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Anterior mandibular positioning device for treatment of snoring and obstructive sleep apnoea*

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SUMMARY

The aim of this study was to determine the severity of side effects and the influence on snoring and the AHI (apnoea-hypopnoea index = number of apnoeas and hypopnoeas per hour recording) of an anterior mandibular positioning device (AMP device) for treatment of snoring and obstructive sleep apnoea.

Questionnaires were mailed to a consecutive series of 30 patients who had started treatment with an AMP device. The mean follow-up interval from receiving an AMP device to answering the questionnaire was 22 months.

The perceived degree of sore teeth increased statistically significantly ($p<0.01$) as a result of the AMP device treatment, but there was no increase in the degree of facial pain, salivation, or temporomandibular joint pain.

The AMP device treatment resulted in a statistically significant reduction ($p<0.01$) of the mean AHI and of the mean percentage of the recording time with loud snoring ($p< 0.05$).

Twenty-two patients out of 30 were still using the device at the time of follow-up.

In conclusion, AMP device treatment was associated with only mild side effects and resulted in a statistically significant reduction of the AHI and of the percentage of the recording time with loud snoring.

Key words: obstructive sleep apnoea, snoring, sleep disorders, dental appliances, mandibular advancement.

INTRODUCTION

There is an increasing interest in the use of oral devices for treatment of obstructive sleep apnoea (OSA) and snoring. Presently, 38 oral devices are cleared by the US Food and Drug Administration for treatment of snoring and 14 are cleared for treatment of OSA (Ivanhoe and Attanasio, 2001). The devices are either a) anterior mandibular positioning devices (AMP device) that act by advancing the mandible or b) tongue retaining devices that retain the tongue in an anterior position.

Two basic theories explain how oral appliances work. One is that the device increases the upper airway calibre, thus collapse from the negative pressures produced during inspiration is avoided. This theory has been supported by MRI studies (Cobo et al., 1995). Another theory is that oral devices cause stretch-induced activation of the pharyngeal muscles. This activation provides sufficient stiffness to the upper airway to prevent collapse. This theory is supported by the observation that electromyographic activity in the tongue increases with the use of an oral device (Ono et al., 1996). Oral device treatment is reversible and cost-effective, but there are limited data concerning the efficacy, side effects and compliance of this treatment.

OSA is widely treated by continuous positive airway pressure (CPAP) through a nasal mask, but alternative treatments are required for those patients who cannot tolerate CPAP or who are not interested in using such a device. Various studies have demonstrated that up to half of the patients supplied with CPAP are not using the device regularly (Nino Murcia et al., 1989; Kribbs et al., 1993; Engleman et al., 1994; Chervin et al., 1997; Wright et al., 1997).

OSA has also been treated surgically. However, failures and complications have limited the indications for surgery in OSA. In a recent Cochrane review, Bridgman and Dunn failed to find any randomised or quasi-randomised trials comparing surgical intervention for OSA with other surgical or non-surgical interventions or no intervention. The authors concluded that

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there is an urgent need for high quality randomised controlled trials to be carried out in the field of surgery for OSA (Bridgman and Dunn, 2000).

The primary aim of this study was to describe the efficacy of an AMP device for treatment of snoring and OSA and to evaluate the satisfaction of the patients and their spouses. Also the side effects of the AMP device treatment and the compliance were studied.

MATERIALS AND METHODS

Subjects

All 58 patients who had been referred for AMP device therapy to the Faculty of Dental Sciences, University of Aarhus, Denmark, between 1-1-1992 and 31-12-2001, were recruited for this study. The patients were all referred from the Sleep Disorders Clinic at the Department of Otorhinolaryngology, University Hospital, Aarhus, Denmark.

Patients were referred to AMP device therapy when they complained about severe snoring but did not fulfil our criteria for OSA (AHI of 10 or more and Epworth score of 12 or more). OSA patients were treated by CPAP. Two OSA patients who had tried CPAP for OSA, but did not tolerate CPAP due to claustrophobia were, however, referred for AMP device treatment. Three OSA patients who preferred AMP device therapy to CPAP were also referred for AMP device treatment.

