Mandibular advancement devices for the control of snoring

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ABSTRACT: Patients presenting with the complaint of antisocial snoring have very few options available to them of proven efficiency. Mandibular advancement devices worn intra-orally at night, have recently been shown in controlled trials to help mild to moderate obstructive sleep apnoea. However, there are no properly controlled studies with objective measurements on the use of such appliances for the management of antisocial snoring.

Fifteen patients, already established on mandibular advancement devices for the control of snoring, were asked to participate in this study. They were studied over two nights, using a portable sleep monitoring device at home, both with and without their mandibular advancement devices in place (in randomized order). Snoring was measured using a surface throat microphone. In addition oxygen saturation and indirect beat to beat blood pressure were measured. The latter (using pulse transit time) provided an index of autonomic "arousals" and a measure of inspiratory effort.

In nearly all of these highly selected patients the mandibular advancement devices reduced significantly the amount of snoring from a median of 193 to 20 snores·h⁻¹ ($p < 0.0001$). In addition there was a reduction in respiratory effort, implying enlargement of the upper airway whilst wearing the appliance.

These patients only represent those who were able to tolerate the appliance. With such clear evidence of their potential efficacy, and no suggestion from other studies of any harm, it would seem reasonable to introduce this approach into the management of antisocial snoring.

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There has been considerable recent interest in the use of mandibular advancement devices, which are worn intra-orally at night to advance the lower jaw, and used to control snoring and sleep apnoea [1]. The assumed mechanism of action is to enlarge the upper airway, mainly behind the tongue, and thus reduce the degree of obstruction and tendency to collapse or vibrate. Most trials of these devices have either not been controlled or have not allowed for regression to the mean following the diagnostic study performed to identify trial entrants [2–8]. A notable exception were the trials from Vancouver [9, 10] which showed clear benefits on mild to moderate sleep apnoea, using both fixed and adjustable mandibular advancement devices; the latter version being adjustable to increase the degree of mandibular advancement as required. No objective measurements of snoring were reported. This latter device, however, is quite complex, expensive and not freely available outside North America.

There are far more patients seeking help for their snoring than there are with sleep apnoea, and there is much need for a simple and inexpensive device with proven efficacy for the control of snoring. Most of the above studies have looked at the occurrence of apnoeas and have not objectively measured the effect on snoring. Recent studies on the control of snoring by surgical techniques have suggested that the subjective reporting of improvement in snoring following interventions is unreliable and not con-

firmed by objective recordings [11]. In addition the reporting of snoring is unreliable in epidemiological studies [12]. A study by O'SULLIVAN *et al.* [7] only studied the acute effects of a mandibular advancement device inserted during a one night study, but an objective reduction in snoring level was shown.

There are many "gadgets" and devices sold to alleviate snoring, most of which are not backed by satisfactory evidence at all. Therefore the purpose of this straightforward study was to establish whether a simple and inexpensive mandibular advancement device could be shown objectively to control snoring in the home setting. Such a device could alleviate much misery.

Methods

Patients

The patients in this study are a highly selected group. They were recruited retrospectively from about 100 patients referred for the provision of a mandibular advancement device. The criteria for inclusion in this study were: a) proven snoring on hospital sleep study or home tape recording; b) insufficient sleep apnoea and/or sleepiness for the patient and physician to feel that a trial of nasal

continuous positive airway pressure (nCPAP) was appropriate; c) living close enough to the Oxford Sleep Unit to make domiciliary visits feasible; and d) a claim by the patient and spouse that the device had worked ($>50\%$ improvement in snoring) and that they wore it on a regular basis (>4 nights·week⁻¹) to control their snoring. Thus, this group of patients are those whose partners say the device works, and this study was designed to verify this. The proportion of patients referred for a mandibular advancement device who eventually say they use it on a long-term basis will be the subject of another paper.

Techniques

Sleep monitoring. Home monitoring was performed using the RM50 (Parametric Records, London, UK). This device measures overnight arterial oxygen saturation (SaO_2) (finger oximeter), snoring (from a throat microphone), posture, cardiac frequency (f_c), chest movements (by impedance), and beat to beat blood pressure (BP) by an indirect method (pulse transit time (PTT) [13]). Measurement of oronasal airflow is also possible, but in our experience it is this sensor that causes the most subjective sleep disturbance and we chose not to use it.

