



Monoblock and twinblock mandibular advancement devices in the treatment of obstructive sleep apnea

MAD and OSAS

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Abstract

Aim: Mandibular advancement devices (MADs) are an alternative to continuous positive airway pressure (CPAP) for patients with obstructive sleep apnea syndrome (OSAS). There is conflicting evidence of how different MAD designs may affect OSAS outcomes in certain patients. This study aimed to assess and compare the effectiveness of two different MADs in treating OSAS, based on subjective and objective measurements. **Material and Method:** A randomised crossover design trial was carried out on 38 patients with OSAS. A monoblock and a twinblock MAD were tested in each patient. Changes in objective outcomes (apnea-hypopnea index (AHI), total sleep time (TST), oxygen desaturation index >4% (ODI4%), total duration of oxygen saturation with less than 90% (SpO₂<90%), total arousal index (TAI) and sleep efficiency) were assessed by polysomnography, changes in subjective outcomes by the Sleep Apnea Quality of Life Index (SAQLI) and Epworth Sleepiness Scale (ESS). **Results:** Both MADs proved to be effective in improving several objective parameters from baseline, but when compared there was a significant difference in favor of the monoblock in terms of improving AHI, ODI 4% and total duration with SpO₂<90% (p=0.032; 0.046 and 0.043, respectively). Both MADs were efficacious in improving patients' SAQLI score and ESS score (all p<0.05), but no significant difference was observed between the two MADs. **Discussion:** Use of the monoblock MAD should be considered when patients with OSAS choose MAD treatment, as it was more efficient in improving objective OSAS parameters compared to twinblock MAD.

Keywords

Obstructive Sleep Apnea; Mandibular Advancement; Quality of Life

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Introduction

The obstructive sleep apnea syndrome (OSAS) is the most common sleep-related breathing disorder. Population-based studies across the world estimate a prevalence of approximately 6% to 49% [1]. Patients suffering from OSAS experience a range of adverse health outcomes such as heart failure, cerebrovascular insult, impaired neuro-cognition, impaired quality of life and social life [2,3]. Different treatment options are now available for effective management of this disease, but continuous positive airway pressure (CPAP), after more than three decades from its first use, is still recognized as the treatment of choice to control this disorder [4]. However, its efficacy is highly reliant on patient compliance. Not all patients with OSA tolerate CPAP, some patients complain about some side effects such as dryness of the airway and mouth, increased number of awakenings, blocked up nose, rhinitis, mask pressure and mask leaks [5,6].

Patients were more likely to stop using the CPAP because of poor tolerability, and decreased adherence rates [5]. Oral appliances (OAs) offer a non-invasive treatment option for patients with OSAS. The American Academy of Sleep Medicine (AASM) recommends OAs therapy for patients with mild to moderate OSAS and for those with more severe OSAS who cannot tolerate CPAP and refuse surgery [7]. A variety of OAs is available such as tongue retaining devices, soft palate lifters, and mandibular advancement devices (MADs). These were the most commonly used oral appliance in the treatment of OSAS [8]. The MAD works by increasing the retropalatal and retrolingual spaces while decreasing the length of the soft palate and the angle of mouth opening [9]. Several types of MAD have been created for OSAS treatment. Some appliances have fixed advancements, where the distance of advancement can't be adjusted, whereas others are adjustable. One study showed that adjustable appliances resulted in a greater reduction in apnea-hypopnea index (AHI) and improvements in Epworth Sleepiness Scale (ESS) compared to fixed appliances [10]. MADs have a variety of side effects with many of them being only temporary: jaw discomfort, tooth tenderness, excessive salivation, and occlusion changes [11].

Understanding which type or design of MAD is most effective and tolerated in the treatment of OSA should be examined for offering the optimum treatment options to patients. However, few studies have investigated this [12]. For this reason, we carried out a study on patients with OSAS to evaluate the efficacy of two different MADs on subjective Sleep Apnea Quality of Life Index (SAQLI), ESS and objective polysomnography (PSG) parameters.

Material and Method

This prospective, randomized cross-over trial was conducted between April 2017 and October 2017 in the Otolaryngology Unit of the Santa Marta e Santa Venera Hospital in Acireale, Catania, Italy, after the approval by the ethical committee of the Unità Operativa Complessa (UOC) Otorinolaringoiatria - ASP 3 CT. The study involved a sample of consecutively adult ASOS patients which had been prescribed treatment with MADs at the Dental Unit of the same hospital.

