

Original Research Article

DOI: <http://dx.doi.org/10.18203/issn.2454-5929.ijohns20200069>

Analysing the efficacy of polidocanol in injection snoreplasty

Manjunath K.*, Amardeep Singh, Manjunatha Rao S. V., Akash Aradhya S.

Department of ENT, Basaveshwara Medical College and Hospital, Research Centre, Chitradurga, Karnataka, India

Received: 31 December 2019

Revised: 16 January 2020

Accepted: 18 January 2020

*Correspondence:

Dr. Manjunath K.,

E-mail: drmanjunathk21@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Injection snoreplasty was recently introduced as a safe, effective, and minimally invasive treatment for primary snoring. The objective of the study was to assess the effectiveness of the treatment in our patients.

Methods: The study was a prospective, non-randomised study done on 40 patients with primary snoring. Study was done in the Department of Otorhinolaryngology and Head and Neck Surgery at Basaveshwara Medical College and Hospital, Chitradurga over 8 months between March 2019 to October 2019. The data was collected from patients about their symptoms. Detailed clinical and radiological examination was done in all patients. Almost each and every causes of snoring were ruled out. 1-3% polidocanol injection of about 1 ml with insulin syringe was administered in all the patients in 1 to 3 sittings after 10% LOX spray application on the site. Patients were assessed after 1, 3 and 6 months and their improvement was noted.

Results: There were 24 (60%) males and 16 (40%) females enrolled in our study with mean age as 42 ± 5 years. The average BMI of patients was 27.14 ± 3.1 kg/m². All the patients except 4 were initially injected 1% polidocanol injection; the others were injected 3%. 4 (10%) patients were re-injected at 1 month and 4 (10%) had 2nd re-injection at 3 months follow up. The mean improvement in symptoms was 58%. Eleven patients (27.5%) had moderate snoring while the rest had severe snoring. The only side effect was pain which in majority of patients was mild. There was no correlation between BMI and percentage of improvement.

Conclusions: Injection snoreplasty is a safe and cost-effective treatment for primary snoring.

Keywords: Injection snoreplasty, Snoring, Polidocanol

INTRODUCTION

Snoring is a common problem, affecting 20% of the general population and 60% of men aged older than 40 years.¹ It generally results from the narrowing and partial obstruction of the upper airway during sleep due to unfavorable positioning of the uvula, soft palate, and tongue. Because snoring is so common, treatment modalities continue to evolve to meet this demand, with emphasis on developing simple, effective, and less invasive procedures that are well tolerated by the patient. Treatments include weight loss, exercise programs, smoking cessation, nasal and oral appliances, and dietary

changes. All of these methods depend on patient compliance.

Surgical treatments for snoring are varied and controversial. Uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatopharyngoplasty (LAUP), radio-frequency ablation, cautery-assisted palatal stiffening operation, and injection snoreplasty are the most accepted techniques.^{2,3} LAUP was introduced as an alternative to UPPP since it can be performed with local anesthesia in an office setting.^{4,5} However it has lost popularity because it is more painful than other more recently developed procedures, usually needs multiple visits, and

requires expensive equipment. In addition, long-term success rates are reported to be under 50%.⁶ Thus it seems logical to perform minimally invasive procedures.

There are many causes for snoring. Simple snoring can occur due to deviated nasal septum, mass in nasopharynx or in the nasal cavities, excessive palatal flutter and bulky base of tongue. Among all these, palatal flutter is the most common cause for snoring in habitual snorers. It occurs due to large, floppy soft palate or bulky and elongated uvula. It is logical that patients with palatal flutter would benefit from palatal surgery, whereas those with tongue base or other types of snoring would not benefit.

Injection snoreplasty, first introduced by Brietzke et al in 2001, has been well received with increasing popularity as a primary treatment for palatal snoring because of its comparative advantages over other snoring procedures.⁷ Its primary objective is to stiffen the soft palate to reduce palatal flutter which causes snoring. Polidocanol is a sclerosing agent and causes fibrosis at the site of injection into soft palate. Fibrosis leads to stiffening and reduced vibration of the palate thus reducing the snoring. It is very simple to perform during a routine clinic visit, is minimally painful and inexpensive. The procedure was initially presented using the well-described sclerotherapy agent Polidocanol as the palatal sclerosing agent.⁷ This agent was selected because of its excellent safety record and established efficacy over several decades in the literature. We assess the efficacy of polidocanol in our patients.⁷

METHODS

This prospective, non-randomized human use pilot study was first approved by our local institutional review board before any patient enrollment. The study was conducted after obtaining institutional ethical committee clearance. Informed consent was obtained from all the patients before recruiting for the study.