The patients were informed about the study objectives and gave written informed consent to participate. The study was performed in accordance with the Declaration of Helsinki and was approved by the local Ethics Committee.

AMP device

The patients were fitted with a removable, custom made, Herbst appliance (Figure 1). The AMP device consisted of 2 separate appliances that snapped onto the dental arches. These separate appliances were connected with a rod and tube device (called a Herbst attachment), which allowed for opening, and protrusive and some side-to-side movements but no retrusive movements. The Herbst appliance moved the mandible forward in a specific distance relative to the maxilla. The degree of mandibular advancement was determined individually for each patient. It was based on a voluntary mandibular protrusive manoeuvre by the patient during the evaluation. The patients had to pay approximately 500 Euro for the AMP device.

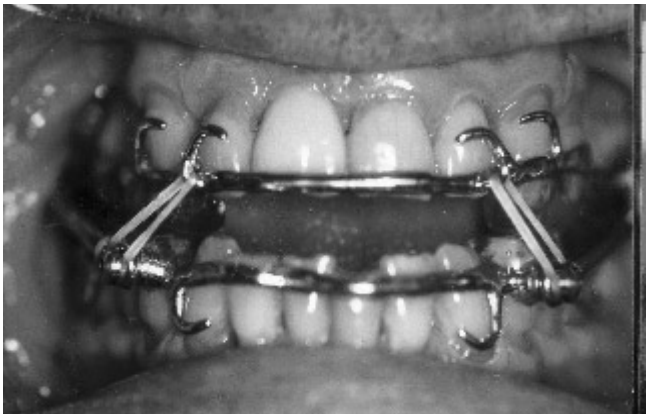

Figure 1. The Herbst anterior mandibular positioning device used in this study to move the mandible forward during sleep.

Diagnostic sleep studies

Each patient had a diagnostic overnight sleep study prior to treatment. These baseline studies were either performed at the patients home (43 patients) using AutoSet, ResMed (AutoSet, version 3.03, ResMed Ltd., North Ryde, Australia) or in hospital using a screening device based on oximetry and snoring sound (15 patients). The AutoSet device relied on nasal pressure fluctuations in the anterior nares measured by nasal prongs and included pulse oximetry and thoracoabdominal movements.

The AutoSet has been validated by comparisons with full polysomnography (Fleury et al., 1996; Mayer et al., 1998; Rees et al., 1998). The AutoSet studies and the studies using the screening device were automatically scored for apnoeas and hypopnoeas by the software. The scoring criteria of the AutoSet device were based on ventilation drops. An apnoea was classified if the ventilation dropped below 25% of the recent average for at last 10 consecutive seconds. A hypopnoea was classified if the ventilation dropped below 50% of the recent average for 10 consecutive seconds. The AutoSet device detected snoring from the nasal pressure fluctuations. The AutoSet software displayed the snoring signal in arbitrary units. Loud snoring was classified as a snoring signal above 2.5 arbitrary units.

The screening device detected desaturations of 4% or more and calculated the DI (desaturation index = number of desaturations per hour recording). The duration of snoring (sound level of 55 dB or more) and the duration of loud snoring (sound level of 65 dB or more) were also determined.

The diagnostic devices used in this study did not record neurophysiologic data (electroencephalography, electrooculography and electromyography) necessary to characterise sleep stages.

Questionnaires and physical examination

The patients first underwent a physical examination including an examination of the nose and the upper airway using a fiberoptic endoscope. A questionnaire including questions about nasal symptoms, prior treatment, daytime symptoms, sleep symptoms, and daytime sleepiness (the Epworth Sleepiness Scale) was administered before referral to AMP device treatment. Patients who were referred for AMP device treatment but rejected treatment after receiving detailed information by the dentist were interviewed regarding the reason for rejection.