The criteria for inclusion were: (a) ages of 18 and older; (b) con-

firmed diagnosis of OSAS by PSG as defined by an AHI score of ≥ 10 ; (c) inability to tolerate CPAP or reported noncompliance to CPAP use as defined by CPAP usage for < 4 hours for 70% of the nights; (d)

a score of >10 on the ESS; (e) a body mass index (BMI) <35 kg/m²; (f) complete or functional dentition. Exclusion criteria were: (a) previous surgery to upper respiratory airway; (b) presence of unstable cardiovascular disease, neurological, mental, or psychiatric disorders; (c) pregnancy; (d) presence of temporomandibular joint dysfunction (TMD); (e) unsuitable periodontal or teeth for an oral appliance.

Custom-made MADs were realized following the patient's anatomic variability and used for each patient. The MADs were: a one-piece (monoblock) and a two-piece (twinblock) appliances made out of a thermal acrylic material. Alginate impressions, a central wax bite, and a protrusive wax bite were taken by an orthodontist for the construction of each appliance realized by a dental technician (both not involved in this study). The protrusion and the opening of the bite were individually adjusted for each patient according to a construction bite; in the sagittal plane, MADs were designed to hold the mandible to 75% of the maximal protrusion and in the vertical plane about 6 mm, to ensure retention of the device. The George Gauge, an instrument for bite registration, was used to determine where the bite registration was recorded. Each device was fitted and then reviewed 2-4 weeks later at a second visit to start the study. Patients were taught how to use the MADs every night during sleep properly.

Before the start of the study a biostatistician, who is not involved in the data recruitment nor collection, created the allocation schedule using a computer-assisted random sequence generator. This schedule was used in order to generate the list of patients who will be assigned to the 2 equal treatment groups, where each treatment consists of a sequence of two treatments (AB or BA). Patients assigned to study group AB, received the monoblock MAD first, followed by the twinblock MAD. For those patients assigned to study group BA, this sequence was reversed. At the end of 10 weeks with the first MAD (T1), patients underwent PSG at our hospital to assess the efficacy of the treatment modality. At this appointment, the first MAD was collected from the patient. After that patients have gone through a 2 weeks wash-out period during which patients did not wear any MAD, to avoid any possible effect of the first MAD for the response to the second MAD. The patients were then fitted with the second MAD for 10 weeks (T2). At the end of this study period with the second MAD, patients underwent a final PSG at our hospital and conclusive assessment and data collection. Each patient included in the study underwent a subjective sleep assessment by the SAQLI and the ESS and an objective assessment by PSG at baseline and follow-up data collection points (T1 and T2).

The SAQLI is a disease-specific quality of life (QoL) questionnaire, which was developed in order to detect more subtle effects of sleep apnoea on health-related QoL. Items are scored on a 7-point scale with "all of the time" and "not at all" being the most extreme responses. Item and domain scores are averaged to yield a total composite score between 1 and 7. Higher scores represent better quality of life [13]. The ESS is a validat-

ed 8-item questionnaire that measures subjective sleepiness. Each question was answered on a scale of 0 to 3. ESS values ranged from 0 (unlikely to fall asleep in any situation) to 24 (high chance of falling asleep in all 8 situations). Scores of 11 or greater are considered to represent an abnormal degree of daytime sleepiness [14].

A standard overnight full PSG (Sonnoscreen plus-16 channels; Somnomedics, Bellusco, MI, Italy) was performed in our hospital and included the recording of several parameters such as thoracoabdominal movements (detected using respiratory inductance plethysmography), oronasal airflow, bilateral electro-oculography, chin and tibial electromyography, electrocardiography, and the oxygen arterial blood saturation. Obstructive apnea was defined as a 90% drop in respiratory amplitude lasting at least 10 s, associated with continued or increased inspiratory effort. A hypopnoea was defined as a 30% drop of respiratory amplitude lasting 10 s, associated with repeated respiratory effort and (arousals or) oxygen saturation drops of 4%. The AHI was calculated as the number of apnoeas and hypopnoeas per hour of total sleep time. The diagnosis of OSAS was defined as an AHI greater than 5, in accordance with the American Academy of Sleep Medicine recommendations. According to the AHI, the severity of the disease was classified (mild 5–15/h, moderate 15–30/h, and severe greater than 30/h) [15]. All studies were manually reviewed by a medical doctor expert in sleep medicine not involved in the study.

