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Main Article

Silencing the snorers: no gain without pain?

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Abstract

Objective: To compare the estimated effects of conservative surgery to those of a mandibular advancement splint (MAS) in the treatment of habitual snoring.

Method: Prospective, observational, non-randomized cohort study.

Results: Adequate follow-up data were available for 88 participants (23 following coblation, 65 after provision of an MAS). The mean reduction in snoring symptoms inventory (SSI) score for the 23 subjects undergoing coblation was 9.83 ($\pm$ standard deviation 11.43). Reported pain duration was greatest with uvula amputation, but uvula coblation did not always adequately reduce its bulk. Of the 65 MAS patients, 39 (60 per cent) used the device regularly, with a mean fall in SSI of 12 ($\pm$16.4, $p = 0.001$). Approximately one in four patients in both groups achieved a significant fall in SSI (>15 points), and the measured effect sizes were close to 0.75 for both treatments.

Conclusions: Mandibular advancement splints and coblation have similar efficacies. However, their efficacy does not match that of radical surgery.

Key words: Snoring; Mandibular Advancement; Prostheses and Implants; Surgical Procedures, Operative; Treatment Outcome

Introduction

Snoring is a common presentation in the ENT outpatient clinic. The prevalence of snoring has been reported to be 44–53 per cent for men and 22–38 per cent for women.[1,2] Frequently, the patients themselves sleep well whilst their partners and family complain of disturbed sleep.[1,3] Snoring is due to partial obstruction at the oro- and hypo-pharynx[4] which, when combined with pharyngeal muscular hypotonia, causes the pharyngeal soft tissues to vibrate.[5,6]

The treatment of the snoring patient must be tailored to the individual's symptoms and needs. Conservative measures such as weight loss and avoidance of alcohol, sedatives and smoking are the usual first line management, but these are frequently ineffective. The most common surgical strategy is to reduce the volume of the soft palate, combined with stiffening or supporting the remaining tissues. Laser-assisted uvulopalatoplasty (LAUP) and uvulovelopharyngopalatoplasty, are well established surgical treatments[1,2,7,8] but both carry significant morbidity.[1,5,8,9]

Another, less radical intervention is bipolar radiofrequency thermal ablation, also known as 'coblation'. This procedure produces an ionized saline layer that causes molecular dissociation at low temperatures. Radiofrequency currents are channelled under the mucosa, which lead to localized heating and palatal stiffening. This results in tissue removal with minimal collateral tissue necrosis. The proposed advantages are less pain, faster healing and reduced post-operative care requirements.[5,9]

Some patients, however, prefer a non-surgical approach. Mandibular advancement splints (MAS) have been designed to cause mandibular protrusion. This anterior and inferior positioning of the lower jaw increases the calibre of the resting upper airway. It is also thought that MAS may cause secondary, stretch-induced activation of the pharyngeal musculature, preventing collapse.[6,10] Treatment with MAS is reversible and does not exclude the patient from surgical treatment at a later date.

Assessment of the success of snoring interventions has involved many different variables, with very few

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robust direct comparisons cited in the literature. The snoring symptoms inventory (SSI)[11] is a validated, patient-reported measure that assesses both the psychological and physical effects of snoring. The SSI is a questionnaire that comprises 25 items scored on a five-point Likert scale from 'strongly disagree' to 'strongly agree' and the responses graded from zero to four, respectively. The total SSI score ranges from 0 to 100; patients scoring 100 will be the most severely affected by snoring. The SSI has been shown to be sensitive to changes following interventions such as LAUP.[12]

The aim of this study was to use the SSI to estimate the size of the effect of soft palate coblation and MAS provision, in order to inform future prospective, randomized trials.

Materials and methods

All patients referred to us for snoring therapy completed both the Epworth sleepiness scale (ESS)[13] and an SSI. All patients underwent an assessment of their nasal airway and oropharynx and measurement of their body mass index and collar size. If there was a history suggestive of apnoea and/or the ESS was greater than 10, the patients were referred for a sleep study before any treatment was considered. The patients in each arm of the study (coblation and MAS) completed post-intervention ESS and SSI questionnaires and these scores were compared to baseline scores. The effect size from the SSI was used to compare the treatment efficacy between the groups. Based on a previous study, a fall of 15 points or greater in the SSI was regarded as a clinically significant improvement.[12]

The post-operative pain severity was also recorded on a scale of zero to five (corresponding to no pain and unbearable pain, respectively).

Treatment

LAUP

In a previous study in our unit, LAUP was used for treatment of fifty-five snoring patients with Apnoea/Hypopnoea Index (AHI) of less than 25.[12] Their SSI was checked pre-operatively and then six months post-operatively. The SSI data from the LAUP study were used for comparison with the data from the coblation and the MAS group in our study.

