Efficacy of custom-made mandibular advancement appliance on patients with obstructive sleep apnea: A prospective clinical trial

Parul Agarwal, Padma Ariga, Ashish R. Jain*

ABSTRACT

Background: Sleep apnea obstructive sleep apnea (OSA) is defined as frequent episodes of apnea and hypopnea and functional impairment. OSA treatment options are the use of oral appliance (OAs) in mild-to-moderate cases and use of continuous positive airway pressure or surgery in cases of severe sleep apnea. However, their efficacy in the treatment of OSA is questionable. Aim: The aim of this study was to evaluate the efficacy of OAs in patients diagnosed with severe OSA.

Materials and Methods: Seventeen individuals (13 males and 4 females) with age of patient 26.27 ± 2.66; apnea-hypopnea index (AHI) 47.35 ± 7.92 events/h, and mean body mass index 29.42 ± 5.67 were enrolled for the clinical trial. The patients had to wear a custom-made mandibular advancement device for 1 month. Out of 17, 15 subjects completed the protocol, 2 individuals with AHI levels 50.1 and 37.1 were unable to tolerate the device and withdrew from the study. Results: The MAA resulted in a reduction of baseline AHI index in 14 out of 15 individuals (93.3%). The mean AHI index reduced from 47.35 ± 7.92 to 23.03 ± 13.62, which is statistically highly significant (P < 0.001). The subjective outcome with Epworth sleepiness scale (ESS) score reduced for 13 out of 15 patients (87%). The baseline ESS score also reduced after 1 month of the study which was statistically significant (P < 0.007). Conclusion: Continued wear of OAs brings down the AHI from severe to mild or moderate OSA reducing the incidence of systemic complication and improving the quality of life of these patients.

KEY WORDS: Custom, Hypopnea, Mandibular appliance, Sleep apnea

INTRODUCTION

“Sleep disorder breathing” (SDB) is a term which includes simple snoring, upper airway resistance syndrome, and sleep apnea. Sleep apnea is clinically defined as frequent episodes of apnea (cessations) and hypopnea (discrete reductions) and symptoms of functional impairment, which could be life-threatening and associated with extreme daytime hypersomnolence, dysfunction, discrements in health-related quality of life, automobile accidents, and cardiovascular morbidity and mortality. Sleep apnea is the most prevalent of all the upper airway disorders and is classified as central, obstructive, and mixed. Obstructive sleep apnea (OSA) which may be mild, moderate, or severe is a disorder characterized by repetitive collapse and reopening of the upper airway during sleep, which impairs ventilation and can result in intermittent hypoxemia and hypercapnia. Etiopathogenic factors that contribute to OSA include reduced upper airway dilator muscle activity during sleep, upper airway anatomical features, ventilatory control insufficiency, lung volume, and rostral fluid shifts. Age, gender, and obesity are interrelated in a complex manner and considered to be risk factors for incidence of OSA. Early recognition and appropriate therapy could ameliorate the neurobehavioral consequences. Cardinal manifestations include loud snoring, witnessed breathing pauses during sleep, fitful sleep quality, fatigue, dry mouth, morning headache, and excessive daytime sleepiness. The cutoff value of body mass index (BMI) for obesity in the Caucasian populations is at 30 kg/m², but some Asian-Indian populations have redefined obesity at a lower BMI of 23 kg/m² for both the sexes. The World Health Organization (WHO) task force on obesity suggested that Asian-Indian populations have different associations between BMI, percentage of body fat, and health risks than do Caucasians (WHO, 2000). Clinically, neck circumference has been reported to be a useful predictor of OSA.