Outcomes of interest were changes both in subjective outcomes by the SAQLI and ESS questionnaires and in objective PSG measurements as AHI, total sleep time (TST), oxygen desaturation index >4% (ODI4%), total duration of oxygen saturation with less than 90% (SpO₂<90%), total arousal index (TAI) and sleep efficiency. All subjects gave written informed consent. In calculating sample size, the principal outcome measure was taken to be the mean ESS score [16]. If there were to be a difference in ESS score of 2.5 (assuming that the standard deviation is 1.2 units) between those patients treated with monoblock and twinblock appliances and setting the significance level at 5% and sample power at 80%, a sample size of 38 subjects would be required.

Data are reported as means ± SD for continuous variables, while categorical variables were expressed as frequencies and percentages. Student t-tests were used to compare the means for continuous data. If the normality test failed, the Mann-Whitney U test was applied. For categorical data, the chi-square test was used. All statistical tests were performed with the MedCalc Statistical Software, v. 9.2.1.0 (MedCalc Software, Belgium) and p values of less than 0.05 were regarded as statistically significant.

Results

Of the 40 patients who met the inclusion criteria and consented to take part in this study, 38 subjects completed both treatment periods. Two subjects (5%), one belonging to the AB group and one belongs to BA group, were lost during washout periods, so a total of 38 patients were included in the final analysis. Patient demographic characteristics were similar between groups as shown in Table 1.

Overall mean score for SAQLI showed significant improve-

Table 1. Demographic characteristics of the patients included in the study (n=38)

Demographic characteristics	AB group N=19	BA group N=19	p-value
Age, in years			
Mean±SD	49.6±11.6	47.5±10.2	0.516
Median	47	46	-
Range	29-64	29-63	-
Gender, n (%)			
Male	12 (63.2)	13 (68.4)	0.675
Female	7 (36.8)	6 (31.6)	
BMI (kg/m ²)	27.1±3.3	27.6±3.1	0.702
Social habits, n (%)			
Smoking alone	4 (21.1)	3 (15.8)	0.424
Alcohol alone	0 (0)	1 (5.3)	0.679
Both	3 (15.8)	4 (21.1)	0.424
None	12 (63.2)	11 (57.9)	0.559

SD: standard deviation; BMI: Body Mass Index

ment both with monoblock appliance (p=0.024) and twinblock (p=0.023) when compared to baseline values. On the contrary, no significant difference was observed between the two MADs (p=0.639). Patients' perceived levels of daytime sleepiness as assessed by ESS was significantly reduced after treatment with the two MADs (p=0.029 for monoblock appliance and p=0.031 for the twinblock appliance). But, also, in this case, no significant difference was observed between monoblock and twinblock treatment (9.4±1.7 vs. 9.8±2.1, p=0.574) (Table 2).

Table 2. Effect of monoblock and twinblock MADs on subjective outcomes.

Subjective OSAS outcomes	Baseline (B) N=38	After Monobloc (M) N=38 M vs. B	After Twinblock (T) N=38 T vs. B	p-values		
				M vs. T		
SAQLI	3.9±0.7	4.8±0.5	4.9±0.7	0.024*	0.023*	0.639
ESS	13.5 ± 2.6	9.4±1.7	9.8±2.1	0.029*	0.031*	0.574

SAQLI: Sleep Apnea Quality of Life Index; ESS: Epworth Sleepiness Scale
*p<0.05

The analysis of objective PSG measurements revealed a highly significant reduction in AHI from 28.5±5.7 (events/h) to 8.5±3.2 (p<0.001), as well as other indicators such as ODI4% (p<0.001), total duration with SpO₂<90% (p=0.009) and TAI (p=0.044). No significant change was observed in TST and sleep efficiency as compared to baseline values. Significant reduction in AHI was also reported after the treatment with the twinblock MAD (p=0.003) as well as in ODI4% (p=0.002) and total duration with SpO₂<90% (p=0.022). No significant change was observed for the others PSG parameters. When the PSG results were compared between the two MADs, AHI, ODI4% and total duration with SpO₂<90% were found to be reduced in favor of the monoblock treatment (p=0.032; 0.046 and 0.043, respectively) (Table 3).

Discussion

The American Association for Sleep Medicine recommends prescribing OAs to patients with mild to moderate OSAS who

Table 3. Effect of monoblock and twinblock MADs on objective PSG parameters.

