ABSTRACT

Background: Obstructive sleep apnea (OSA) is a common sleep disorder, associated with disturbed nocturnal oxygenation profile and altered sleep structure, associated with significant health problems. Oral appliances (OA) are used as an alternative therapeutic option for patients with mild to moderate OSA. Although the application of OA does not always result in a complete resolution of the sleep-disordered breathing, greater patient adherence is demonstrated. We have decided to evaluate the effect of individually constructed OA on sleep disordered breathing and sleep structure in patients with OSA.

Materials and methods: 20 patients (18 men) with OSA (age 46.3±8.1 years (mean±SD), body mass index 29.0±4.8 kg.m⁻²) were subjected to a full-night polysomnography (PSG), at baseline and one month after the introduction of an OA.

Results: A significant decrease in AHI (33.4±31.1 vs 45.5±30.8, p<0.001), hypopnea index (10.3±9.1 vs 18.2±11.0, p=0.023), mean duration of apneas (20.9±6.9 vs 24.1±6.4 sec, p=0.005) and average desaturation (5.6±2.4 vs 8.5±3.0 %, p<0.001), after therapy and at baseline, respectively, was registered. Sleep structure was improved as indicated by an increase in REM (16.1±6.2 vs 12.3±8.2 % of total sleep time, p=0.016) and a decrease in arousal index (31.0±14.2 vs 46.4±12.0, p<0.001).

Conclusion: OA is a reasonable alternative for the treatment of patients with moderate and severe OSA, resulting in an improvement of the polysomnographic parameters and expressed by excellent patient compliance.

Keywords: oral appliance, obstructive sleep apnea, polysomnography.

INTRODUCTION

Obstructive sleep apnea (OSA) is a common sleep disorder, characterized by repetitive complete (apneas) or partial (hypopneas) cessations of breathing during sleep, resulting in disturbed nocturnal oxygenation profile and altered sleep structure [1]. If left untreated, OSA is known to be associated with significant health problems, such as an increased risk of cardiovascular and cerebrovascular incidents [2, 3, 4].

The management of OSA includes a variety of options, depending on the severity of symptoms and etiology of the obstruction, which range from conservative measures such as weight reduction, change in the sleep position, avoidance of alcohol and surgical ones, like uvulopalatopharyngoplasty, tracheostomy or maxillo-facial surgery. Therapy via positive pressure in the airways (continuous positive airway pressure, CPAP) is currently accepted as being the „golden standard“ for the treatment of moderate and severe OSA, demonstrating high efficiency in eliminating the respiratory events and assuring a good prevention of the negative consequences of this condition [5], however sometimes being limited by low patient compliance [6]. Oral appliances (OA) are considered the main alternative therapeutic option for patients with mild to moderate OSA [7, 8, 9]. Oral appliances (OAs) are indicated as a primary treatment option for snoring and mild to moderate obstructive sleep apnea (OSA) and are also being implemented as a noninvasive alternative for patients with severe OSA who are unwilling or unable to tolerate continuous positive airway pressure (CPAP) for the management of their disease [10]. Therefore, OAs play an important role in the therapy for patients with OSA. There is continued emergence of studies demonstrating the ability of OAs to eliminate or significantly reduce the symptoms of OSA and produce a measurable influence on the long-term health effects of the disease [11]. OA advance the mandible and the tongue, thus increasing the oropharyngeal space and improving upper airway patency during sleep. Although as compared to CPAP, OA does not always result in a complete resolution of the sleep-disordered breathing [12, 13], greater patient adherence is demonstrated [14]. However, no prediction on the therapeutic effect with OA is possible, despite the fact that several studies have established some parameters, such as younger age, low BMI, small neck circumference, low baseline AHI, to be associated with a higher treatment success [15].

Therefore, the aim of our study was to elaborate individually constructed OA in patients with diagnosed OSA.
and evaluate the therapeutic effect in terms of reduction of breathing disturbances and sleep structure.

MATERIALS AND METHODS

Twenty patients, diagnosed with moderate and severe OSA through a standard attended polysomnography in the Sleep Laboratory of Pathophysiology Department, Medical University Plovdiv, who have signed an informed consent form and met the inclusion criteria (age>18years, AHI>15/h, at least two OSA symptoms (e.g. snoring, witnessed apneas during sleep, excessive daytime sleepiness, morning headaches), were enrolled in the study.

Oral appliances (OA)

An extensive dental examination, including extra- and intraoral exploration of the anatomical structures and features, was performed by a dentist in the Department of Prosthetic Dentistry, Faculty of Dental Medicine, Medical University Plovdiv.

Upper and lower teeth jaws were fixed, and impressions of the teeth rows in the upper and lower jaws were made (Fig. 1). The position of the lower jaw was fixed to the frontal plane at 75% of the maximum protrusive position, aiming at keeping the anatomical resources in the temporomandibular joints (TMJ), thus preventing any overload.

Fig. 1. Impressions of the teeth rows of the upper and the lower jaw.

The fixation of the mandible position was performed by means of George Gauge (Fig. 2), which allowed absolute accuracy in determining the protrusive position of the lower jaw. Bite silicone impression materials were applied on the intraoral part of the George Gauge. The impressions taken from both of the jaws and the bite position were delivered to the dental laboratory for pouring plaster models and fixing them into the occludator (Fig. 3). The intraoral device was planned and assembled according to the type of the retention elements, borders of the resin base and facial antireflective barriers.

Fig. 2. Determination of the mandible position using George gauge.

Fig. 3. Fixation of the lower and the upper plaster models.

