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Effect of Mandible Advancement Splint in Mild, Moderate and Severe Obstructive Sleep Apnea

- The need for sleep registrations in the follow up.

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Summary

Objective and design: Our aim was to evaluate the effect of mandible advancement splint (MAS) in mild, moderate and severe obstructive sleep apnea (OSA). We also determined, if and in which OSA-groups the adequate forward movement in MAS could be quantified without sleep registration for different OSA levels. A retrospective study.

Settings: The effect of MAS was measured with clinical methods and by sleep registration.

Participants: The series consisted of 103 patients, 75 males and 28 females (mean age 52 yrs) suffering from mild (32 %) moderate (32 %) or severe (36 %) OSA, who were treated with MAS at Helsinki University Hospital, Finland during the years 2011-2012. 70 % of the patients had tried continuous positive airway pressure (CPAP) before MAS.

Results:

The lower the BMI was the bigger the probability was to get AHI values $<5/h$ with MAS ($p < 0.01$). The total AHI decreased significantly from the baseline with MAS: 23/h (range 5-89) to 6/h (range 0.3-54), ($p < 0.001$). The mean ODI4% improved significantly from 16/h (range 1-76) to 5.3/h (range 0.2-49), ($p < 0.01$), and the minimum oxygen saturation improved significantly from 84 % (67-91) to 87 % (68-93), ($p < .01$). The reduction of AHI with MAS was significantly bigger in patients with a previous CPAP experience (73 %) than those who did not tried CPAP therapy. The positive correlation was found between the decrease in AHI and the increase of the protrusion in MAS.

Conclusion: Both sleep recordings and subjective indicators demonstrated that MAS therapy was successful in OSA based on ESS, total AHI, ODI4% and minimum oxygen saturation values. It seems useful to increase the protrusion at its maximal clinical tolerance. An experienced dentist could make therapeutically decision concerning the follow up of MAS efficacy regardless of the result of sleep study. We suggest that MAS is a valuable treatment alternative for CPAP. However, the previous use of CPAP with MAS as well as lower baseline BMI seem to have a positive correlation with the success of MAS-therapy.

Introduction

Obstructive sleep apnea is the most common respiratory disorder and thus a serious public health problem (1, 2). The treatment of choice in obstructive sleep apnea (OSA) is continuous positive airway pressure (CPAP) therapy (3). Although mandible advancement splint (MAS) are shown to be less effective in reducing the apnea/hypopnea index (AHI), compared with CPAP therapy, they offer an option for patients with mild or moderate OSA, who refuse or are unable to tolerate CPAP therapy. The main reasons for abandoning CPAP are lack of motivation, nasal symptoms, breathing discomfort, and discomfort related to air leak, futility of the device, and sleeping difficulties (4, 5). MAS reduces daytime sleepiness, snoring, obstructive breathing events, lowers blood pressure and improves AHI by protruding the mandible and maintaining pharyngeal airway open (6, 7).

The use of MAS in severe OSA is controversial. Although CPAP is highly efficacious in preventing upper airway collapse, patient acceptance, tolerance, and adherence is often low, thereby reducing effectiveness. Several studies have confirmed that CPAP is superior in reducing OSA parameters on sleep registrations. However, the greater effect does not necessarily translate into better health outcomes in clinical practice. MAS has been attributed to higher nightly use compared to CPAP, suggesting longer periods of non-apneic events and thus better treatment results to OSA (8).

Recently, Haviv et al. (9) showed in a two-year follow-up study MAS to be successful for treating severe OSA in patients who failed to comply with CPAP. The most crucial factor for the success rate of MAS treatment is the quantity of mandible advancement (10). In patients with mild and moderate OSA, the proportion of 50 % or 75 % mandibular forward movement of maximum advancement in MAS has not been shown to affect AHI in successfully treated OSA patients (11). However, in severe OSA patients, 75 % of maximum advancement in MAS seems to be more important (12). Titration of MAS is based on a combination of both subjective improvement and objective overnight monitoring with sleep registration to find the optimally effective advancement level (7).

Aim

The primary aim of the present study was to evaluate the effect of MAS therapy subjectively, clinically and objectively by sleep registration in mild, moderate and severe OSA. The secondary aim was to determine, if the adequate forward movement in MAS could be quantified subjectively and clinically without sleep registration in different levels of OSA and thus, if sleep registration with MAS could be targeted only for the patients with severe OSA and professional drivers.

