 24.

Endoscopy

All patients were subjected to routine general and ENT examination. In addition, transnasal fiberoptic laryngoscopy was carried out in all patients using flexible laryngoscope as an out-patient procedure under local anaesthesia. During the procedure the dynamics of soft palate and uvula was assessed using Müller's manoeuvre.

Polysomnography

The patients thereafter underwent a full night baseline conventional multi-channel polysomnography (PSG) according to the established standard criteria at the Department of Respiratory Medicine. During the procedure the arterial oxygen saturation (SpO₂) was measured continuously with a finger probe using pulse oximeter. Ribcage and abdominal motions were monitored employing bands placed over the thorax and abdomen. Nasal airflow was assessed with a nasal cannula. All signals were recorded continuously with a polygraph. Respiratory events were scored as apnoea when there was a cessation of airflow lasting ≥ 10 s, and as hypopnoea when any clear discernible reduction in airflow lasting ≥ 10 s was observed, associated with an arousal or with $\geq 3\%$ dip in SpO₂. Arousals were defined according to the scoring rules of the American Sleep Disorders Association. ⁽¹⁾ Apnea-hypopnea index (AHI), was used to assess the severity of sleep apnea based on the total number of apnoea and hypopnea occurring per hour of sleep. In general, the AHI of < 10 was considered normal, 10 - 15 as mild, 15 - 30 as moderate and > 30 as severe sleep apnoea. Those with AHI scores upto 15 (normal and mild) were included in this study.

DRUG INDUCED SLEEP ENDOSCOPIC EVALUATION (DISE)

All patients with AHI upto 15 were subjected to DISE in the OT set up using the same anaesthetic drugs for all the candidates under the guidance of anesthesiologist. The subjects having flapping palate or bulky palate were included in the study. A dynamic study to detect the level and degree of obstruction. The subjects having the obstruction at the level of palate were included in the study whereas the other subjects were taken up for different modalities of treatment depending upon the requirement.

Metabolic status

Metabolic status of the patient was evaluated with the following biochemical tests:-

- a) Blood sugar
- b) Blood Urea/ Serum Creatinine
- c) Serum Triglycerides
- d) Thyroid hormone status with T3/T4/ TSH

Other tests as required by the anesthesiologist for pre-anaesthetic evaluation were carried out.

Quality of life

A Snoring Outcome Survey (SOS) was used to assess the quality of life index in selected subjects prior to and after the intervention. This is a validated instrument for measuring the quality of life following treatment for snoring.

Intervention

All subjects so selected underwent volumetric tissue-reduction procedure under local anaesthesia in operation theatre. After each patient irrigated his or her mouth with oral antiseptic, the soft palate and root of the uvula were infiltrated with local anesthetic (3 to 5 ml of lignocaine 2%). Tissue reduction was performed via a channeling technique with the use of a Coblation device. The channeling procedure is designed to shrink the tissue surrounding the treatment zone. The palate was treated at three separate sites, and each channel was completed in approximately 11 seconds. This device has been cleared for marketing by the U.S. Food and Drug Administration (USFDA) and its use by this technique for

this study was cleared by the Institutional Ethics Committee prior to the initiation of the study.

It uses radiofrequency which excites the electrolytes in a conductive medium saline creating a precisely focused plasma field. The energized particles in the plasma possess sufficient energy to break molecular bonds and thereby dissolve soft tissue at relatively low temperatures (typically 40°C to 70°C).

Follow up

Patients were followed up in two phases. In the first phase, after the intervention the patients were followed up and assessed using self-assessment questionnaire on 01, 03, 07 and 14 days. The parameters assessed were pain, bleeding, difficulty in swallowing, breathing and alteration in voice using a numerical scoring system.

In the second phase, the patients were followed up at 6 weeks, 6 months and 12 months after the procedure. This was to assess the efficacy of the procedure on snoring and sleep apnoea. The following parameters were assessed during this phase of follow up.

- i. Perceptual Score for snoring (PSS) for severity of snoring as assessed by bed partner.
- ii. Epworth Sleepiness Scale (ESS) for daytime somnolence.
- iii. Snoring Outcome Survey (SOS) for quality of life.
- iv. Polysomnography (PSG) for AHI.

Data compilation

The data so obtained was compiled using SPSS software and analysed statistically applying appropriate tests of significance.

RESULTS

The period of study was one year from 01 Aug 2010 to 31 July 2011 and the follow up was done till 31 Jul 2012 for the last patient.

46 cases reported to the ENT OPD during the period from 01 Aug 2010 to 31

Jul 2011. From these 32 cases were selected for the study after applying inclusion and exclusion criteria. Of these, 28 patients reported with complaints of snoring and 04 were referred with the diagnosis of mild sleep apnoea after evaluation for snoring with polysomnography at other centres. Two subjects, however, did not complete the prescribed follow up - one subject was untraceable after 3 months and the other shifted residence to a different city. Finally 30 subjects were included in the study.

The study group comprised of 18 males and 12 females with a male to female ratio of 3:2. The range of age in years was 32 years to 60 years. The gender and age statistics of the group is given in Tables 1 and 2.