Forty patients were enrolled in the study in the Department of Otorhinolaryngology and Head and Neck Surgery at Basaveshwara Medical College and Hospital and Research Centre, Chitradurga, India over 8 months between March 2019 to October 2019. A detailed informed consent was taken from all the patients. Patients as well as their spouses were questioned and a detailed history was obtained. Patients were specifically questioned about any symptoms suggestive of sleep apnea, morning headaches, irritability, decreased concentration span and day time somnolence. This is relevant because all these features are seen in patients with obstructive sleep apnea which may not improve after injection snoreplasty.

Snoring was graded using the VAS scale from 1-3 as mild, moderate and severe snoring.⁸ Objective measurement of the snoring sound in decibels was not

done as it was not feasible. A detailed clinical examination was done in all the patients. Flexible nasopharyngoscopy and laryngoscopy was done to visualize the nasopharynx, oropharynx and the larynx and the site of obstruction was inferred. Radiological examination included X-ray PNS water's view, X-ray skull lateral view, and X-ray soft tissue neck lateral view and X-ray chest PA view. All enrolled patients underwent an overnight sleep study confirming the diagnosis of primary snoring with a respiratory disturbance index (RDI) of less than 10.⁹ Exclusion criteria included tonsillar hypertrophy on physical examination (defined as greater than 1+), a known history of co-morbid disease that could alter routine healing patterns (e.g., vascular disease, diabetes mellitus, significant periodontal disease, etc.), or a history of prior surgical snoring treatments.

All the patients who were habitual snorers were included in the study. The patients had palatal flutter on nasopharyngoscopy during simulated snoring and had obstruction at palatal level. This was the inclusion criteria and was mandatory for case enrollment. Other exclusion criteria included patients having sleep apnea syndrome; diabetics; age above 70 years; multiple levels of obstruction; primary bulky tongue and allergy to Polidocanol.

One ml of 1 to 3% polidocanol injection was administered in all patients in 1 to 3 sittings after giving topical anesthesia using 10% xylocaine spray. 1% polidocanol was used for primary injection and 3% Polidocanol was used for re-injections. 1% polidocanol is recommended for primary injection and cures snoring in habitual snorers. 3% polidocanol should be injected in failed cases as they require more stiffening of the soft palate to cure snoring. First injection is indicated when patient comes to us with diagnosis of habitual snoring. Patient is re-assessed at 4 weeks after first injection to see the response to polidocanol. If there is significant reduction in snoring, no further injection is required. But if patient still complains of snoring as before the treatment, re-injection is indicated. The site of injection was at the root of uvula in midline as shown in (Figure 1). Site for re-injection, which was done after 4 weeks of the first injection, was paramedian in the soft palate re-injection in soft palate should be done at paramedian site as the first injection as shown in (Figure 2) would cause stiffening in the median part. 1 ml insulin syringe was used to administer the sclerosant. Patients were only given pain killers for 1 to 3 days. Patients were assessed at 1, 3 and 6 months after treatment. All 40 patients were followed up at all time periods. Snoring improvement was noted subjectively using visual analogue scale (VAS) and objectively using sleep study.⁸ It showed the improvement in apnea-hypopnea index (AHI) and oxygen saturation after injection snoreplasty.¹⁰ Degree of pain was also graded as no pain, mild, moderate and severe on visual analogue scale (VAS).⁸ All procedures were done by the principal investigator with total duration of 20 minutes. Mean and standard deviation method and

Pearson's correlation co-efficient tests were used for statistical analysis.⁸



Figure 1: Site of injection polidocanol, over midline of soft palate (initial injection site).