Patients and methods

Patients

We retrospectively reviewed the clinical records of 103 patients treated with MAS (75 males (73 %) and 28 females (27 %) (mean age 52 yrs, range 25-77) suffering from mild (32 %, AHI $5 \leq < 15/h$), moderate (32 %, AHI $15 \leq < 30/h$) or severe (36 %, AHI $\geq 30/h$) OSA. The patients had a sleep registration performed before MAS and with MAS, at the Department of Oral and Maxillofacial Diseases, HUH, Helsinki, Finland during the years 2011-2012. The inclusion were OSA based on anamnestic, clinical and sleep registration study and MAS treatment at least 3 months before sleep registration with MAS. Patients' that do not fulfill the sleep apnea criteria (AHI ≥ 5) and those who refused the sleep study with MAS were excluded.

Data were collected on gender, age, general health, body mass index (BMI), former treatment of OSA, CPAP treatment, AHI, oxygen desaturation index (ODI4%), otorhinolaryngological treatments, Charlson Comorbidity Index (CCI) and Epworth Sleepiness (ESS). Effectively we studied the gender and the age effect on our MAS results and it was negative. The patients went through clinical dental examination by an orthodontist. The maximal opening, protrusion and lateral movements of the mandible were recorded.

The sleep registration data were collected at baseline and with MAS. In addition, data for mandibular protrusion in MAS and addition of protrusion in MAS before and after the sleep registration were recorded. Problems with the use of MAS were also registered. The protocol of the retrospective study was approved by the Institutional Research Ethics Board (03.05.2012, § 105).

Sleep studies

Sleep studies were performed by a Type III (American Academy of Sleep Medicine Classification 2005; **13**) ambulatory polygraph Embletta (Embla, Denver, Colorado, USA). Apnea was defined as the complete cessation of nasal airflow for at least 10 seconds. Hypopnea was defined as a reduction in nasal airflow of at least 50% for at least 10 seconds, accompanied by a decrease in saturation of peripheral oxygen (SpO₂) of at least 3% (**14**).

The indication of CPAP therapy

The indication for CPAP therapy trial was an AHI greater than 15/h or an AHI greater than 5/h along with a considerable daytime sleepiness.

The indication of MAS therapy

The indication of MAS therapy trial was an AHI greater than 15/h or an AHI greater than 5/h along with a considerable daytime sleepiness and either failed or the patients refuse to begin CPAP therapy. In addition, patients using bite splint were quite often guided to start MAS therapy.

MAS therapy

Inter-occlusal wax bite registration was performed to obtain approximately 70% of the maximal protrusion of mandible. Alginate impressions of the upper and lower dentition were obtained to make working models, which were surveyed to construct a customized MAS. The appliance has maxillary and mandible acrylic splints with bilateral telescopic arms preventing retrusion of mandible (15) (Figure 1). The follow-up visits for the patient with the appliance were arranged at three months, and then on demand. To find the ideal protrusion, metallic insets ranging from one to three mm could be added to the MAS during the follow-up. At the first three months evaluation an additional one to two mm increase in the forward movement of MAS was administered if clinical and subjective signs or symptoms of snoring/apneas and/or daytime sleepiness were noticed by the patient. None of the patients had a MDSA appliance.

Statistical analysis

The data were collected to SPSS (IBM SPSS® Statistics 19.0, Armonk, New York, USA). We reported values as medians with ranges for descriptive purposes. The difference between the MAS groups was evaluated using the Mann–Whitney test for continuous variables and Kruskal–Wallis test for categorical data. The efficacy of MAS treatment was assessed with related samples Wilcoxon signed rank test. The correlation between the baseline and post-treatment findings was determined by using non-parametric Spearman correlation coefficients. All *P* values are two sided and the significance level was set at 0.05 throughout the study.

Results

Patient demographics

The sample consisted of 75 male and 28 female patients (mean age 52 yrs; range, 25-77) suffering from mild (n=33, 32 %), moderate (n=33, 32 %) and severe (n=37, 36 %) OSA. Median BMI did not change significantly (Table 1). The BMI had a significant correlation with the success rate of the MAS treatment evaluated with AHI values, i.e. the lower the BMI was the bigger the probability was to get AHI values <5/h with MAS ($p<0.01$). The median EES at baseline decreased significantly (Table 1). The mean CCI was 0.34 and median CCI 0.0 (range 0-3), 75.2 % (n= 77) of the patients had CCI 0 and 24.8 % (n=26) had CCI ≥ 1 .