Table 1: Gender Distribution

Gender	Number (n=30)
Male	18
Female	12

Table 2: Age Distribution

Age Group (Years)	Number (n=30)
31 - 40	06
41 - 50	08
51 - 60	12
61 - 70	04

After obtaining informed consent the subjects were registered with a unique Patient Identification Number. The pre and post intervention evaluation has been done using the various validated questionnaires and results of polysomnography. The bed partner of the subject was administered the questionnaire for PSS. This numerical score was arrived at by the partner's subjective assessment of the severity of snoring on the night previous to the day of study. Majority of the patients were in Grade II and III with a small number at the either end of the spectrum. All subjects were then administered ESS, a validated numerical scale for assessment of daytime somnolence. All these subjects were thereafter administered Snoring Outcome Survey (SOS) a validated questionnaire. The result of polysomnography was measured in Apnoea – Hypopnoea Index (AHI).

All these four parameters were evaluated at 06 weeks, 06 months and 12

months after the volumetric palatal reduction with Coblation. The comparative results of PSS, ESS, SOS and AHI is given in the subsequent tables 3, 4, 5 and 6 respectively.

The pre-intervention PSS shows the majority of patients (27/30) were falling in groups of moderate to heroic snoring Gr III to Gr V. Immediate post intervention scores at 06 weeks show remarkable reduction in

these categories to 08/30 and a corresponding increase in grades I and II from 03/30 to 22/30. The 06 months scores show that 10/30 have returned to Grades III and after 12 months 06/30 returned to Grade IV & V. Despite a mild reversal after 12 months still there was a statistically significant improvement post intervention with the p value being <0.005.

Table 3: Comparison of pre and post-intervention Perceptual Score for Snoring (PSS)

Grade	Description	Pre-intervention	Post-intervention (6 weeks)	Post-intervention (6 months)	Post-intervention (12 months)
Grade I	No snoring	00	04	04	02
Grade II	Mild snoring	03	18	14	06
Grade III	Moderate snoring	12	07	10	16
Grade IV	Severe snoring	13	01	02	05
Grade V	Heroic snoring	02	00	00	01

Table 4: Comparison of pre and post-intervention Epworth Sleepiness Scale (ESS)

Numerical Score	Pre-intervention	Post-intervention (6 weeks)	Post-intervention (6 months)	Post-intervention (12 months)
0 - 8	04	06	05	04
8 - 16	18	22	23	20
16 - 24	08	02	02	06

Table 5: Comparison of pre and post-intervention Snoring Outcome Survey (SOS)

Numerical Score	Pre-intervention	Post-intervention (6 weeks)	Post-intervention (6 months)	Post-intervention (12 months)
00 - 10	04	16	14	12
10 - 20	18	12	14	14
20 - 30	08	02	02	04

Table 6: Pre and Post intervention Apnoea-Hypopnoea Index (AHI)

AHI	Pre-intervention	Post-intervention (6 weeks)	Post-intervention (6 months)	Post-intervention (12 months)
00 - 10	22	26	26	25
10 - 15	08	04	04	05

Changes in ESS scores do not show significant changes with marginal predilection for improvement in the short term which reverts statistically to the original status at 12 months. This result should be interpreted in the light of the fact that the scales are significantly affected in severe sleep apnoea, which was actually not considered in this study.

The quality of life scoring done with SOS suggests significant improvement in the first six weeks extending up to 06 months. Most of them who achieved a significant improvement continued to retain till twelve months. Irrespective of other objective measures quality of life seem to have been favourably affected by this procedure in the twelve months following the intervention.

Observation on the variation of AHI is significant. There is an statistically significant decrease in AHI score by nearly 50% in the immediate post-intervention phase and upto 6 months which to a large extent persists till twelve months. AHI being a functional indicator of sleep and respiration disorder, improvement of AHI in mild cases of sleep apnoea is a definitive additional benefit of the procedure.

DISCUSSION

Snoring is the vibration of respiratory structures and the resulting sound, due to obstructed air movement during breathing while sleeping. Snoring during sleep may be a sign, or first alarm, of obstructive sleep apnea (OSA) causing family and social embarrassment. ^(5,6)

Generally speaking the structures involved are the uvula and soft palate. As the sufferer falls asleep the muscles tone in the upper pharyngeal airway decreases leading to upper airway narrowing. This, in turn, produces an increase in inspiratory effort in an attempt to overcome this airway narrowing which then leads to a transient arousal from deep sleep to wakefulness or a lighter sleep phase which allows restoration of normal airway muscular tone and calibre. The patient then falls more deeply asleep again and the whole cycle repeats itself. The purpose of a sleep study is to confirm the clinical suspicion of Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) and to assess its severity in order to guide the therapeutic choices to offer patients. The various sleep studies are;

1. **Polysomnography** - Records sleep and breathing patterns simultaneously.
2. **Oximetry** - Oximetry alone is often used as the first screening tool for OSAHS due to the universal availability of cheap recording pulse oximeters.
3. **MRI** - Dynamic MRI is used as one of the confirmatory tests to locate the site of narrowing.
4. **Drug Induced Sleep Endoscopy**- This also simulates the actual physiological state and the site of narrowing.