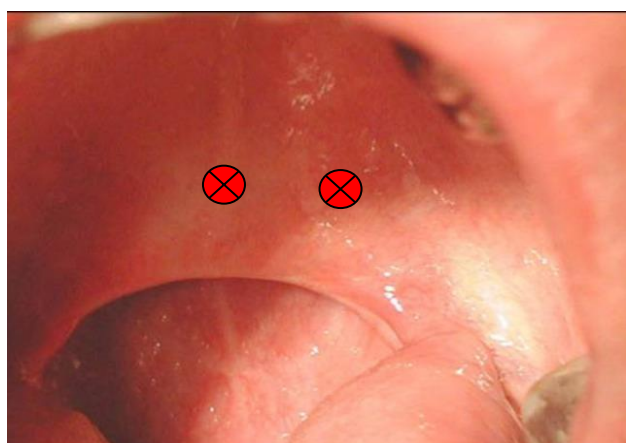


Figure 2: Site of injection, over para-median in the soft palate (re-injection site).

The guidelines are divided into three parts. The first part entitled "definition and classification of sleep-related breathing disorders in adults. Different types and indications for sleep studies" refer to different syndromes related to breathing disorders during sleep such as: central apnea syndromes, Cheyne-stokes respiration, obstructive sleep apnea syndrome, upper airway resistance syndrome, and alveolar hypoventilation syndrome. In addition, major types of sleep studies such as: full polysomnography, limited sleep study, attended sleep study, unattended sleep study, split-night study were mentioned, along with their indications for diagnostic and therapeutic purposes. The second part entitled "treatment of obstructive sleep apnea syndrome (OSAS) in adults" refers to different types of treatment for OSAS in adults such as positive airway pressure application, oral appliances and surgical treatment. Different types of positive airway pressure devices were presented, along with benefits related to their application.

Finally, the issue of compliance to CPAP use. The third part entitled "OSAS in children: diagnosis and treatment" refers to obstructive sleep apnea syndrome in children. Clinical features, pathogenesis, diagnosis and treatment are also mentioned.⁹

The recent revision to the International Classification of Sleep Disorders (ICSD-2) has changed both the name and diagnostic criteria for obstructive sleep apnoea (OSA), now OSA (adult). The daytime consequences that previously defined the OSAS syndrome have been de-emphasized in the ICSD-2, and are no longer an essential criterion. Instead, the presence of 15 or more apnoeas, hypopnoeas, or RERAs is sufficient to define the disorder. Polysomnographic measurement of the apnoea hypopnea index (AHI) has therefore acquired the status of a diagnostic test. While it is conventional for clinical laboratories to report an observed AHI value as a diagnostic indicator of OSA and a proxy measure of OSA severity, this single value can be misleading. The AHI reported for a patient after a single night of laboratory assessment can be better described by a confidence interval (CI) based on these reliability estimates.¹⁰

RESULTS

There were 24 (60%) males and 16 (40%) females enrolled in our study (Table 1) with mean age of 42.3 ± 5 years. All had undergone a previous overnight sleep study confirming the diagnosis of primary snoring. ($RDI < 10$ events/hour). The RDI ranged from 0 to 10 with a mean of 2.6 events per hour. The average BMI of patients was 27.14 ± 3.1 kg/m².

Table 1: Gender distribution (n=40).

Sex distribution	No. of patients (N)	Percentage (%)
Males	24	60
Females	16	40
Total	40	100

Eleven patients (27.5%) had moderate snoring while the rest had severe snoring. All the patients were initially injected with 1% polidocanol injection; the others were injected 3%. 4 (10%) patients were re-injected at 1 month and 4 (10%) had 2nd re-injection at 3 months follow up. The mean improvement in symptoms was 58%. The only side effect was pain which in majority of patients was mild. There was no correlation between BMI and percentage of improvement.

The main side effect was pain. Some patients developed difficulty in swallowing which lasted for 7 days; 2 (5%) patients developed severe mucosal ulceration which did not require any intervention. No other side effect was observed during the study.

Table 2: Pain associated with snoreplasty according to VAS scale.