All patients who began AMP device therapy and their spouses received a questionnaire. Visual analogue scales (VAS) were presented in the questionnaire in order to evaluate effects and side effects. The patients and their spouses were also asked to which extent they would recommend an AMP device to a snoring friend and they were asked to state their degree of satisfaction with the AMP device on a VAS.

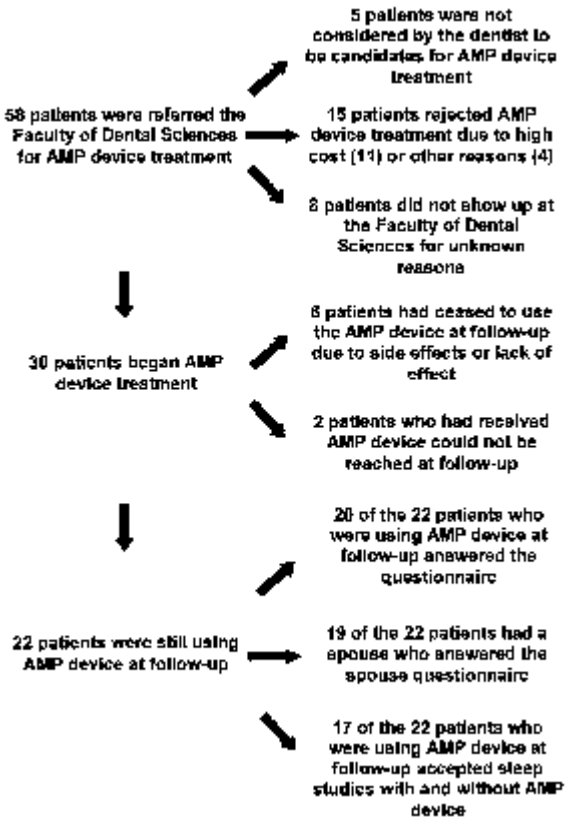

Figure 2. Summary of the patients who were referred for treatment with an anterior mandibular positioning device.

Sleep studies with and without AMP device

The patients who had been fitted with an AMP device and were still using it at the time of follow-up were invited to 2 nights of AutoSet recording (one night with the AMP device and one night without the AMP device). The AHI, snoring time and loud snoring time were measured with and without the AMP device.

Statistical analysis

Means and standard deviations (SD) were used for descriptive purposes. The AMP device treatment effect was estimated using paired t-tests regarding the difference of the pairs of observations (with and without AMP device). Statistical analyses were carried out using SPSS for windows, version 9.0.0. and a 5% level of significance was applied.

RESULTS

Patient characteristics

A total of 58 patients were referred to the Faculty of Dental Sciences, University of Aarhus, Denmark for AMP device treatment, including 40 males and 18 females.

Thirty of the 58 patients began AMP device treatment (Figure 2). Twenty-three did not receive an AMP device because they were not interested after receiving detailed information regarding the AMP device (15 patients), or because they did not show up at the Faculty of Dental Sciences (8). Eleven patients rejected AMP device therapy after receiving information from the Faculty of Dental Sciences regarding the cost of the AMP device. One patient rejected the AMP device because he had lost weight and his symptoms had diminished. One patient was a dentist himself and decided to make his own AMP device. One patient wished to postpone the AMP device treatment due to another severe illness and one patient due to working abroad for a longer period. Five patients were not eligible candidates due to missing teeth (4 patients), or jaw joint pain (1 patient).

Characteristics of all the referred patients (58), the patients who received an AMP device (30), and the patients who did not receive an AMP device (28) are shown in Table 1.

Sleep studies with and without the AMP device

Seventeen of the 22 patients (77%) who were still using an AMP device accepted a sleep study using AutoSet with and without the AMP device on two different nights. The mean (SD) dura-

Table 1. Baseline characteristics of all referred patients (N = 58), of the 28 patients who did not receive an AMP device (–AMP device), and the 30 patients who received an AMP device (+AMP device).

