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Oral appliances for the management of severe snoring: a randomized controlled trial

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SUMMARY The aim of this randomized controlled trial was to assess the effectiveness of a mandibular advancement appliance (MAA) in managing severe snoring. Twenty-eight adults with severe snoring and normal overnight oximetry were recruited from sleep disorder clinics. A maxillary placebo appliance and a MAA were worn by each subject for a period of 4–6 weeks each. Questionnaires at baseline and after each appliance period assessed bed partners' reports of snoring severity (loudness and number of nights per week), and patients' records of daytime sleepiness. Twenty-five subjects completed the entire trial.

The MAA was significantly more effective than the placebo in reducing the frequency and loudness of snoring, the reported daytime sleepiness and the frequency of morning tiredness. Excessive salivation was the most commonly reported complication. It was concluded that the custom-made MAA was significantly more effective than the placebo in managing the main symptoms of severe snoring. However, not all subjects' partners reported an improvement with the MAA, with 84 per cent reporting a reduction in snoring loudness and 76 per cent reporting snoring on fewer nights per week.

Introduction

Habitual snoring affects approximately 25 per cent of the adult population (Rice and Perskey, 1986). Although mainly a social problem that can cause marital and relationship difficulties, snoring is also reportedly associated with an increased risk of angina pectoris and cerebral infarction (Leung and Robson, 1992) and may be a symptom of obstructive sleep apnoea (OSA). OSA is believed to be part of the same spectrum of disorders as snoring and is characterized by recurrent upper airway collapse causing frequent arousals from sleep. Approximately 4 per cent of middle aged men and 2 per cent of women are affected with the consequences of untreated OSA including excessive daytime sleepiness and increased cardiovascular mortality and morbidity (Young *et al*., 1993).

In snoring and OSA, reduced pharyngeal muscle tone and unfavourable pharyngeal anatomy are thought to predispose to airway collapse during sleep. The pharyngeal collapsibility is greater in OSA patients than in those with simple snoring (Gleadhill *et al*., 1991). Overnight monitoring of blood oxygen saturation, oronasal airflow, and chest movement can be used to distinguish OSA from snoring.

Treatment of snoring and OSA is aimed at reducing or eliminating the collapse of the pharyngeal tissues. Conservative treatment usually involves advice on weight loss, sleep posture, and avoidance of alcohol, but is frequently inadequate for effective management. Uvulopalatopharyngoplasty (UPPP) is a useful surgical option for snoring patients, but is a painful procedure and the criteria for successful patient selection are unclear (Waite, 1998). Nasal continuous positive airway pressure (CPAP) is a highly

effective treatment for OSA, although its use for simple snoring is difficult to justify as it is inconvenient for the patient and the equipment is expensive. CPAP treatment is often required on a life-long basis with patient compliance being a major problem (Ferguson *et al*., 1996).

Dentists have recently begun to play a role in the management of snoring and OSA with the use of mandibular advancement appliances (MAA; Bonham *et al*., 1988; Cote, 1988; Lowe, 1994). These appliances are inexpensive, are usually well accepted by patients, and any side-effects, such as muscle and temporomandibular joint (TMJ) discomfort, are thought to be reversible. Recently, several commercially available anti-snoring appliances have been promoted, most of which are designed to advance the mandible and tongue during sleep and provide more space in the nasopharyngeal airway behind the soft palate. For the management of simple snoring, oral appliances may be the most cost-effective and reversible treatment for patients who have not responded to other conservative measures, although it remains unclear what proportion of patients actually benefit from the appliances. The effectiveness of oral appliances has not been fully assessed by randomized prospective trials (Lowe, 1994), with most previous publications being case reports of favourably responding patients. The current paper reports the results of a prospective clinical trial of a MAA for the treatment of severe snoring, using a placebo appliance as a control.