Time period	Agonizing (unbearable distress)		Horrible		Dreadful		Uncomfortable		Annoying		None (no distress)	
	10	9	8	7	6	5	4	3	2	1	0	
1 month	1	0	0	0	0	0	4	0	8	10	18	
3 months	0	0	0	0	0	0	4	0	12	5	19	
6 months	0	0	0	0	0	0	3	0	8	8	21	

Four (10%) patients had mild dysphagia after treatment which improved over 2 days of analgesic treatment. The maximum reported convalescence beyond the day of injection was 3 to 5 days, 1 (2.5%) patient with mucosal breakdown, although the great majority of patients required no convalescence. Pain scores reported through visual analog scale (0 to 10 scale) ranged from 0 to 6 and averaged 3.0 for post injection day 1, 2.5 for day 2, 2.2 for day 3, 1.5 for day 4 and less than 1 for day 5 (Table 2).

The correlation of percentage of improvement in snoring was calculated with BMI. This was our observation during the study although it was not the focus of our work. As many patients with snoring had high BMI, we planned to study the correlation of BMI with improvement in snoring. We found negative correlation between BMI and improvement in snoring with correlation coefficient value of -0.56 and p value of <0.05 using Pearson's correlation co-efficient method, thereby implying that higher the BMI lesser would be the improvement. Patient's BMIs had not changed over the one year of the study; although there had been temporary improvement, patients had returned to their original BMI eventually. Sleep improved significantly in 58% patients as shown in (Table 3).

Table 3: Sleep improvement and injection snoreplasty.

Sleep out-come	Patients (N)	Percentage (%)
Improved	23	58
Unchanged	4	10
Disappeared	13	33

Snoring outcome was assessed clinically using VAS scale and by testing the simulated snoring during flexible nasopharyngoscopy and sleep improvement was tested subjectively as well as objectively using overnight sleep study.

DISCUSSION

UPPP was introduced as a first surgical treatment by Fujita in 1981.⁵ The surgery gave good results initially, but with time they dropped significantly. Moreover, the drawback of UPPP included the requirement for general anesthesia and the association with significant postoperative pain and complications. To avoid the

requirement for general anesthesia, LAUP was introduced by Kamami.⁴ However, it can be equally as painful as UPPP. In addition, it may require multiple procedures; thus, it is not a cost-effective procedure. Radiofrequency ablation for tissue volume reduction has been used for snoring treatment.² It provides a minimally invasive office-based therapy with decreased morbidity and less disruption of patient's normal activities in the peri-procedure period. However, it requires a sophisticated equipment which is costly. Injection snoreplasty was introduced as a new treatment for primary snoring with advantages when compared to other snoring procedures.¹¹ It is very simple to perform, minimally painful and inexpensive. Brietzke et al in their follow up of 22 patients over 19 months reported an improvement rate up to 75%.¹²

We used polidocanol as a sclerosant agent, which showed to be safe and USFDA approved. Moreover, higher rates of palatal fistulas are noted with 50% ethanol, another agent commonly used.¹²

The results of the different surgical procedures for snoring are variable. The success rate with UPPP for snoring is 40.7% as reported by Sheret al.¹³ We achieved 57.24% improvement rate in our patients which is quite good comparing with the morbidity of UPPP. The results of other modalities viz. radiofrequency ablation 46.7%, geniotubercle advancement 39-70%, hyoid advancement 53.3%, suture suspension of the tongue (repose procedure) 20-57% and tongue base resection (midline-glossectomy) 25-83% are quite comparable with our results.¹⁴⁻¹⁶ Moreover these surgical procedures demand expertise and have high morbidity. No such morbidity is seen with injection snoreplasty.

It is important to know how injection snoreplasty evolved. As the procedures described earlier for snoring treatment were too morbid requiring hospitalization, they went out of repute when injection snoreplasty was introduced in 2003 as a simple treatment for habitual snoring.

Recently Labra et al have done a pilot study using Polidocanol as submucosal injection in the soft palate in patients with mild obstructive sleep apnea syndrome to treat snoring.¹⁷ They have found good results in OSAS patients as well thereby increasing the scope of this sclerotherapy in OSAS also.

Recently palatal implants have also been introduced.¹⁸ They also stiffen the palate. They are painless and easy to implant. But reports of extrusion and high cost are disadvantages. The allergic reactions to these implants and long-term results are yet to be known as these are in their initial phase. Injection snoreplasty on the other hand is quite safe and established method of palatal stiffening.