Patient characteristic	Referred	+AMP device	–AMP device
Age (years)	48.6 (11.1)	48.8 (11.8)	48.3 (10.6) NS
BMI (kgm^{-2})	26.4 (3.2)	25.9 (3.2)	27.1 (3.2) NS
AHI*	19.6 (16.6)	22.5 (16.6)	16.0 (16.1) NS
Neck circumference (cm)**	40.4 (3.7)	40.6 (3.8)	40.0 (3.6) NS
Epworth Sleepiness Scale	10.1 (4.7)	10.4 (5.1)	9.8 (4.1) NS
Total MCA (cm^2) before decongestion	1.04 (0.32)	1.10 (0.31)	0.99 (0.31) NS
Total MCA (cm^2) after decongestion	1.25 (0.33)	1.30 (0.32)	1.20 (0.33) NS
Relative decongestion effect on total MCA (%)	25.8 (36.8)	23.3 (27.1)	28.4 (45.4) NS

Values are mean (SD). Total MCA = minimum cross-sectional area of the nasal cavity (sum of right and left sides), * apnoea-hypopnoea index = apnoeas and hypopnoeas per hour recording measured by the AutoSet (42 patients) or the screening device (16 patients) without AMP device, ** measured at the cricoid level. NS = Mean difference between the patients who did not receive an AMP device and the patients who received an AMP device was not statistically significantly different from 0, using a paired t-test.

Table 2. Sleep study results with and without the AMP device (N = 17 AMP device users).

	Without AMP device	With AMP device
AHI	21.9 (15.1)	13.8 (12.3) *
Snoring time (%)	58.0 (26.8)	41.8 (27.7) NS
Loud snoring time (%)	13.1 (14.7)	4.3 (6.2) **

AHI = apnoea-hypopnoea index (apnoeas and hypopnoeas per hour recording) determined by the AutoSet. Snoring time (%) = percentage of sleep study time with snoring detectable by the AutoSet.
Loud snoring time (%) = percentage of sleep study time with a snoring level of 2.5 arbitrary units or more determined by the AutoSet.
* $p < 0.01$ using a paired t-test. ** $p < 0.05$ using a paired t-test. NS = Mean difference not statistically significantly different from 0.

Table 3. Influence of snoring on family life before and during AMP device treatment reported by the patients and their spouses (0 = no influence and 100 = very severe influence). Based on the answers to the questionnaires given by the 20 AMP device users and their 19 spouses.

	Without AMP device	With AMP device
Patients	81.6 (23.5)	28.6 (23.8)*
Spouses	82.9 (21.7)	29.3 (26.8)*

* $p<0.001$ using a paired t-test.

Table 4. Severity of symptoms perceived by the patient (0 = no symptom and 100 = very severe symptom) before and during AMP device treatment. (N = 20 patients who answered the questionnaires).

	Before AMP device	With AMP device
Facial pain	7.9 (15.1)	14.1 (18.2) NS
Sore teeth	3.3 (2.4)	21.7 (18.6) *
Salivation	13.5 (19.2)	13.6 (21.3) NS
Temporomandibular joint pain	9.1 (16.8)	17.2 (17.9) NS
Daytime Sleepiness**	9.0 (3.9)	8.1 (4.2) NS

NS = Mean difference not statistically significantly different from 0 using a paired t-test. *$p < 0.01$ using a paired t-test. **The patients answered the questions of the Epworth Sleepiness Scale (0 = would never doze off in any situation and 24 = would most likely doze off in all situations).

Table 5. Degree of satisfaction with the AMP device (0 = not satisfied and 100 = very satisfied) and willingness to recommend AMP device to a friend (0 = would not recommend and 100 = would recommend very strongly). Answered by the 20 patients who were still using AMP device and answered the questionnaires and their 19 spouses.