Materials and methods

Subjects

The subjects were recruited consecutively from dedicated sleep disorder clinics in Belfast City Hospital, Northern Ireland. The patients had been referred by their general medical practitioners because of socially disruptive snoring, and were assessed by an ear, nose, and throat surgeon, an orthodontist, and a respiratory physician. Each patient underwent overnight oximetry, which was carried out at home to screen for the presence of OSA. Patients with an hourly rate of 10 or more desaturations (4 per cent or greater fall in SaO_2) were excluded, thus leaving a sample of non-apnoeic snorers. Also excluded were those with any concurrent serious illness, and those who had been selected to undergo uvulopalatopharyngoplasty (UPPP) based on the presence of tonsillar enlargement or severe palatal or pharyngeal soft tissue redundancy. Thus, a total of 28 subjects (23 male and five females) were included in the study after informed consent was obtained. Ethical approval was obtained from the local Research Ethics Committee.

As the study used a crossover design, each subject completed consecutive trial periods with a MAA and a placebo appliance. They were randomized to decide which appliance they received first.

Appliance design

The MAA was constructed from a bilaminate acrylic material with a soft fitting surface ('Proform Dual Laminate', Dental Resources, Delano, MN, USA). The occlusal record was obtained using softened pink wax and a Projet bite fork (Orthocare, Bradford, UK) with the mandible protruded by 75 per cent of maximum protrusion, with 4-mm inter-incisal vertical clearance (Figure 1). The placebo appliance was a single arch upper anterior biteplane design on a dual laminate base with minimal bite-opening.

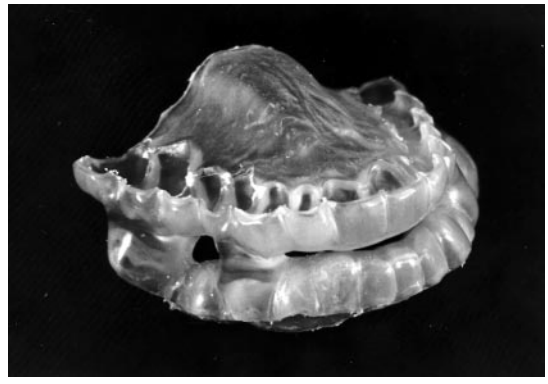

Figure 1 The mandibular advancement appliance used in the study.

Outcome measures and questionnaire design

Each subject was asked to complete three sleep questionnaires: at baseline, and after 4–6 weeks with each appliance. The subjects' bed partners were asked to rate the severity of the snoring using 5-point scales to describe the loudness of snoring and the number of nights per week that the subject snored. In addition, each subject rated how refreshed they felt when waking each morning and also completed a standard Epworth Sleepiness Score (ESS) questionnaire. Therefore, four main outcome measures were evaluated (Appendix 1).

Additional questions also investigated the typical pattern of appliance wear (number of nights per week and hours per night) and incidence of complications (occlusal and TMJ discomfort, dryness of the mouth, and excessive salivation).

Statistical analysis

The four outcome measurements in the crossover data were analysed according to Altman (1991). The between treatment differences were calculated as the differences between the MAA and placebo scores (for each subject and each outcome measure). These differences were compared between the advancement-first group and the placebo-first group using independent samples *t*-tests to assess any period effect. The means of the MAA and placebo scores (for each subject and each outcome measure) were also compared between the advancement-first group and the placebo-first group using independent samples *t*-tests to assess treatment period interactions.

To determine the clinical effectiveness of the MAA compared with the placebo, the MAA and placebo scores for each outcome measure were compared using paired samples *t*-tests.

Results

Of the 28 subjects who agreed to participate in the study, two were unable to tolerate their appliances and withdrew from the study, while another subject failed to return one of their questionnaires. These three subjects were therefore excluded from further analysis. Thus a total of 25 subjects (21 males and four females) with a mean age 48.2 years (range 30.0–68.5 years) completed the trial period with both appliances. Randomization resulted in 12 subjects receiving the placebo first with the remaining 13 receiving the MAA. Comparison of the baseline questionnaire data between these two groups revealed no statistically significant differences (Table 1). One subject failed to complete the ESS score in full for the baseline questionnaire, and another the ESS score and daytime sleepiness response for the appliance questionnaires. These subjects were therefore excluded from analysis of these outcome variables.