Access this article online

Website: jprsolutions.info  ISSN: 0975-7619

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Received on: 05-03-2018; Revised on: 20-04-2018; Accepted on: 25-05-2018
Anatomic factors which predispose to the development of OSA include the size of the tongue and craniofacial morphology. In adult snorers and OSA patients, there is a good correlation between clinical tonsil grade and objective tonsil volume.[15] According to Nuckton et al., the Mallampati score is an independent predictor of OSA and its severity. Polysomnography is a current gold standard diagnostic aid for SDB. It provides data on respiratory effort, airflow, sleep state, and other variables. A dentist plays a vital role in the recognition and management of the sleep disorders. The various treatment options include weight loss, oral appliances (OAs), nasal continuous positive airway pressure (CPAP), and uvulopalatopharyngoplasty. While the gold standard of care combines conservative modalities such as weight loss and nasal CPAP, interest in oral devices has been increasing possibly because of compliance difficulties with CPAP.[15-18]

Currently available treatment modalities in OSA include OAs devices, which increase pharyngeal space by protruding the mandible and advancing the tongue thereby preventing pharyngeal collapse. The American Academy of Sleep Medicine Practice Parameters recommend the use of OAs as an alternative to CPAP for patients who prefer OAs or refuse or are unable to tolerate CPAP, particularly in mild-to-moderate OSA. Most commonly used OAs are the mandibular advancement appliance (MAA) and the tongue retainers. These devices lower the tongue position, reduce the mandibular plane to hyoid distance, advance the mandible, and widen the upper oropharyngeal space (retropalatal and retroglossal). Tongue retainers affect the genioglossus muscle activity in patients with OSA, but the effect on upper airway muscle activity is not clear. Studies have indicated that OAs are less effective than CPAP in overcoming the respiratory disturbance and can cause discomfort but they are inexpensive, are well accepted by the patients and the side effects such as muscle and TMJ discomfort are reversible.[19]

The preliminary subjective evaluation was done with the Epworth sleepiness scale (ESS), and the objective evaluation was done by a four-channel study which recorded the apnea-hypopnea index (AHI) of the subject.[20] The aim of the study was to estimate the efficacy of a custom made OA for the treatment of OSA in subjects diagnosed with severe OSA.

Null hypothesis: OAs are not effective in the treatment of patients with severe OSA.

Alternative hypothesis: OAs are effective in the treatment of patients with severe OSA.

MATERIALS AND METHODS

The subjects for this prospective clinical trial consisted of 17 adults, 13 males and 4 females. The subjects were referred from the Department of Prosthodontics of Saveetha Dental College and a private sleep clinic over a period of 12 months for construction of MAA. All of them had been previously assessed with regard to the sleep-related breathing disorder to establish a diagnosis of mild, moderate, or severe OSA. Ethical approval of the research was obtained from the Research Ethics Committee. Basic demographic data, details of medical and dental history were recorded. The individual’s height and weight were measured, and BMI was calculated using the method described by Revicki and Israel. The neck circumference of each individual was measured at the level of cricothyroid membrane and used in conjunction with patient’s height to calculate the percentage of normal neck circumference. Individuals with the age group of 20–40 years and with severe sleep apnea were included in the study. Patients suffering from systemic diseases such as hypothyroidism, recent myocardial infarction, congestive heart failure, pregnant women or those with inadequate number of teeth to support the appliance, edentulous patients or those who have got the upper airway surgery were excluded from the study. Twenty-one out of forty-eight referrals were included in the study. Four of them dropped out of the study due to time limitations and non-attendance. Seventeen patients were included in both the questionnaire and the four-channel sleep study. Ages of patients ranged from 20 to 30 years. With mean age 26.27 ± 2.66 and mean BMI 29.42 ± 5.67 indicating that 4 subjects were overweight (BMI >23) and 9 subjects were obese (BMI >28). After obtaining informed consent from the participants, the following baseline data were collected before treatment procedures - ESS and results from an overnight domiciliary sleep study (four-channel study). Patients with an AHI index of 30–60 were included in the study. The mandibular advancement device was custom made for each participant. The participants wore the appliance for 1 month and postoperative values were recorded again.[20] Of 17 individuals were unable to tolerate the dental appliance and withdrew from the study. Fifteen individuals completed the protocol.