Subjective OSAS outcomes	Baseline (B) N=38	After Monobloc (M) N=38 M vs B	After Twin-block (T) N=38 T vs B	P values		
				M vs T		
AHI (events/h)	28.5 ± 5.7	8.5±3.2	14.2±4.5	<0.001*	0.003*	0.032*
TST (min)	350.5±28.2	352.2±29.3	352.9±29.6	0.556	0.543	0.739
ODI4% (events/h)	22.6±6.4	7.1±2.8	10.5±4.1	<0.001*	0.002*	0.046*
Total duration with SpO2<90% (min)	14.5±5.8	4.3±1.6	7.9±3.4	0.009*	0.022*	0.043*
TAI (events/h of TST)	22.3±4.9	18.1±2.1	20.8±2.8	0.044*	0.106	0.127
Sleep efficiency (TST/TIB) (%)	77.5±4.2	75.2±3.6	75.9±3.9	0.468	0.485	0.715

AHI: apnoea-hypopnoea index; TST: total sleep time; ODI4%: oxygen desaturation index >4%; SpO2: peripheral oxygen saturation; TAI: total arousal index; TIB: time in bed

*p<0.05

prefer OA therapy to CPAP, who do not respond to or are unsuitable for or are unable to tolerate CPAP [6]. As shown in the literature, MADs are the most commonly used oral appliance in OSAS therapy [8]. The compliance rates for MAD are higher than those for CPAPs [17], and they are used on average 1.1 hours a night more than CPAPs [18]. Although MADs are more effective than other types of OAs in treating OSAS [19], it has been emphasized that the design features of the various appliances may have an impact on treatment efficacy [12], so this study aimed to evaluate the objective and subjective efficacy of a monoblock MAD and a twinblock MAD.

The results of this study showed that both MADs proved to be effective in improving objective PSG parameters. These findings are supported by other studies showing a reduction, for the MADs, in several PSG parameters such as AHI scores, arousals during sleep and oxygen desaturation when compared with placebo treatments [20,21].

Moreover, we also showed that the monoblock MAD has proven to be more efficacious than the twinblock as it reduced 4 out of 6 PSG parameters (AHI, ODI4%, total duration with SpO2<90% and TAI) whereas the twinblock only reduced 3 out of 6 (AHI, ODI4% and total duration with SpO2<90%) with also a lighter extent of improvement compared to monoblock treatment. Indeed, when the reduction in PSG parameters was compared between the two MADs, AHI, ODI4% and total duration with SpO2<90% were found to be reduced in favor of the monoblock treatment. This is in contrast to previous findings indicating no difference in any PSG indicators when a one-piece MAD was compared to a two-piece MAD [22].

The evidence for treatment efficacy on OSAS patients' quality of life is not clear, some studies report improvements in quality of life after treatment with MADs [23,24], however, in others no effect was reported [25,26].

This study showed similar levels of improvement of patients' quality of life for both MADs, as demonstrated by the increment in total SAQLI score from baseline. Our findings are in agreement with the results of Lam *et al.* [27], where 34 patients

showed a significant improvement in total SAQLI scores after ten weeks of treatment with MADs. When comparing the two MADs, we have not found any difference in SAQLI score between the two devices but, in this case, a comparison of findings of the present study to other literature was not possible because there is no study that compared two MADs and utilized the SAQLI to evaluate the impact on QoL.

Excessive daytime sleepiness is experienced by many patients with OSAS. Treatment of OSAS with MADs has shown to reduce daytime sleepiness [21]. This study showed that the monoblock and the twinblock MAD both reduced ESS scores significantly, but when comparing the efficacy of the two MADs, no significant difference was found in ESS scores. Similar results have been found by other studies [22,28].

The findings of this study must be interpreted in light of some limitations. This study applied a short-term design (about six months) so it is not sufficient in length to monitor the efficacy of MAD therapy in the long-term as OSAS has been shown to deteriorate and MAD efficacy may deteriorate with long-term use. Longer follows up assessments are needed to investigate this. Moreover, improving PSG indices and subjective outcomes may depend on a variety of factors ranging from the severity of OSAS, level of advancement and patient satisfaction. It would be interesting to investigate how these factors may affect our results.

In this study, the efficacy of two differently designed MADs in the treatment of OSA was shown in terms of clinical and subjective outcomes, with a significantly better result for the monoblock MAD in comparison with the twinblock MAD. Long-term follow up assessments would be useful to confirm the continued efficacy of MAD therapy for OSAS.

Conflict of interests

The authors have no financial or personal relations that could pose a conflict of interest.

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