Crossover analysis

Statistical analysis showed that there was no evidence of either a period or a carry-over effect for any of the outcome measures. This confirmed that the use of a washout period without any appliance was unnecessary, and also allowed pooling of all the MAA scores and all placebo scores for each outcome measure.

The pooled scores for the MAA were significantly lower than the pooled scores for

Table 1 Baseline patient characteristics and *t*-tests.

	Group A (Placebo first) *n* (12) ± SD	Group B (MAA first) *n* (13) ± SD	*t*-test
Age (years)	45.97 ± 12.04	50.24 ± 11.96	NS
Frequency of Snoring	3.75 ± 0.45	3.69 ± 0.63	NS
Snoring Loudness	3.08 ± 0.79	3.23 ± 0.59	NS
Frequency of awaking unrefreshed	2.50 ± 1.17	2.23 ± 1.74	NS
Epworth Sleepiness Score	7.73 ± 4.61 ($n = 11$)	11.31 ± 4.46	NS

NS, non significant ($P > 0.05$).

the placebo appliances for all four outcome measures (Table 2).

Comparison with baseline data

To further investigate the clinical effects of each appliance, the placebo and MAA scores were compared with baseline scores for each subject to evaluate whether each appliance had provided an improvement in reported snoring loudness and frequency. A 1-point change in the rating scale was classified as 'Some Improvement', and a change of 2 or more points was classified as 'Greatly Improved'. These results are shown in Tables 3 and 4.

Compliance and complications associated with appliance wear

These findings are reported for the MAA only. Eighty-eight per cent of subjects wore their appliances for three or more nights per week, while the remainder wore them less often. Forty-four per cent wore their appliances for six hours or more per night, and 80 per cent reported that the appliances remained in their mouth all night or else came out infrequently (less than once per week).

The most commonly reported complication was excessive salivation when wearing the appliance (64 per cent). Fifty-two per cent of subjects reported temporary occlusal changes in the morning although only 12 per cent stated that this persisted during the day.

Discussion

Decisions about healthcare interventions should ideally be guided by evidence from randomized controlled trials (Cochrane, 1972; Richards and Lawrence, 1995). While oral appliance therapy is becoming a popular treatment for snoring and OSA, there are few well-controlled scientific studies to support their use. A search of the published literature has revealed no prospective controlled trials of the effectiveness of these appliances in managing non-apnoeic snoring.

Table 2 Pooled scores and paired *t*-tests for placebo and MAA.

	Placebo Mean ± SD	MAA Mean ± SD	Difference Mean ± SE	*t*-test
Frequency of snoring ($n = 25$)	3.36 ± 1.07	1.84 ± 1.40	1.52 ± 0.30	$P < 0.05$
Snoring loudness ($n = 25$)	2.76 ± 0.97	1.24 ± 0.97	1.52 ± 0.25	$P < 0.05$
Frequency of awaking unrefreshed ($n = 24$)	2.08 ± 1.28	1.50 ± 0.93	0.58 ± 0.25	$P < 0.01$
Epworth Sleepiness Score ($n = 24$)	7.50 ± 4.38	6.45 ± 4.44	1.04 ± 0.43	$P < 0.01$

Table 3 Reported changes in snoring loudness compared with baseline in 25 subjects.

	Worse	Unchanged	Some improvement	Greatly improved
MAA ($n = 25$)	0	4	3	18
Placebo ($n = 25$)	4	10	8	3

Table 4 Reported changes in snoring frequency (nights per week) compared with baseline in 25 subjects.