CPAP therapy

A total of 72 % (n=74) out of the 103 patients had tried CPAP therapy before the MAS. Thirty-one percent (n=32) of the patients had used CPAP under one month and 69 % (n=71) more than one month (median 2.5, range, 1-120). The reasons for abandoning CPAP were lack of motivation, nasal symptoms, breathing discomfort, and discomfort related to air leak, futility of the device, and sleeping difficulties. The median CPAP pressure was 10.0 (range 4.5-18.0). The pressure of CPAP was 10.5 or higher in 22 patients, variable in 26 patients (the data of CPAP pressure was not available for all patients).

Otorhinolaryngological therapy

Seventy-two percent (n=74) of the patients had been examined and/or treated by an otorhinolaryngologist before MAS therapy, and 43 % (n=32) had had only nose treatment. The patients had various surgical interventions for the nasal and oropharyngeal structures to aid air flow. Eighteen patients had been treated with radiofrequency thermal ablation of inferior turbinates, nineteen with soft palate interstitial radiofrequency surgery, sixteen with uvuloplasty, five with tonsillectomy, two with adenoidectomy, five with functional endoscopic sinus surgery and ten with septoplasty.

No significant correlation was found between the effect of MAS measured with sleep registration either or not the patient had had otorhinolaryngological therapy before MAS therapy.

MAS therapy

The total median forward movement of MAS was 6.5 mm (range, 4-10) before sleep registration. Fifty-eight patients did not clinically or subjectively need or tolerate additional forward movement of MAS at the first follow-up visit. Nineteen patients had 1 mm, twenty-one patients had 2 mm and one patient 3 mm additional forward movement of MAS at the first follow-up visit. After the follow-up visit, the sleep registration was done with MAS. According to these results, 17 patients showing a clear need for additional forward movement of the MAS i.e. having still remarkable amount of apneas, were called for a second follow-up visit, where five patients had 1 mm and twelve patients had 2 mm additional forward movement of MAS. Most of the patients who needed an additional forward movement of their MAS after sleep registration (n=17), had moderate (n=6) to severe (n=7) sleep apnea.

The clinical dental findings

At the baseline, the median maximal opening of the mandible was 47 mm (range, 30-63), the mean lateral movement of the mandible was 12 mm to the right and 11 mm to the left. The median protrusion of the mandible was 9.5 mm (range, 3-15). No significant correlation was noted between the baseline dimensions of the maximal opening, lateral movements or protrusion to the success rate of MAS.

Sleep registration results before and with MAS

The total AHI, AHI in supine and in non-supine-positions decreased significantly from the baseline with MAS. The mean ODI4% and the minimum oxygen saturation improved significantly. The median oxygen saturation did not change significantly (Table 1). The median decrease in the total AHI in different OSA groups (mild, moderate and severe) are shown on Figure 2.

The reduction of AHI with MAS was significantly bigger in patients with a previous CPAP experience (n=75, 73 %) than those who did not tried CPAP therapy (n= 28, 27 %). The median reduction in AHI was 19.5/h (range -6.5 – 75.0) vs 14.9/h (range -11.5 – 50.5), p = 0.001, respectively.

A statistically significant correlation was found between the decrease in AHI with MAS and the increase of the protrusion ($p < 0.01$). Furthermore, the baseline AHI, the amount of forward movement with MAS, and the additional forward movement of MAS at the first follow-up visit before the sleep registration showed significant correlation with the decrease in AHI ($p < 0.01$).

Discussion

This is retrospective evaluation of 103 patients regarding the effect of MAS in mild, moderate and severe OSA. The results clearly indicate a successful outcome measured with sleep registration. Median BMI did not change during the study period indicating that the improved sleep registration values most likely are due to the use of MAS.

Seventy four patients out of 95 patients had been examined and managed by otorhinolaryngologist before MAS therapy. Clinical evidence has shown that especially treatment of nasal breathing is of critical value in providing the best circumstances for MAS therapy. However, according to our present results no significant correlation was found with the effect of MAS therapy measured with sleep registration either or not the patient had had any otorhinolaryngological therapy before MAS-therapy. But it is possible that patients having remarkable problems with nasal breathing may not be able to the use MAS at all.