Patients with higher BMI tend to perform poorly with injection snoreplasty. This is quite understandable as obesity usually leads to multilevel obstruction in the airway. By injection snoreplasty we are only stiffening the palate. It was seen that if these patients reduce their weights then snoring improvement is more.

CONCLUSION

Injection snoreplasty is introduced as a simple, safe, and effective office treatment for primary snoring. Advantages over current snoring procedures include simplicity, decreased expense, decreased post-treatment pain, and minimal/no convalescence. Given the numerous advantages, it has the potential to replace many current snoring treatments.

In summary, injection snoreplasty has been found to be the safe and effective sclerotherapy for treating habitual snoring with 58% cure rate in our study. No adverse effects were found in any of the subjects receiving this therapy.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Hoffstein V, Madeira JH, Mateika S. Snoring and sleep architecture. *AM Rev Respir Dis*. 1991;143:92-96.
- Powell NB, Riley RW, Troell RJ, Li K, Blumen MB, Guilleminault C. Radiofrequency volumetric tissue reduction of the palate in subjects with sleep-disordered breathing. *Chest*. 1998;113:1163-74.
- Mair EA, Day RH. Cautery-assisted palatal stiffening operation. *Otolaryngol Head Neck Surg*. 2000;122:547-55.
- Kamami YV. Outpatient treatment of sleep apnea syndrome with CO₂ laser assisted UPPP. *J Otolaryngol*. 1994;23:395-8.
- Fujita S, Conway W, Zorick F, Roth T. Surgical correction of anatomic abnormalities in obstructive sleep apnea syndrome uvulopalatopharyngoplasty. *Otolaryngol Head Neck Surg*. 1981;89:923-34.
- Levin BC, Becker GD. Uvulopalatopharyngoplasty for snoring long term results. *Laryngoscope*. 1994;104:1150-2.
- Brietzke SE, Mair EA. Injection snoreplasty: How to treat snoring without all the pain and expense. *Otolaryngol Head Neck Surg*. 2001;124:503-10.
- Jaimanti B, Gupta AK, Dash AN, Khandelwal G. Injection Snoreplasty-a simple way to treat habitual snoring. *Br J Med Med Res*. 2014;4(30):4946-55.
- Tsara V, Amfilochiou A, Papagrigorakis MJ, Georgopoulos D, Liolios E. Definition and classification of sleep related breathing disorders in adults. *Hippokratia*. 2009;13(3):187-91.
- Smith S. Reporting the Apnoea Hypopnea Index (AHI). *J Clin Sleep Med*. 2007;3(3):321.
- Brietzke SE, Mair EA. Injection snoreplasty: Extended follow-up and new objective data. *Otolaryngol Head Neck Surg*. 2003;128:605-15.
- Brietzke SE, Mair EA. Injection snoreplasty: Investigation of alternative sclerotherapy agents. *Otolaryngol Head Neck Surg*. 2004;130:47-57.
- Sher AE, Schechtman KB, Piccirillo JF. The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep*. 1996;19:156-77.
- Powell NB, Riley RW, Guilleminault C. Radiofrequency tongue base reduction in sleep-disordered breathing: a pilot study. *Otolaryngol Head Neck Surg*. 1999;120:155-62.
- Kezirian EJ, Goldberg AN. Hypopharyngeal surgery in obstructive sleep apnea. *Arch Otolaryngol*. 2006;132:206-13.
- den Herder C, van Tinteren H, de Vries N. Hyoidthyroidpexia: A surgical treatment for sleep apnea. *Laryngoscope*. 2005;115:740-5.
- Labra A, Haro-Valencia R, Huerta-Delgado AD, Correa UJ, Sanchez-Narvaez F. Efficacy of Submucosal Sodium Tetracycline Sulfate in the Soft Palate as a Treatment of the Mild Obstructive Sleep Apnea Syndrome: A Pilot Study. *Sleep Disorders*. 2012;2012:597684.
- Joachim TM, Hein G, Verse T, Hormann K, Stuck BA. Long-term results of palatal implants for primary snoring. *Otolaryngol Head Neck Surg*. 2005;133:573-8.

Cite this article as: Manjunath K, Singh A, Manjunatha RSV, Akash AS. Analysing the efficacy of polidocanol in injection snoreplasty. *Int J Otorhinolaryngol Head Neck Surg* 2020;6:258-62.