	Patients	Spouses
Satisfaction	71.0 (30.6)	74.0 (28.2) NS
Recommend to a friend	78.0 (30.2)	79.4 (21.8) NS

NS = the mean difference between patients and spouses was not statistically significantly different from 0 using a paired t-test.

tion from receiving an AMP device to undergoing sleep studies with and without AMP device was 22.6 months (27.4 months).
AMP device treatment resulted in a statistically significant reduction ($p<0.01$) of the mean (SD) AHI from 21.9 (15.1) to 13.8 (12.3) and of the mean (SD) percentage of the recording time with loud snoring from 13.1% (14.7%) to 4.3% (6.2%), ($p< 0.05$). AMP device treatment did not result in a statistically significant reduction of the percentage of the recording time with detectable snoring (Table 2).

Patient and spouse questionnaires

Twenty of the 22 patients (91%) who were still using an AMP device answered the questionnaire. Nineteen of the 22 patients had a spouse (86%), who answered the spouse questionnaire The mean (SD) follow-up interval from receiving an AMP device to answering the questionnaire was 22 months (26.5 months).
There was a statistically significant influence of the AMP device treatment on the reported influence of snoring on family life among the patients and the spouses (Table 3).

AMP device treatment also had a statistically significant influence on the perceived degree of sore teeth among the patients. However, the treatment had no statistically significant effect on the degree of facial pain, salivation, temporomandibular joint pain, or daytime sleepiness measured using the Epworth Sleepiness Scale (Table 4).

The patients and their spouses reported a high degree of satisfaction with the AMP device and a great willingness to recommend the AMP device to a friend. There was no statistically significant difference between the satisfaction and the willingness to recommend the AMP device between the patients and their spouses (Table 5).

Compliance

At the time of follow-up, 22 of the 30 patients who had received an AMP device were still using the AMP device (73%) while 6 patients stated that they had discontinued the use of the AMP device. The reasons for discontinuing AMP device treatment were: worsening of paradentosis (1), jaw joint pain (1), feeling unattractive when using the AMP device (1), not experiencing any effect on snoring (1), and headache caused by the AMP device (1). One patient discontinued AMP device treatment because her ENT specialist informed her that sleep studies with and without the AMP device showed no effect. Two patients could not be contacted and it was therefore uncertain whether they were still using the AMP device or not. The patients who were still using the AMP device at the time of follow-up reported a mean (SD) daily AMP device use of 7.3 hours (1.2 hours). They reported a mean (SD) use of the AMP device of 5.6 nights per week (1.9 nights).

DISCUSSION

Snoring objectively

In the present study, AMP device treatment resulted in a statistically significant reduction ($p<0.05$) of the mean (SD) percentage of the recording time with loud snoring from 13.1% (14.7%) to 4.3% (6.2%). The percentage of detectable snoring time of the total recording time was, however, not influenced by the use of an AMP device. Only a limited number of previous studies have measured the effect of oral appliances on snoring intensity objectively. Bloch et al. (2000) investigated 2 different AMP device devices (a Herbst device and a Monobloc device) in 24 OSA patients in a randomised, controlled crossover trial. The snoring index was reduced statistically significantly ($p<0.05$) by 36% (Herbst device) and 58% (Monobloc device) compared with the baseline snoring index without AMP device. In another study by Fransson et al. (2002) the mean peak intensity of the snoring sound decreased statistically significantly from 71.6 dB to 62.0 dB ($p < 0.001$) in 22 OSA patients and from 63.5 dB to 57.5 dB ($p < 0.05$) in 13 snorers. Walker-Engstrom et al. (2002) also found a statistically significant reduction in the snoring index ($p<0.01$) when they performed measurements after 4 years of follow-up in 32 patients. O´Sullivan et al. (1995) studied 57 subjects with habitual loud snoring, 39 of whom had an AHI of 10 or more and found that the number of snores per sleep minute and the proportion of snores of 50 dB or more decreased statistically significantly with the AMP device compared to measurements without the AMP device.