The snoring microphone is air-coupled to the skin with a small air leak to attenuate very low frequency noise from body movements, similar to the approach used in the Madaus Electronics Sleep Apnoea Monitor (MESAM) system (Madaus Electronics, Freiburg, Germany) [14]. The 1.5 cm disc bearing the microphone was stuck to the neck, using double-sided adhesive rings, level with the thyroid cartilage prominence but 2 cm laterally. The frequency response of this system was 50–1,000 Hz (-3 dB). The sensitivity of the device was set with a special calibration rig designed for this purpose. The threshold (12 units) we took for defining a snore is necessarily arbitrary, but the level chosen was established by experimentation to be approximately equivalent to a sound level meter registering 55 dB ("A" weighting) 1 m in front of the face during snoring.

PTT reflects beat to beat BP through changes in the pulse wave velocity. This velocity depends on arterial wall tension which in turn depends on arterial BP [13]. The higher the BP, the tenser the arterial wall, and the faster the pulse shock wave travels from the aortic valve (in practice the electrocardiogram (ECG) R wave is used) to a peripheral site. PTT to the finger is about 250 ms in an average sized person, and a rise in BP of 1 mmHg shortens it by approximately 1 ms. The ability to register changes in BP on a beat to beat basis allows one to measure the swings in BP due to inspiratory effort [15], and the rises due to transient arousal [16]. It has been shown that respiratory swings in PTT quantitatively reflect swings in oesophageal pressure [17, 18], and that falls in PTT over a slower time course of 20 s or so reflect the rise in BP following arousing stimuli, even when there are no discernible changes on the electroencephalogram (EEG) (so called sub-cortical "arousals") [19].

Mandibular advancement device. The mandibular advancement device we use essentially consists of two customized sports-type mouth guards (one for the top teeth and one for the bottom teeth) fused together in such a way that

when the appliance is bitten into, the mandible is held passively in a protruded position. Construction of the appliance requires upper and lower dental impressions from which plaster models are cast. A wax interocclusal record is taken with the patient posturing the lower jaw forward to about 75% of the maximum possible. Thermoplastic polyvinyl acetate/polyethylene blanks are moulded onto the models and trimmed. The models are then placed on a dental articulator in the previously recorded protrusive relationship and the upper and lower parts of the device are heat-sealed together in this position. Finally, this bond is reinforced by heat moulding a thin layer of the thermoplastic material over the inner and outer surfaces. Both the clinical and laboratory stages of construction are straightforward using inexpensive materials and widely available techniques. The current cost in the UK is under £200 (US\$320). Experience has shown that these appliances usually last for at least 6 months before requiring replacement.

Protocol

Patients were approached at least 4 months after provision of the mandibular advancement devices. Following contact by phone, and agreement to participate in the study, patients were shown how to use the RM50 recorder. Some were instructed in out-patients and took the recorder home, and some were visited at home, depending on patient preference. Because all the patients were settled into a routine of using their oral appliances, it was necessary to ask them not to use them for the two nights prior to the control recording. There is some evidence of a short "carry over" effect when successful treatment of sleep apnoea is withdrawn [20]. Thus patients were randomized either to recording a night with the mandibular advancement device in (following at least two previous nights with the device also in), and then with the device out (following at least two previous nights with the device also out), or vice versa. The RM50 recorders were set to run from 23:00–07:00 h.

Analysis

Each study was reviewed manually to identify the approximate main period of sleep estimated from the major periods of body movements that were easily seen on the chest impedance channel, prior to sleep and on waking in the morning. Time synchronous periods during assumed sleep from the patient's two studies were used to ensure that there was no confounding from time-of-night effects. The RM50 provides a range of indices, but for this study we used: the number of $>4\%$ SaO_2 dips·h⁻¹ of study; number of snores·h⁻¹; time spent snoring (time above the threshold); mean sound level across the whole night; number of arousals·h⁻¹ (from the indirect BP tracing [19]); and average respiratory effort across the whole study period (again from the indirect BP tracing [18]). Time spent supine was compared to ensure that wearing the mandibular advancement device did not alter this, and thus influence the degree of snoring indirectly. Differences between the nights with and without the mandibular advancement device were compared by the paired Wilcoxon rank-sum test.

Fig. 1. – The effect of using the mandibular advancement device on: a) the number of snores·h⁻¹ (log scale); b) mean sound level averaged across the whole night (log scale in arbitrary units, where above 12 is the level which defines an individual snore); c) duration of snoring across the whole night (time spent above the threshold, log scale in seconds); d) number of arousals·h⁻¹ (inferred from blood pressure (BP) rises measured by pulse transit time (PTT)); e) respiratory effort (using respiratory swings in BP measured from changes in PTT in milliseconds); and f) number of >4% arterial oxygen saturation (SaO₂) dips (log scale in dips·h⁻¹). Log scales are used where the data were not normally distributed. Out: control; In: wearing the appliance; AU: arbitrary units. *, †, +: p<0.05, p<0.002, p<0.0002.