TREATMENT OPTIONS

Deciding which of the various treatment options is most appropriate for the management of snoring and possible OSAHS depends on both the severity of the condition and the characteristics of an individual patient. Treatment options can be broadly divided into behavioral interventions, non-surgical options and surgical options. Current evidence from randomised controlled trials (RCTs) indicate that improvements with treatment can be found in symptomatic patients with AHI 15 or a 4% oxygen saturation dip rate at the level of 10/hour. ⁽⁷⁻⁹⁾

BEHAVIOURAL INTERVENTIONS

Overweight patients should be advised to lose weight. ^(10,11) Alcohol should not be taken in the evenings and sedatives and sleeping tablets avoided as all of these decrease airway dilator function and worsen OSAHS. These measures may suffice in simple snorers or in those with very mild OSAHS and few symptoms but most patients with OSAHS need additional treatment.

NON-SURGICAL INTERVENTIONS

1. **Continuous Positive Airway Pressure:** Continuous positive airway pressure (CPAP) functions as a pneumatic splint to maintain upper airway patency throughout all phases of sleep breathing. CPAP has been established as the treatment of OSAHS with the firmest evidence base. ^(7,12)
2. **Bi-Level Positive Airway Pressure:** These machines allow independent adjustment of inspiratory and expiratory pressures rather than having a fixed pressure as with CPAP.
3. **Intra-Oral Devices:** Intra-oral devices (IODs) are a range of appliances designed to alter upper airway patency. Several techniques have been employed, but mandibular advancement has gained most acceptance. ⁽¹³⁾
4. **Pharmacotherapy:** The evidence base to support pharmacological treatment as an effective therapeutic option is small. ⁽¹⁴⁾

SURGICAL TREATMENT

Many different surgical approaches have been used in the treatment of OSAHS, all with the intention of increasing pharyngeal calibre and reducing pharyngeal resistance during sleep. The following procedures can be performed:

1. Uvullectomy
2. Coblation Palatoplasty
3. Uvulopalatopharyngoplasty (UPPP)
4. Hyoid Suspension

Coblation Palatoplasty

This operation is performed to reduce snoring and alleviate sleep apnoea. This operation involves the trimming away

of tissues causing airway obstruction at the back of the palate, therefore improving the airflow and reducing snoring. Most operations are straightforward however as with any surgical procedure there is a small chance of side-effects or complications. Radio frequency ablation of the soft palate was used to gain volumetric reduction as a treatment of snoring by many surgeons in the past. ^(15,16) Following the inauguration of the laser-assisted uvulopalatoplasty (LAUP) by Kamami et al in 1994, ⁽¹⁷⁾ various surgical techniques using lasers have been developed. Although LAUP and uvulopalatopharyngoplasty (UPPP) are the most widespread procedures, they are associated with significant postoperative morbidity and, especially in the case of UPPP, are usually performed under general anesthesia.

Therefore, much effort has been invested in establishing minimally invasive techniques like the one done in our study for the treatment of snoring. Concerning postoperative complications, no serious adverse events were reported with the coablation palatoplasty. The most frequently reported complication was a mucosal erosion or ulceration. An important advantage of this technique lies in the minimally invasive nature of the procedure. Nevertheless, the necessity of repeated treatment sessions should be kept in mind as a disadvantage of this technique. The results of this study indicate that a significant number of patients who undergo PRAP for the treatment of snoring obtain a satisfactory response when assessed subjectively and objectively by pre intervention and post intervention with the various outcome measures. While perceptual scores significantly improved in the immediate post intervention period lasting till 06 months, there was a reversal trend seen after twelve months. All these point to the fact that volumetric reduction of palate has a positive influence on snoring and significant improvements were noted in indices of quality of life and sleepiness.

This also raises the question whether it is rational to repeat the procedure at intervals of twelve months. It is likely that the outcome results will be much longer lasting if the procedure is repeated. These results raise several concerns about the continued use of PRAP as a treatment for snoring and mild sleep apnoea. Of particular concern is the reversal of initial effects objectively as well as subjectively.

CONCLUSION

It can be concluded that PRAP is a safe procedure with minimal morbidity. No adverse symptoms were reported in this study. The morbidity data of PRAP suggests that post- procedure symptoms of pain, dysphagia and dysphonia persist in the first ten days. The efficacy of the procedure was established as evidenced by the improvement in outcome scores of Apnoea-Hypopnea Index, Snoring Outcome Survey and Epworth Sleepiness Scale in the initial phase after the procedure lasting upto 12 months. Safety and efficacy of repeating of the procedure in the reversed subjects needs to be corroborated. The economic impact of the procedure needs to be factored when recommending the procedure considering the huge capital cost of the equipment. Such procedures should be reserved only for those patients where other measures fail and these procedures should be carried out at only limited centres where the sleep evaluation and management facility exists.

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How to cite this article: Singh SK, Manoj KK, Mokamati S et al. Coblation palatoplasty, a treatment for snoring: Our experience. *Int J Res Rev*. 2016; 3(3):37-44.