FABRICATION OF THE APPLIANCE

Primary impressions were made with irreversible hydrocolloid material - alginate impression material (Tulip, Cavex). Diagnostic casts were obtained and face-bow transfer completed. Maxillary casts were mounted. Interocclusal records were made at centric and 75% of the maximum protrusive position with the help of bite registration paste (O - bite, DMG) [Figures 1-3]. Mandibular casts were then mounted...
to the articulator with the protrusive interocclusal record. Thermoplastic sheets (Duran, Scheu dental) (0.75 × 125 mm) were adapted to the maxillary and mandibular casts and an expansion screw (hyrax) was positioned on the maxillary cast. The mandibular arch sheet had a retentive element to position the appliance at the desired protrusion to be worn overnight [Figures 4 and 5]. Patients were instructed to wear the appliance overnight every day and report after 1 week and 1 month for a follow-up [Figure 6]. After 1 month, the patients were asked to fill the ESS questionnaire again. Following this, they were subjected to objective evaluation with the four-channel study. The posttreatment ESS score and

Figure 1: Bite registration

Figure 2: Ice cream stick with centric (C) and maximum protrusion (MP) markings

Figure 3: Interocclusal record made at 75% protrusion with bite registration paste

Figure 4: Custom-made mandibular advancement appliance adapted on the maxillary cast

Figure 5: Custom-made mandibular advancement appliance adapted on the mandibular cast

Figure 6: Mandibular advancement appliance in the patient’s mouth (closer view)
the AHI index were compared with the pretreatment values.

RESULTS

Seventeen individuals (13 males, 4 females; age 26.27 ± 2.66; AHI 47.35 ± 7.92 events/h, BMI 29.42 ± 5.67) were enrolled for the clinical trial. The patients had to wear a custom-made mandibular advancement device for 1 month. Fifteen individuals completed the protocol. Two individuals were unable to tolerate the device and withdrew from the study.

Primary Outcome

The MAA resulted in partial response (8 individuals) and complete response (6 individuals) in 14 out of 15 individuals (93.3%). The mean AHI index reduced from 47.35 ± 7.92 to 23.03 ± 13.62. The reduction is almost half of the baseline value. The mean reduction is statistically highly significant (P < 0.001). However, the AHI value increased for 1 subject [Table 1].

Secondary Outcome

The baseline ESS score reduced after 1 month of the study. The proportion of reduction was statistically significant (P = 0.007). The baseline ESS score “1” was observed in 10 patients and it reduced to “0” (80%) after 1 month. It remained the same for 2 patients (20%). The baseline ESS score “2” was observed in 5 patients and all of them (100%) reduced to score “1” after a month. The overall ESS score reduced for 13 out of 15 patients (87%) [Table 2].

Primary and Secondary Outcomes

It was also observed that both AHI index and ESS scores reduced for 12 patients (80%) after 1 month of the study [Tables 3-5].

Table 1: Paired t-test to compare baseline and postoperative mean scores

<table>
<thead>
<tr>
<th>AHI index</th>
<th>n</th>
<th>Mean±SD</th>
<th>t-value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>15</td>
<td>47.35±7.92</td>
<td>5.861</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-operative</td>
<td>15</td>
<td>23.03±13.62</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AHI: Apnea–hypopnea index, SD: Standard deviation

Table 2: Chi-square test to compare pre- and post-operative ESS scores

<table>
<thead>
<tr>
<th>Post-operative ESS score</th>
<th>Total</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>1</td>
<td>8 (80.0)</td>
<td>2 (20.0)</td>
</tr>
<tr>
<td>2</td>
<td>0 (0.0)</td>
<td>5 (100.0)</td>
</tr>
<tr>
<td>Total</td>
<td>8 (53.3)</td>
<td>7 (46.7)</td>
</tr>
</tbody>
</table>

*Fisher’s exact test. ESS: Epworth sleepiness scale

DISCUSSION

OAs are a simpler alternative to CPAP for the treatment of moderate-to-severe OSA patients. They are often considered to be a more acceptable treatment modality compared to CPAP, as they are quiet, portable, and do not require a power source. In this study, when the subjective evaluation was done with an ESS, the baseline score reduced for 87% of the individuals. This proportion of reduction is highly significant (P = 0.007) which is in agreement with a study done by Johns and Chan, who concluded that there was an improvement in the ESS score of the patients with the CPAP, and a placebo.[21] Although the magnitude of this effect was comparable to that of treatment with CPAP, another study found that the treatment with CPAP was superior. On comparison of a custom-made device with a thermoplastic device, it was concluded that the former device turned out to be more effective than a thermoplastic device in the treatment of OSA.