Snoring subjectively

In the present study, the influence of snoring on family life perceived by the patient and the spouse was reduced statistically significantly as a result of AMP device therapy ($p<0.001$). In a randomised, controlled crossover trial Bloch et al. (2000) investigated the subjective effectiveness of 2 different AMP device devices (a Herbst device and a Monobloc device). Nineteen of 20 partners were disturbed by the patients snoring when AMP device devices were not used as compared to 9 partners during use of the Herbst device and 5 partners during use of the Monobloc device (Bloch et al., 2000). In a study by Schmidt-Nowara et al. (1991) including 68 snorers and/or OSA patients the subjectively perceived severity of snoring decreased significantly from 8.5 to 1.5 rated by a scale ranging from 0 (absent) to 10 (very severe snoring) as a result of AMP device use.

Effect on AHI

In our study AMP device treatment resulted in a statistically significant reduction ($p<0.01$) of the mean (SD) AHI from 21.9 (15.1) to 13.8 (12.3). This represents a 37% mean decrease from baseline without an AMP device. In 1995, Schmidt-Nowara et al. (1995) published a systematic review including 20 publications reporting the efficacy of AMP device treatment in 304 OSA patients. The review demonstrated a mean reduction of the AHI of 56%. However many patients did not reach normal levels of AHI during AMP device treatment and 13% of the patients even had a greater AHI with the AMP device than before treatment (Schmidt-Nowara et al., 1995). In more recently published studies, the magnitude of the decrease of AHI has been between 39% and 65% compared with the baseline AHI (Clark et al., 1996, Bloch et al., 2000; Engleman et al., 2002). One of the explanations for the varying results is that the advancement of the mandible varies in different publications. Kato et al. (2000) applied AMP devices with 2-, 4-, and 6-mm advancement of the mandible. Overnight oximetry was performed. Each 2-mm mandibular advancement resulted in approximately 20% reduction in number and severity of nocturnal desaturations (Kato et al., 2000). Improvement of nocturnal oxygenation therefore seems to depend on the degree of mandibular advancement. Another explanation for variations in the impact on AHI by the AMP devices is differing definitions of apnoeas and hyponoeas between studies and variations in the studied populations (consisting of mild or severe OSA patients and/or snorers without OSA) and differences in the types op AMP devices used in the studies (Clark et al., 1996).

Side effects

The perceived degree of sore teeth increased statistically signifi-

cantly as a result of AMP device treatment in our study ($p<0.01$), but the degrees of facial pain, salivation, and temporomandibular joint pain were not influenced by AMP device treatment in our patients. Pantin et al. (1999) evaluated side effects of AMP device therapy using questionnaires and dental examinations of patients after a mean (SD) follow-up interval of 31 (18) months of use. Excess salivation was reported by 30%, xerostomia by 24%, temporomandibular joint pain by 27%, dental discomfort by 27%, myofacial discomfort by 25% and bite changes by 12%. One hundred six patients were objectively examined and 28% had increased maximal opening compared with pre-treatment records. Temporomandibular joint noises were found in 8%, and occlusal changes in 14% (Pantin et al., 1999). Clark et al. (2000) studied 65 consecutive patients with mild-to-moderate OSA and snoring and found that 40% reported jaw/facial muscle pain, 40% had occlusal changes, 38% reported tooth pain, 30% reported jaw joint pain and 30% experienced xerostomia. Walker-Engstrom et al. (2002) did not find any changes in the maximum mouth-opening capacity or the maximum protrusive capacity when they performed measurements after 4 years of follow-up in 32 patients treated with an AMP device. They found that 13% noted minor changes in tooth contacts at intercuspidation and 3% could not occlude the teeth in the same way as before treatment and reported temporomandibular joint pain on movement of the mandible. Unilateral temporomandibular joint sounds were reported by 16%, but 9% had reported this symptom before treatment (Walker-Engstrom et al., 2002).

Patient satisfaction

There was a high degree of satisfaction and a great willingness to recommend AMP device to a friend as reported by the patients and their spouses in our study. In other studies the percentage of patients who were satisfied with the AMP device treatment has been between 68% (Ferguson et al., 1996) and 80% (Ferguson et al., 1997). The majority of the randomised, controlled trials comparing AMP devices with CPAP have demonstrated larger patient satisfaction with AMP devices than with CPAP (Clark et al., 1996; Ferguson et al., 1996; Ferguson et al., 1997; Tan et al., 2002), but in a recent study by Engleman et al. (2002) the patients did not prefer AMP device treatment to CPAP or vice versa.