According to Bratton et al. (16) CPAP seemed to be a more effective treatment than MAS, and had an increasingly larger effect in more severe OSA patients. Marklund et al. (1998) (17) and also other authors suggest that the use of MAS should be limited to mild and moderate OSA patients. (1). In a review by Lim et al. 2006, (18), MAS could be recommended for patients with only mild OSA or in patients who cannot tolerate CPAP (1). MAS is an effective alternative treatment if CPAP is not tolerated. Our result are in agreement with their results and seem also to refer to the previous attempt of CPAP before MAS due to the positive correlation in the improvement of total AHI and the previous use of CPAP.

The percentage amount of maximal protrusion in forward movement of MAS had been discussed generally. The greater the level of advancement, the better the treatment effect, although this must be balanced against potential increase in side effects (8). In a study of mild-to-moderate OSA patients randomized to either 50% or 75% of maximum advancement, there was no difference between these levels in treatment AHI or proportion of patients successfully treated (79% vs. 73%). However in severe OSA, more patients achieved treatment success with 75% compared to 50% maximum advancement (52% vs. 31%), suggesting maximizing advancement may be more important in severe disease. However, above 50% of maximum advancement there was an associated increase in reported side effects. A titration approach to determine optimal level of advancement with gradual increments over time is thought to optimize treatment outcome (19, 12). Our results also showed a positive correlation between the decrease in AHI and the increase of the protrusion in MAS. The positive correlation in the reduction of AHI was also found in patients, who had forward movement of MAS at the first follow-up visit before the sleep registration. Thus, the titration of the MAS is of essential value and should be approximately 70 % in the beginning of MAS therapy.

In addition to the previous CPAP treatment, the BMI had a significant correlation with the success rate of the MAS treatment evaluated with AHI values, i.e. the lower the BMI was the bigger the

probability was to get AHI values $<5/h$ with MAS. Thus, the weight loose in obese patients is of essential value before MAS. In patients with normal BMI, the skeletal structures of jaws and oropharynx i.e. retrognathic position of the mandible, its short dimension, high face height, and closing jaw relationship might have an essential effect to the development of OSA (4, 20). In these patient group the advancement of mandible with MAS could seriously be consider as a primary option in OSA treatment.

According to the review of Serra-Torres et al. 2015 (1) the advantage of adjustable MAS used in the present study compared to fixed oral sleep apnea appliance, is also the better results for daytime sleepiness in addition to equally effectiveness in improving AHI, snoring and oxygen saturation. Same effect has been detected in ESS in MAS with the possibility to adjust the appliance (21). Thus the adjustment ability in MAS compared to fixed sleep apnea appliances, is essential. In the present study, all the MAS treatments were done by or under supervision of an experienced dentist. The total median forward movement of MAS was 6.5 mm before sleep registration. After the sleep registration, 16 % the patients showed a clear need for additional forward movement of the MAS. Thus, it seems that in most cases, titration of MAS to find the optimally effective advancement level was reliable based on a combination of subjective symptom improvement as well as dentists experience as least in mild OSA. According to our results, most of the patients who needed for an additional forward movement of the MAS after sleep registration, had moderate to severe sleep apnea. No significant correlation was noted between the baseline dimensions of the maximal opening, lateral movements or protrusion to the success rate of MAS. Thus, it seems that also patient with minor protrusion at the baseline can be successfully treated with MAS. Banhiran et al. 2014 (22) found significant reduction in AHI when adjusting MAS 0.5-1 mm every one to two weeks for 4 to 6 months to find the most effective forward movement in MAS, which could be another alternative. However, either very good co-operation of the patient to activate the appliance by themselves or much chair-side dentist time will be needed.

Limitations of the study

Our study has some limitations. The retrospective nature of the study prevented us from making solid conclusions. Moreover, we did not use the gold standard sleep study i.e. polysomnography, because of practical reasons. The total number of patients was limited and our results thus only reflect one center sexperience and one MAS-type.

Conclusion

Both sleep recordings and subjective indicators demonstrated that MAS therapy was successful in mild, moderate and severe OSA based on ESS, total AHI, ODI4% and minimum oxygen saturation values. It seems useful to increase the protrusion at its maximal clinical tolerance as we showed that the decrease of AHI with MAS was significantly correlated with the amount of mandibular protrusion.