Results

Fifteen patients (two females, 12 males; mean age 50.3 (range 32–65) yrs; body mass index (BMI) 27.0 (22–33) kg·m⁻²; neck circumference 41.7 (34.3–45.7) cm completed the study. In one the PTT data were not available due to electrode displacement. In seven patients the control night was first, and in eight patients the night using the mandibular advancement device was first.

There was a clear and consistent effect on snoring, measured either as snores·h⁻¹ (median 193 *versus* 20 snores·h⁻¹, p<0.0001), time spent snoring (818 *versus* 50 s, p<0.0002) or mean sound level across the night (1.5 *versus* 0.2 arbitrary units, p<0.0001, where above 12 is the level which defines an individual snore) control and appliance nights respectively (figure 1). (If a patient snored on every breath all night then, at a respiratory frequency *f*_R of 15·min⁻¹, the snores·h⁻¹ index would be 900). There was no significant difference in the time spent supine, 43 *versus* 49%, control and appliance nights respectively.

The improvements in the other measures with the appliance were all significant: >4% SaO₂ dips·h⁻¹ (5.3 *versus* 3.8, p<0.03); arousals·h⁻¹ (19.0 *versus* 15.0, p<0.05); and respiratory effort (13.5 *versus* 9.7 ms, p<0.002) control and appliance nights respectively. If Bonferroni's correc-

tion for multiple comparisons is used, then the changes in arousals and >4% SaO₂ dips·h⁻¹ are no longer significant.

For comparison, the values for >4% SaO₂ dips·h⁻¹, arousals·h⁻¹ and respiratory effort using the RM50 device in 344 randomly selected adults (35–65 yrs) are median (95% range) 0.4 (0.1–7.9) dips·h⁻¹; 17.0 (5–43) arousals·h⁻¹; 9.6 (6.2–15.6) ms, respectively (unpublished data).

Discussion

This study has shown clearly that these simple dental appliances do greatly reduce objectively measured snoring in this highly selected group of patients. Because they were restudied after a period with the device, and acted as their own controls, we are confident that this is a real effect. Although in surgical series the subjective improvement in snoring is hard to verify objectively [11, 21], this has not proved to be the case with these devices. It must be acknowledged that this group of patients was largely self-selected by their continued use of the device, compared to those who had abandoned such a device and were not therefore eligible for the trial. These trial patients had worked through the almost universal initial side-effects of excessive salivation, teeth and jaw discomfort, which do

prevent a significant number of patients accepting these devices long-term.

The mechanism of action of mandibular advancement devices is not clear, but is usually assumed to be enlargement of the retroglossal space by anterior displacement of the tongue whose major muscle, genioglossus, is of course attached to the lingual surface of the anterior mandibular arch. In studies done so far there has not been agreement as to which are the important anatomical changes produced by mandibular advancement devices, or the specific features of a patient's anatomy that might predict a good response [2, 4, 22]. An alternative explanation for their effect might be that by pulling the mandible forward the lateral walls of the pharynx could be made taut and thus be less likely to vibrate or collapse, without necessarily increasing the retroglossal space or lowering upper airway resistance. In the present study there was no suggestion that mandibular advancement devices might work indirectly through altering sleeping posture, if anything the amount of time spent supine was higher during their use.

Our data, showing that respiratory effort is significantly less on the night using the device, suggests that there is at least some reduction in upper airway resistance as part of the effect of these devices. As one might predict from this reduced respiratory effort [23], there was also a small drop in the number of arousals measured by blood pressure rises, although most of the patients were within the range that we have found within a randomly selected population for arousals measured in this way.

On the basis of this evidence it would seem reasonable to introduce correctly-made mandibular advancement devices into the range of approaches used to help patients with antisocial snoring. At present it is not possible to predict who will respond to (or be able to tolerate) such devices, but they clearly work in some individuals. A recent literature review concluded that they did not seem to cause any significant harm to teeth or temporomandibular joints, although reversible side-effects often prevented early acceptance [1].