Compliance

At the time of follow-up, 22 patients out of the 30 patients in our study who had received an AMP device were still using it (73%). The mean (SD) follow-up interval from receiving an AMP device to answering the questionnaire was 22 months (26.5 months).

The overall compliance rate varies in different studies between 51% and 82% and may be related to the length of follow-up (Clark et al., 2000; Shadaba et al., 2000; McGown et al., 2001; Walker-Engstrom et al., 2002). The reasons for discontinuing AMP device treatment include side effects and lack of efficacy (Schmidt-Nowara et al., 1995).

Strengths and limitations of the present study

It is an advantage of the present study that a relatively large group of consecutive patients was studied with a mean (SD) follow-up interval of 22 months (26.5 months). Detailed information could be obtained through questionnaires regarding effects and side effects before and during AMP device treatment using visual analogue scales. The patients were able to compare their symptoms during AMP device treatment with the symptoms before AMP device treatment using these visual analogue scales.

It is a disadvantage that the group of patients rejecting AMP device treatment was not followed-up. Twenty-eight out of the 58 patients referred for AMP device treatment did not receive a device mainly because they were not interested after receiving detailed information (15 patients), or because they did not show up at the Faculty of Dental Sciences (8). Follow-up of this group of patients could, however, not be accomplished satisfactorily because a number of patients did not respond to our letters and some patients had received surgical treatment in the mean time.

It is a disadvantage of follow-up studies that recall bias may interfere with the answers because the patients may not have been able to remember the severity of their symptoms before AMP device treatment. There is also a risk of a placebo effect associated with non-randomised retrospective studies, which could have been avoided by performing a prospective, randomised trial of an AMP device using a placebo AMP device.

In most studies assessments of snoring intensity have been based on patient or spouse reports and not on objective measurements. It is strength of our study that snoring and AHI was measured objectively.

Comparison with CPAP

A limited number of randomised controlled trials comparing AMP devices with CPAP treatment have been published (Clark et al., 1996; Ferguson et al., 1996; Ferguson et al., 1997; Engleman et al., 2002; Tan et al., 2002). In these studies, the AHI was lowered more with CPAP than with an AMP device, but in most of the studies there was larger patient satisfaction with AMP device treatment than with CPAP. In a study by Engleman et al. (2002), however, the patients did not prefer AMP device treatment to CPAP or vice versa.

Patient acceptance and compliance are major problems associated with CPAP treatment. Between 50% and 81% of patients accept CPAP and the machines are switched on for 3.7 to 6.0 of the 24 hours as demonstrated in a systematic review by Wright et al. (1997).

Comparison with UPPP

Walker-Engstrom et al. (2002) compared the effect of an AMP device with the effect of uvulopalatopharyngoplasty (UPPP) in a randomised study with a follow-up period of 4 years.

"Normalization" of breathing during sleep ($AI < 5$ or $AHI < 10$) was observed in 63% of the AMP device group and 33% of the UPPP group after 4 years of follow-up. The difference between the groups was statistically significant ($p < 0.05$).

Compared with UPPP surgery AMP devices cost less and AMP treatment can easily be terminated without sequelae (Schmidt-Nowara et al., 1995).

CONCLUSION

In conclusion, AMP device treatment appears to offer benefits for patients with snoring and/or mild to moderate OSA. AMP devices reduce snoring and sleep disordered breathing in the majority of patients. The side effects are minor and reversible and the degree of patient and spouse satisfaction is high compared with CPAP.

AMP device treatment should be considered particularly for snorers whose problem is not alleviated by other conservative means, and for OSA patients who are unable or unwilling to tolerate CPAP therapy. More studies are needed to define the role of AMP devices and to improve the selection of therapy for different patient groups.

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