An experienced dentist could make therapeutically decision concerning the follow up of MAS efficacy regardless of the result of sleep study. We suggest that MAS is a valuable treatment alternative for CPAP. However, the previous use of CPAP with MAS as well as lower baseline

BMI seem to have a positive correlation with the success of MAS-therapy. The need for sleep registration with MAS seems to be indicated only in patients with severe sleep apnea. The MAS therapy showed a significant reduction of the apnea and hypopnea index in patients with a variable degree of sleep apnea severity.

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Figure 1. The MAS appliance (Herbst-type).



Figure 2. The median AHI values in the different OSA at the baseline and with MAS.

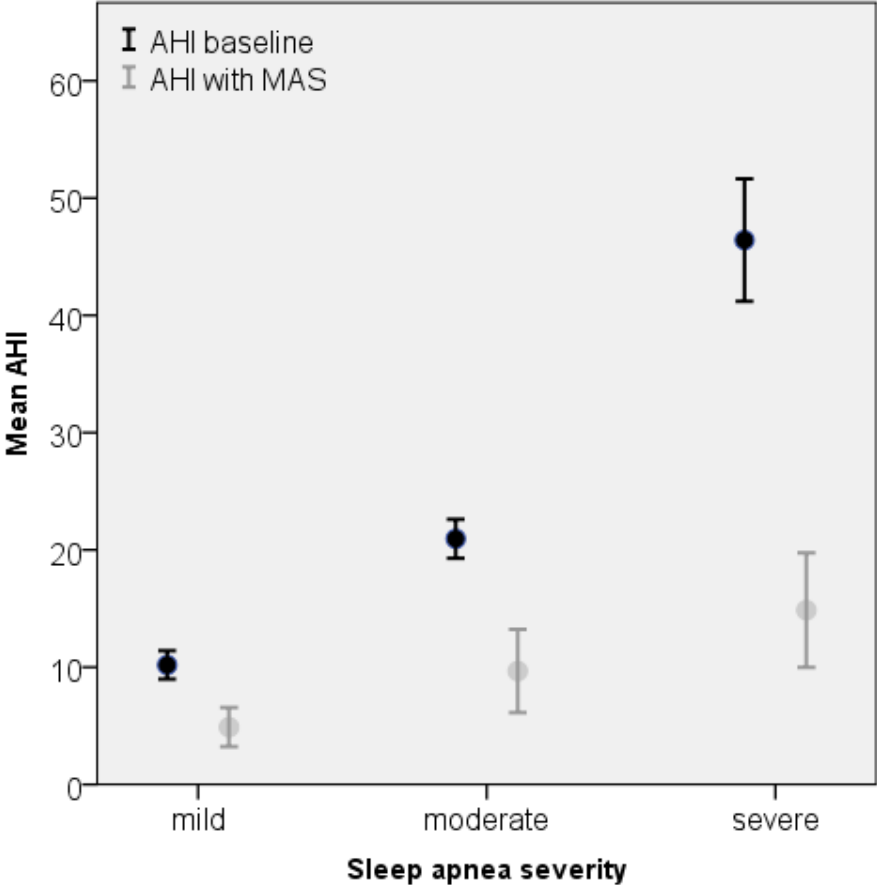


Table 1. The median BMI, ESS, total AHI, AHI (supine), AHI (non-supine), ODI4%, median and minimum oxygen saturation in the beginning of MAS therapy and at the time of sleep registration with MAS. Number of patients (n). Related samples Wilcoxon signed ranks test.

	n	At baseline	With MAS	p (Related samples Wilcoxon signed ranks test)
BMI kg/m ²	70	27.0 (17–45)	27.6 (19-52)	ns
ESS		9/24 (2-19)	5/24 (0-18)	p<0.001
Total AHI/h	101	23 (5-89)	6 (0.3-54)	p<0.001
AHI supine/h	77	37	19	p<0.001
AHI non-supine/h	36	6	2	p<0.01
ODI4%/h	86	16 (1-76)	5.3 (0.2-49)	p<0.001
Median oxygen saturation %	71	94.2 (86.8-97.3)	93.9 (90.1-97.3)	ns
Minimal oxygen saturation %	46	84 (67-91)	87 (68-93)	p<0.01