References

- Schmidt Nowara W, Lowe A, Wiegand L, Cartwright R, Perez Guerra F, Menn S. Oral appliances for the treatment of snoring and obstructive sleep apnea: a review. *Sleep* 1995; 18: 501–510.
- Bonham PE, Currier GF, Orr WC, Othman J, Nanda RS. The effect of a modified functional appliance on obstructive sleep apnea. *Am J Orthod Dentofacial Orthop* 1988; 94: 384–392.
- Clark GT, Arand D, Chung E, Tong D. Effect of anterior mandibular positioning on obstructive sleep apnea. *Am Rev Respir Dis* 1993; 147: 624–629.
- Eveloff SE, Rosenberg CL, Carlisle CC, Millman RP. Efficacy of a Herbst mandibular advancement device in obstructive sleep apnea. *Am J Respir Crit Care Med* 1994; 149: 905–909.
- Ichioka M, Tojo N, Yoshizawa M, et al. A dental device for the treatment of obstructive sleep apnea: a preliminary study. *Otolaryngol Head Neck Surg* 1991; 104: 555–558.
- Nakazawa Y, Sakamoto T, Yasutake R, et al. Treatment of sleep apnea with prosthetic mandibular advancement (PMA). *Sleep* 1992; 15: 499–504.
- O'Sullivan RA, Hillman DR, Mateljan R, Pantin C, Finucane KE. Mandibular advancement splint: an appliance to treat snoring and obstructive sleep apnea. *Am J Respir Crit Care Med* 1995; 151: 194–198.
- Schmidt Nowara WVV, Meade TE, Hays MB. Treatment of snoring and obstructive sleep apnea with a dental orthosis. *Chest* 1991; 99: 1378–1385.
- Ferguson KA, Ono T, Lowe AA, Keenan SP, Fleetham JA. A randomized crossover study of an oral appliance vs nasal-continuous positive airway pressure in the treatment of mild-moderate obstructive sleep apnea [see comments]. *Chest* 1996; 109: 1269–1275.
- Ferguson KA, Ono T, Lowe AA, Al-Majed S, Love LL, Fleetham JA. A short term controlled trial of an adjustable oral appliance for the treatment of mild to moderate obstructive sleep apnoea. *Thorax* 1997; 52: 362–368.
- Miljeteig H, Mateika S, Haight JS, Cole P, Hoffstein V. Subjective and objective assessment of uvulopalatopharyngoplasty for treatment of snoring and obstructive sleep apnea. *Am J Respir Crit Care Med* 1994; 150: 1286–1290.
- Bearpark H, Elliott L, Grunstein R, et al. Snoring and sleep apnea. A population study in Australian men. *Am J Respir Crit Care Med* 1995; 151: 1459–1465.
- Pollak MH, Obrist PA. Aortic-radial pulse transit time and ECG Q-wave to radial pulse wave interval as indices of beat-by-beat blood pressure change. *Psychophysiology* 1983; 20: 21–28.
- Penzel T, Amend G, Meinzer K, Peter JH, von Wichert P. MESAM: a heart rate and snoring recorder for detection of obstructive sleep apnea. *Sleep* 1990; 13: 175–182.
- Lea S, Ali NJ, Goldman M, Loh L, Fleetham J, Stradling JR. Systolic blood pressure swings reflect inspiratory effort during simulated obstructive sleep apnoea. In: Horne J, ed. *Sleep 90*. Bochum, Pontenagel Press, 1990; 178–181.
- Davies RJO, Belt PJ, Robert SJ, Ali NJ, Stradling JR. Arterial blood pressure responses to graded transient arousal from sleep in normal humans. *J Appl Physiol* 1993; 74: 1123–1130.
- Brock J, Pitson D, Stradling JR. Use of pulse transit time as a measure of changes in inspiratory effort. *J Amb Mon* 1993; 6: 295–302.
- Pitson D, Sandell A, van de Hoot R, Stradling JR. Pulse transit time as a measure of respiratory effort in patients with obstructive sleep apnoea. *Eur Respir J* 1995; 8: 1669–1674.
- Pitson D, Chhina N, Knijn S, van Herwaarden M, Stradling J. Changes in pulse transit time and pulse rate as markers of arousal from sleep in normal subjects. *Clin Sci Colch* 1994; 87: 269–273.
- Kribbs NB, Pack AI, Kline LR, et al. Effects of one night without nasal CPAP treatment on sleep and sleepiness in patients with obstructive sleep apnea. *Am Rev Respir Dis* 1993; 147: 1162–1168.
- Smithson AJ, White JE, Griffiths CJ, et al. Comparison of methods for assessing snoring. *Clin Otolaryngol* 1995; 20: 443–447.
- Johnson LM, Arnett GW, Tamborello JA, Binder A. Airway changes in relationship to mandibular posturing. *Otolaryngol Head Neck Surg* 1992; 106: 143–148.
- Gleeson K, Zwillich CW, White DP. The influence of increasing ventilatory effort on arousal from sleep. *Am Rev Respir Dis* 1990; 142: 295–300.