Coblation

Those patients with moderate or severe snoring occurring almost every night, a favourable pharyngeal configuration (tonsil size two or less, Friedman's classification)[14] and without an occlusive tongue base (Malampatti grade one to three) or gross nasal obstruction, were offered soft palate coblation. Patients were excluded if they were diagnosed with sleep apnoea demonstrated by sleep study, had tonsillar hypertrophy (Friedman grade three or four) or had an occlusive tongue base (Malampatti grade four).

One surgeon (JAW) performed all the procedures. The coblation settings were on an intensity scale of five with a 10 second duration. All patients received two parallel paramedian channels and two to three further vertical channels plus one further higher transverse mucosal channel (Figure 1). Where clinically enlarged, the uvula was also reduced. Initially, this was undertaken with two vertical upward coblation passes, but this did not always adequately reduce the uvula. Therefore, a third group had the uvula amputated with a cutting diathermy. Patients completed the ESS and SSI questionnaires together with a pain severity and duration assessment when reviewed at a mean interval of 14 weeks.

Mandibular advancement splint

In a parallel observational study, patients were referred for conservative therapy using an MAS.[15–17] Referrals were taken from both the snoring clinic and the sleep clinic. One dentist (GMcC) undertook a dental examination to ensure dental fitness prior to taking upper and lower alginate impressions of the dentition. A record of the patient's occlusion (i.e. bite) was taken with the mandible protruded by approximately 50 per cent full protrusion. Patients then returned to have an MAS fitted and adjusted if necessary and were given instructions on its use and storage. A follow-up appointment was made for six to eight weeks later, when patients repeated ESS and SSI questionnaires with supplementary questions. The additional questions assessed the patient's subjective impression of the splint, their level of compliance and the nature of any difficulties encountered; a single question requested an estimate of the percentage of reduction in snoring, and a free comments area was also provided.

Analysis

The data were analysed using SPSS software and were interpreted under the supervision of a statistician. Up to two missed items on the SSI were corrected prior to

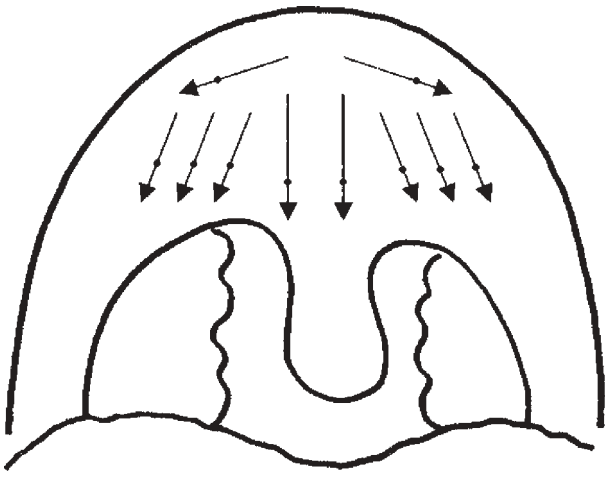

FIG. 1

Typical channels in a 10-pass coblation. Arrows = channels; • = typical area of scarring near probe tip

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generation of the mean score. The estimated efficacy of the two procedures was compared using the effect size. This was calculated from the mean difference in SSI divided by the standard deviation (SD) of the baseline SSI for each group.[18]

Results

Coblation

Out of the 29 patients initially enrolled, 23 (79 per cent) completed all questionnaires appropriately (Table I). Six patients (26.1 per cent) attained the predetermined clinically significant improvement in their SSI (i.e. ≥15 points). Based on SSI results, the effect size for the surgery was 0.74 for the whole coblation group (Table II), but in the subgroup receiving coblation of the uvula a smaller effect size (0.49) was seen. The improvement in mean ESS was 2.1 (SD 2.7) for the whole group. The mean pain severity was 3.6 (SD = 1.2). There was a wide variation in pain duration, ranging from one to 30 days. Those patients receiving uvular amputation reported the most persistent pain (this was not significant following Mann–Whitney testing).

Mandibular advancement splint

Mandibular advancement splints were provided for 95 patients. Sixty-five patients (68 per cent) completed all pre- and post-insertion questionnaires (Table III). Approximately one-third of these patients were referred from the ENT snoring clinic and two-thirds from the sleep clinic (ENT referral = 23, sleep clinic referral = 40, others = two). Patients who reported using their splint for half of the nights or less, for whatever reason, were deemed to be poor compliers. In 39 of 65 patients, the device was used for at least half of the nights within the follow-up period, with a mean SSI fall of 12 points (SD = 16.4, $p = 0.001$). A fall in SSI of at least 15 points was achieved by seven out of the 39 (18 per cent) in this group. The effect sizes for the whole MAS group and for the MAS compliers were calculated as 0.45 and 0.76, respectively (Table II). The effect size for the MAS compliers was approximately the same as that of patients receiving coblation, but less than that reported for patients receiving LAUP (Table II).