When the objective evaluation after wearing the OA was done using a four-channel study which measures the AHI, pulse oximetry, and heart rate during sleep, there was a statistically significant (P < 0.001) amount of reduction in the AHI index of the subjects. The mean AHI index reduced from 47.35 ± 7.92 to 23.03 ± 13.62. Although the AHI reduced from severe to mild or moderate levels for 93.3% of the subjects, one subject showed an increase in the AHI index (from 39.5 to 50). This is in agreement with studies done by Johnston et al. and Atul Mehta who concluded that the MAA was more effective in reducing the frequency

Table 3: Proportion of reduction in AHI Index in postoperative

<table>
<thead>
<tr>
<th>Reduction in AHI</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Yes</td>
<td>14 (93.3)</td>
</tr>
<tr>
<td>Total</td>
<td>15 (100.0)</td>
</tr>
</tbody>
</table>

AHI: Apnea-hypopnea index

Table 4: Proportion of reduction in ESS score in postoperative

<table>
<thead>
<tr>
<th>Reduction in ESS score</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Yes</td>
<td>13 (86.7)</td>
</tr>
<tr>
<td>Total</td>
<td>15 (100.0)</td>
</tr>
</tbody>
</table>

ESS: Epworth sleepiness scale

Table 5: Proportion of reduction in both AHI and ESS score in postoperative

<table>
<thead>
<tr>
<th>Reduction in both AHI index and ESS score</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>12 (80.0)</td>
</tr>
<tr>
<td>Total</td>
<td>15 (100.0)</td>
</tr>
</tbody>
</table>

AHI: Apnea-hypopnea index, ESS: Epworth sleepiness scale
and loudness of snoring, the reported daytime sleepiness and the frequency of morning tiredness in patients with severe sleep apnea. Lam B concluded that the OAs reduce the severity of sleep apnea, and the effect is maintained for 1 year in subjects with retrognathism. It was also observed that both AHI index and ESS scores reduced for 12 patients (80%) after 1 month of the study. This is in agreement with the study done by Tan, according to which the subjective and objective scores reduced significantly with the mandibular advancement splints (MAS) and there was not much statistical difference between the results obtained by CPAP and the MAA. On comparison of MAS with a tongue stabilizing device (TSD), the ESS score and AHI index reduced significantly with the MAS compared to the TSD.

Although the exact mechanisms are unknown, differences in obesity, upper airway anatomy, breathing control, hormones, and aging are all thought to play a role in response to OAs. The selection of the type of OAs depends on the level of obstruction – retropharyngeal or retroglossal. The precise level of obstruction can be evaluated by using a CT scan or an MRI. In retropharyngeal obstruction, soft palate lifters are indicated whereas OAs are indicated for the patients with retroglossal obstruction. These appliances enlarge the anteroposterior diameter of the retroglossal space and thus reduce pharyngeal collapse. Of particular interest in this context are MAA, which are capable of advancing the lower jaw. These anatomic changes are not uniformly seen in all patients, and this may explain the differences in the treatment response. Rodenstein et al. showed that in patients with OSA, the long axis of the pharyngeal cross-section may lie in the sagittal plane rather than in the coronary plane. As a result, forward protrusion of the mandible may even diminish the size of the retroglossal space. This might explain the increase in the AHI index after wearing the OA in one individual in the present study.

On comparison among the various types of OAs, Herbst MAA proved to be more effective and popular than a twin - block appliance for reducing daytime sleepiness. When two different MAAs (a single piece and a 2-piece appliance) were compared, there was a reduction in AHI to <10/h in 88% of the patients who used 2-piece appliance.