	Worse	Unchanged	Some improvement	Greatly improved
MAA ($n = 25$)	0	6	4	15
Placebo ($n = 25$)	1	18	4	2

A sleep-symptom questionnaire was used in the current clinical trial to obtain bed partner reporting of the typical severity of snoring symptoms over the entire duration of the trial period with each appliance. Questionnaire outcome measures have been widely used in previous studies of snoring severity and prevalence (Hillerdal *et al*., 1991; Stradling and Crosby, 1991; Davies *et al*., 1992; Ali *et al*., 1994; Kump *et al*., 1994) investigating treatment outcome with MAAs (Bonham *et al*., 1988; Ichioka *et al*., 1991; Schmidt-Nowara *et al*., 1995; Clark *et al*., 1993; O'Sullivan *et al*., 1995; Bernhold and Bondemark, 1998; Cameron *et al*., 1998) and for uvulopalatopharyngoplasty (Vukovic and Huthings, 1996; Lim and Curry, 1999; Tytherleigh *et al*., 1999). The use of questionnaire outcome measures is nevertheless recognized to be subjective, and more objective assessment techniques are available. Measurement of snoring using sound activated tape recorders has been described in the literature (Stradling, 1993), although this method has the limitation of only providing an estimation of the total length of time spent snoring on the individual night of the recording. Furthermore, many subjects do not snore every night and it is also recognized that the duration, timing, and loudness of snoring may vary from night to night in individual snorers. As a consequence, single-night tape recording techniques may poorly assess the true severity of snoring. Several commercially available OSA monitoring systems include the facility to record snoring severity, although these are often limited by having a fixed loudness threshold below which snoring sounds are not registered.

The questionnaire in the current study was based on a questionnaire that has been shown to be valid in characterizing snoring symptoms (Kump *et al*., 1994). As subjects and their bed partners were asked to assess the symptoms over a period of at least 4 weeks it is believed that this provided an accurate estimation of the typical severity of snoring in terms of loudness and number of nights per week. Nevertheless, when planning the study it was recognized that the subjective nature of the outcome measures would result in some variation between bed partners in scoring the severity of snoring. To help overcome these problems, the study utilized a randomized crossover design in which each subject and bed partner acted as their own controls during statistical analysis. This approach minimized the influence of between-subject variation in questionnaire responses.

The observed clinical response to the MAA in the current trial is similar to previously published case reports. Schmidt-Nowara *et al*. (1995) reviewed nine papers investigating the treatment of snoring with oral appliances and reported that the various appliances used could be effective in reducing or eliminating snoring in many patients. Bed partner reporting of snoring was the most commonly used outcome measure, although no studies used controls. Bernhold and Bondemark (1998) reported that 22 of 25 snorers reported an improvement when wearing a magnetic MAA, while a recent study by Cameron *et al*. (1998) reported that 12 out of 16 patients had a reduction in the level of partner-reported snoring. In the current clinical trial the MAA produced a range of responses between subjects, which may be due to anatomical and gender differences, and variations in the absolute amount of mandibular protrusion and vertical opening with the MAA. The current study was designed to evaluate the appliance design that is currently being used routinely by the authors. This appliance is constructed with a standardized 4-mm interincisal opening and 75 per cent of maximum advancement. Nevertheless, it is recognized that the absolute amount of advancement and the depth of the overbite may have influenced treatment response. Further cephalometric investigation might have shown whether these factors were significant.

The current results included data from four females and 21 males. The prevalence of OSA and snoring is known to differ between males and females (Leung and Robson, 1992; Douglas, 1995). However, although the small number of females in the current study precluded any meaningful comparisons between males and females, there is no published evidence to indicate that MAA treatment response is influenced by patient gender.

While the current results indicate that the reported loudness and frequency of snoring

were significantly lower with the MAA than with the single jaw placebo appliance, it was surprising to also identify significant differences in reported daytime sleepiness between the two appliances. It is important to note that all subjects had baseline overnight oximetry results that were within the normal range, thus excluding a clinical diagnosis of sleep apnoea. Elevated levels of overnight desaturation are associated with the presence of OSA and excessive daytime sleepiness. The normal upper limit of ESS scores is 10 (Johns, 1993), but in the present study 10 subjects had baseline ESS scores of more than 10 indicating that these subjects apparently had increased baseline levels of daytime sleepiness. The lower ESS scores reported with the MAA may reflect that these subjects experienced less disturbed sleep with this appliance although, as these subjects had normal baseline oximetry, the clinical significance of these findings should be interpreted with caution.