TABLE II

EFFECT OF ALL INTERVENTIONS ON SNORING SYMPTOMS INVENTORY (SSI)

Treatment	Subgroup	*n*	Mean SSI difference	Pre-op SSI SD	Effect size
LAUP*	Total	55	17.6	10.9	1.61
MAS	Total	65	6.6	14.6	0.45
	Compliers	39	12.0	15.8	0.76
Coblation	Total	23	9.8	13.3	0.74
	CoP	6	12.5	14.2	0.88
	CoPU	9	5.1	10.5	0.49
	CoP/AmpU	8	13.1	16.6	0.79

*Reference 12. Pre-op = pre-operative; SD = standard deviation; LAUP = laser-assisted uvulopalatoplasty; MAS = mandibular advancement splint; CoP = coblation of palate; CoPU = coblation of palate and uvula; CoP/AmpU = coblation of palate and amputation of uvula

Discussion

Coblation is a technique that has been proven safe in arthroscopy, skin resurfacing, tonsillectomy and turbinate reduction.[5] Although monopolar radiofrequency tissue reduction for snoring has been well explored in the literature, there is relatively little published evidence on the use of bipolar techniques in snoring surgery. This pilot study aimed to assess the overall success of the treatment as well as the best application.

TABLE I

SNORING, SLEEPINESS AND PAIN RESULTS* FOR THE COBLATION GROUP

Result	Intervention			
	Total coblation ($n = 23$)	CoP ($n = 6$)	CoPU ($n = 9$)	CoP/AmpU ($n = 8$)
SSI				
Mean pre-op (SD)	60.2 (13.3)	62.5 (14.2)	60 (10.5)	58.6 (16.6)
Mean post-op (SD)	50.4 (14.6)	50 (7.8)	54.9 (13.4)	45.5 (19.2)
Mean difference (SD)	9.8 (11.4)	12.5 (17.9)	5.1 (9.1)	13.1 (6.5)
ESS				
Mean pre-op (SD)	6.9 (4.3)	7.7 (3.3)	5.6 (4.6)	7.8 (4.6)
Mean post-op (SD)	4.7 (3.2)	4.5 (3.9)	4.2 (2.6)	5.5 (3.9)
Mean difference (SD)	2.1 (2.7)	3.2 (3.5)	1.3 (2.6)	2.3 (2.2)
Pain				
Severity (SD)	3.6 (1.2)	4.0 (0.9)	3.1 (1.2)	3.8 (1.5)
Duration (days)				
n (SD)	7.7 (7.2)	6.5 (5.0)	5.8 (5.0)	10.6 (10.1)
Range	1–30	2–15	1–14	1–30
Median	5	4.5	4	7

*Assessed by the snoring symptoms inventory (SSI), Epworth sleepiness scale (ESS) and a pain scale (0–5), for each intervention. CoP = coblation of palate; CoPU = coblation of palate and uvula; CoP/AmpU = coblation of palate and amputation of uvula; pre-op = pre-operative; post-op = post-operative; SD = standard deviation

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TABLE III

SNORING AND SLEEPINESS RESULTS* FOR MAS TREATMENT†

Result	Mean score (SD)	Range	Mean difference (SD)	p‡
SSI				
Pre-treatment	61.4 (14.6)	29–91	6.6 (13.5)	0.000
Post-treatment	54.8 (17.4)	13–91		
ESS				
Pre-treatment	10.1 (5.0)	1–24	1.0 (4.3)	0.083
Post-treatment	9.1 (5.2)	0–24		

*Assessed by the snoring symptoms inventory (SSI) and Epworth sleepiness score (ESS). †$n = 65$.
‡Comparing pre- and post-treatment results, Wilcoxon test. MAS = mandibular advancement splint; SD = standard deviation

This study provides preliminary evidence that coblation is an effective and safe treatment and that palatal coblation alone appears to be sufficient. Uvula amputation with cutting diathermy may necessitate general anaesthetic for many patients; however, bipolar diathermy has been shown to be feasible and acceptable to patients in the office setting, under local anaesthetic.[5,19] This permits easier access to the procedure, which could be repeated after a week's interval if required. It has been shown that the benefits from LAUP and uvulopalatopharyngoplasty (UPPP) lessen over time.[1,11] If the benefits of coblation follow the same pattern, then re-application under local anaesthetic may be an acceptable further course of action. Such individualization of treatment may lead to even better results. The duration of post-operative pain in our patients was similar to that reported by Rombaux *et al.*,[9] who showed coblation of the soft palate to be significantly less painful than UPPP and LAUP.