The modification of the health risk associated with OSA is a key goal of the treatment. Cardiovascular outcomes represent an important measure of the clinical impact of the treatment for OSA. The degree of oxygen desaturation during each obstructive apnea has been directly related to the magnitude of the increase in the blood pressure (BP) following the apnea. Hypoxia during the obstructive apneas may directly depress cardiac contractility, or reduce cardiac performance indirectly by causing pulmonary vasoconstriction and increasing pulmonary arterial pressure. In the present study, the individuals were young individuals (Age 26.27 ± 2.66) and no change was noticed in the BP of the subjects after wearing the OA. Gotsopoulos and Barnes assessed the effect of OA treatment on BP. Both studies showed a modest reduction in the 24-h BP (2–4 mm of Hg) over a period of 1 month and 3 months. OA also reduced the systolic BP in hypertensive OSA subjects at 3 months and 1 year. Hence, OAs are effective in reducing the probable cardiovascular health risks in the patients.

The effect of OA treatment on neuropsychological functioning has been examined in studies using inactive oral devices placebo tablets and CPAP as a comparison. A small-to-moderate improvement in psychomotor speed was found after treatment for 1 month with an OA, but there was no change in the other aspects of neuropsychological functioning. Comparisons of effects of OAs and CPAP on neuropsychological functioning are conflicting. Although no differences were reported in one study, another study found that the OAs and CPAP had differing effects on a range of neuropsychological parameters. However, more research in this field is required.

Although CPAP is considered as the gold standard in the treatment of OSA, there was no statistical difference noticed between the two treatment options - MAA and the CPAP in a randomized controlled trial. Clark et al. found a reduction in the respirator disturbance of 39% with an “anterior mandibular positioning device” and 50% with CPAP. Although a clearly greater improvement in the respiratory disturbances was seen with CPAP, no relevant disturbances were observed between the two modalities in terms of sleep profile, and there was no improvement versus baseline in sleep profile. With regard to compliance, the OAs also proved to be clearly superior to CPAP treatment. On the basis of these data, the use of MAAs is recommended in severe OSA cases if the patients refuse CPAP or surgical options.

The small number of females in the study precluded any meaningful comparisons between males and females. Although the prevalence of sleep-disordered breathing in men (24%) is almost three times higher than in the women (9%), there is no published evidence to indicate that MAA treatment response is influenced by patient gender.

The limitations of the OAs need to be considered when making the treatment decisions. OAs have no known effect on central sleep apnea and hypoventilation. When an immediate treatment response is required (e.g. when driver safety or occupational safety issues...
exist), an OA would be inappropriate as the period of acclimatization would cause unnecessary delay. Similarly, if marked oxygen desaturation occurs during sleep, CPAP would be more appropriate given its superiority in improving oxygen saturation. On applying the outcome criteria, a complete response (reduction of the AHI to <5 events/hr) can be expected in approximately 35–40% of the patients and a partial response (≥50% reduction in AHI compared to baseline, but residual AHI remaining >5 events per hour) in 25% of the patients which is in agreement with this study where the partial response was noticed in 8 out of 15 subjects (53%) and complete response was noticed in 6 patients (40%). Approximately two-thirds of the patients can expect a clinically important response to OA treatment.

Reported long-term adverse effects of the OAs are a reduction in overjet, increase in the facial height, increase in the degree of mouth opening, changes in the inclination of incisors and increase in the mandibular plane angle. However, it has been proved through the longitudinal studies that these changes occur over a period of 7 years. It was suggested that the likelihood of these long-term occlusal changes can be predicted by the pre-treatment dental characteristics. A smaller change in overjet (<1 mm) at follow-up was more common in those who had a baseline overbite of >3 mm, an overjet of <3 mm, or in those who had used a soft elastomeric device rather than a hard acrylic device.

**CONCLUSION**

Within the limitation of the study, it can be concluded that the continued wear of OAs brings down the AHI from severe to mild or moderate OSA reducing the incidence of systemic complication and improving the quality of life of these patients.

**REFERENCES**


Source of support: Nil; Conflict of interest: None Declared