The placebo used in the present investigation was similar to that previously employed in a parallel group controlled trial of the effectiveness of oral appliances in managing OSA (Hans *et al*., 1997). In that study, the placebo was shown to be ineffective in managing sleep apnoea. However, in the current study, the placebo was unexpectedly found to reduce snoring loudness from baseline levels in 11 subjects, and to reduce frequency of snoring in six subjects. Statistical analysis failed to identify the presence of any carry-over effect in those subjects who received the MAA first and this can therefore be excluded as an explanation of the apparent effectiveness of the placebo in some subjects. Ferguson *et al*. (1996) also failed to identify any carry-over effects with MAAs in a crossover trial of MAA and CPAP therapy in OSA patients. There are several other possible explanations for the observed benefits of the placebo in some subjects: first, that they are simply due to a placebo effect or, secondly, that the placebo may have produced a change in oropharyngeal muscle tone. While the exact mode of action of MAA is still unclear, they are thought to exert their effects by increasing the anteroposterior dimensions of the pharynx and also by improving oropharyngeal muscle tone, which reduces airway collapsibility. Hence, although the placebo would not have produced any change in the anteroposterior dimensions of the pharynx, an increase in muscle tone may have occurred.

Although the current results from this short-term study indicate that the custom-made MAA was effective in the management of snoring, the long-term effectiveness of these types of appliances is unclear. The possible effects on the occlusion and TMJ are also unknown, although full occlusal coverage is thought to be important in order to reduce the risk of vertical occlusal changes. Investigation of the long-term effectiveness of the appliances in the trial is ongoing.

Due to the possibility of underlying pathology or OSA in patients who present with snoring, it is important that oral appliance treatment is carried out in conjunction with the patient's physician (Lowe, 1994). In clinical practice it is essential that those patients with OSA are identified by appropriate overnight monitoring so as to allow consideration of other treatment regimens (Schmidt-Nowara *et al*., 1995).

Conclusions

The customised MAA was significantly more effective than a placebo appliance in reducing the severity of non-apnoeic snoring in this short-term study. Nevertheless, not all subjects reported an improvement in symptoms and there was a range of observed responses. Further investigation is required to clarify the factors important in patient selection and long-term effectiveness.

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Appendix 1: details of questionnaire

Questions

1. How often does your partner snore?
0 Never
1 Less frequently than once a week
2 1 or 2 nights a week
3 3–5 nights a week
4 Every or almost every night

2. How loud is your partner's snoring usually?
0 Doesn't snore or seldom snores
1 Soft
2 Moderate (sometimes keeps you awake)
3 Loud (often/usually keeps you awake)
4 Very loud and disturbing (disturbs someone sleeping in another room)

3. Do you feel tired or unrefreshed on waking in the morning?
0 Never
1 Less frequently than once a week
2 1 or 2 mornings a week
3 3–5 mornings a week
4 Every or almost every morning

Epworth Sleepiness Scale

Subjects are asked how likely they would be to fall asleep in the following situations:
(a) Sitting and reading.
(b) Watching TV.
(c) Sitting inactive in a public place (for example in a theatre or a meeting).
(d) As a passenger sitting in a car for an hour without a break.
(e) Lying down to rest in the afternoon when circumstances permit.
(f) Sitting and talking to someone.
(g) Sitting quietly after lunch, without having consumed any alcohol.
(h) As the driver of a car, stopped for a few minutes in traffic.

For each situation, scoring is as follows:
0 No chance
1 Slight chance
2 Moderate chance
3 High chance

ESS score is the cumulative score (maximum 24 points).