Mandibular advancement splints have been used in the treatment of patients with obstructive sleep apnoea for over a decade and, more recently, have also been used for snoring. There are many different designs, including off-the-shelf, self-fitting devices and splints incorporating adjustable advancement of the mandible. In this study, a splint design with fixed advancement of 50 per cent full protrusion of the mandible was selected. Compliance appears to be the main problem with the MAS. At present, our group does not have the information to enable prediction of which patients will respond to or be able to tolerate these devices.[20] The compliance rate with MAS was 60 per cent for the group studied. For the whole cohort, there was a statistically significant fall in SSI. But, this was below the a priori change needed for clinical significance, a fall in SSI > 15 points, with only 18% of patients achieving this reduction.

The most common MAS side effects reported by patients in previous studies were sore teeth, sore jaw muscles, excessive salivation and difficulty chewing in the morning.[3,4,10,15] Long-term MAS compliance rates have previously been reported as being between 50 and 100 per cent.[15,16] However, the side effects of wearing a splint are generally short-lived, and if the patient persists beyond four weeks then tolerance is generally achieved.[3,10,15,20] Side effects have been shown to be reversible and to resolve either with longer usage or when treatment is discontinued.[3,4,16]

This study involved an initial fitting visit and a single follow-up visit during which questionnaires were administered. However, introduction of an intermediate visit might possibly increase the level of compliance and the success rate. This visit would allow any splint adjustments to be made based on the patient's immediate feedback. It would also provide an opportunity to reassure the patient about the transience of many symptoms. A second visit would, however, affect the treatment's cost-effectiveness.

There are many methods described to assess the efficacy of interventions to treat snoring. Various techniques, such as throat microphones[20] and full sleep studies, have been used to establish an objective assessment of patients' snoring. However, these outcome measurements add another layer of abnormality to the sleep process. These methods are also not without problems; they are expensive, labour intensive and generally only take a single 'snapshot' of the problem. The SSI was specifically developed to include questions about the impact of snoring on patients' lives and those of their partners and families. It also investigates the psychological aspects of these effects, and the impact that the problem has on the lives of those involved.[11]

Effect size[18] was used to allow a comparison of data recorded with different research tools and enabled translation into a meaningful measure of change in health status. The use of the SSI allowed calculation of comparable effect sizes for the two treatments described here. In both arms of the study, the effect size approached 0.8, which represents a large, positive effect on health status as a result of the intervention.

Limitations of the study

The two groups compared in this study were not matched, as they were not the same patients. Also, there was a difference in the nature of the problem, as most of the MAS group were obstructive sleep apnoeic patients who had usually tried continuous positive airway pressure treatment, without benefit (differences were apparent in the baseline ESS scores). This might have had an effect upon how the MAS cohort responded, as it may have been more difficult to achieve good results in this apnoeic group.

Although this was a prospective trial, we acknowledge an inevitable selection bias as treatment was based upon the subjective judgement of the individual clinicians and also upon individual differences amongst patients. There was a selection bias within the coblation treatment group as the uvula was treated if the surgeon considered it to be enlarged.

From a statistical point of view, the results in the coblation subgroups need to be interpreted with care as the numbers were low. Also, interpretation of the pre- and post-intervention results was

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confounded by possible regression to the mean effects; however, this is true in any non-controlled pre- and post-intervention study in which the population is selected as outliers from the general population.

Conclusion

Comparison of surgical and non-surgical methods of treating snoring is possible.

If coblation is to be used, coblation of the palate alone is sufficient and provides the best outcome. Coblation of the uvula produces a worse outcome and morbidity. Amputation of a large uvula provides good results and the worst morbidity. The MAS may be a viable alternative in patients wishing to avoid surgical intervention but tolerance and compliance are unpredictable; however, MAS treatment benefits from relatively favourable financial and morbidity considerations, compared with surgery. Use of the MAS in compliers and coblation appear to be equally effective in the treatment of snoring but both are less effective than LAUP.

- **Coblation of the palate is used for the treatment of snoring at the velopharyngeal level**
- **The best results with coblation are achieved if the uvula is spared**
- **Amputating the uvula in palatal coblation produces the greatest morbidity**
- **Mandibular advancement splints and coblation have similar efficacy**
- **Mandibular advancement splints and coblation are not as efficient as laser-assisted uvulopalatoplasty**

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