The device was additionally adjusted by being carefully inserted first on the lower jaw and after that the patient was asked to close the teeth in the position already determined. The appliance was finally placed by connecting the upper and lower jaw in the protruding position, maintaining the desired maxillomandibular relationship of the patient (Fig.4).
The patients were advised to wear the OA every night for the whole sleep period, and a polysomnographic study was made at baseline (before OA) and one month after the introduction of the device to evaluate the change of the sleep variables.

Polysomnographic study

Standard full-night polysomnography was performed with a computerized system (Embla Titanium, Embla, Ottawa, Ontario, Canada) at baseline and one month after the use of the OA. Subsequent manual analysis of sleep staging and breathing disturbances was done in concordance with the latest recommendations of the American Academy of Sleep Medicine (AASM) [16, 17]. Oronasal airflow was registered by oronasal cannula (PureFlow, Braebon, Ontario, Canada). Respiratory effort was registered with thoracic and abdominal respiratory inductance plethysmography (RIP) belts. Pulse transit time (PTT) and blood oxygen saturation (SpO2) were obtained by Nonin 3012 finger pulse oximeter (Nonin, Plymouth, Minnesota, USA).

Apnoeas were defined as a decrease in the oronasal airflow ≥ 90% for > 10 sec. Hypopneas were scored if there was ≥ 30% reduction of the baseline oronasal airflow for > 10 sec with a consecutive decrease in SpO2 > 3% or arousal. Apnea-hypopnea index (number of apneas and hypopneas per hour of sleep) > 5 was used to diagnose sleep apnea.

Statistical analysis

Statistical analysis was performed using specialized statistical software SPSS v17.0 and Microsoft Excel. Normality of distribution was tested by Kolmogorov-Smirnov test. Independent sample t-test was used to compare normally distributed data.

RESULTS

Overall 20 patients (18 men, 2 women) completed the study protocol. The mean (±SD) anthropometric parameters of the whole group are presented in Table 1.

Table 1. Main anthropometric parameters of the study group as measured at the baseline visit

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>46.3±8.1</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>1.8±0.01</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>88.8±13.8</td>
</tr>
<tr>
<td>BMI (kg.m⁻²)</td>
<td>29.0±4.8</td>
</tr>
</tbody>
</table>

Legend: BMI – body mass index

The mean values of the respiratory and sleep parameters of the two polysomnographic recordings (at baseline and 1 month after OA use) are presented in Table 2.
Table 2. A comparison between the main polysomnographic parameters of the whole group (n=20) before and after treatment with OA.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Baseline (Mean±SD)</th>
<th>Oral Appliance (Mean±SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRT (min)</td>
<td>386.0±122.5</td>
<td>467.9±73.9</td>
<td>.002</td>
</tr>
<tr>
<td>TST (min)</td>
<td>307.3±126.2</td>
<td>372.8±70.5</td>
<td>.004</td>
</tr>
<tr>
<td>Latency (min)</td>
<td>26.8±18.1</td>
<td>24.7±14.6</td>
<td>.409</td>
</tr>
<tr>
<td>N1%</td>
<td>5.5±2.3</td>
<td>4.9±4.3</td>
<td>.534</td>
</tr>
<tr>
<td>N2%</td>
<td>65.7±13.3</td>
<td>62.7±11.9</td>
<td>.088</td>
</tr>
<tr>
<td>N3%</td>
<td>16.5±13.0</td>
<td>16.2±11.1</td>
<td>.786</td>
</tr>
<tr>
<td>REM%</td>
<td>12.3±8.2</td>
<td>16.1±6.2</td>
<td>.016</td>
</tr>
<tr>
<td>Awakenings</td>
<td>22.0±10.2</td>
<td>31.8±23.2</td>
<td>.050</td>
</tr>
<tr>
<td>WASO</td>
<td>51.9±22.7</td>
<td>70.5±32.8</td>
<td>.028</td>
</tr>
<tr>
<td>AHI</td>
<td>45.5±30.8</td>
<td>33.4±31.1</td>
<td>.001</td>
</tr>
<tr>
<td>AHINREM</td>
<td>44.0±30.9</td>
<td>30.8±32.8</td>
<td>.001</td>
</tr>
<tr>
<td>AHIREM</td>
<td>52.7±32.4</td>
<td>39.6±24.4</td>
<td>.036</td>
</tr>
<tr>
<td>AI</td>
<td>27.3±28.3</td>
<td>23.1±29.1</td>
<td>.159</td>
</tr>
<tr>
<td>HI</td>
<td>18.2±11.0</td>
<td>10.3±9.1</td>
<td>.023</td>
</tr>
<tr>
<td>ApMeanDur</td>
<td>24.1±6.4</td>
<td>20.9±6.9</td>
<td>.005</td>
</tr>
<tr>
<td>HypoMeanDur</td>
<td>32.1±5.8</td>
<td>27.9±7.4</td>
<td>.042</td>
</tr>
<tr>
<td>ArIndex</td>
<td>46.4±12.0</td>
<td>31.0±14.2</td>
<td>.000</td>
</tr>
<tr>
<td>SpO2mean</td>
<td>92.9±1.8</td>
<td>93.5±1.9</td>
<td>.011</td>
</tr>
<tr>
<td>SpO2nadir</td>
<td>77.9±7.3</td>
<td>79.9±7.0</td>
<td>.126</td>
</tr>
<tr>
<td>SpO2desatav</td>
<td>8.5±3.0</td>
<td>5.6±2.4</td>
<td>.000</td>
</tr>
<tr>
<td>HRmin</td>
<td>51.4±6.2</td>
<td>52.5±7.2</td>
<td>.437</td>
</tr>
<tr>
<td>HRmax</td>
<td>92.0±13.4</td>
<td>96.7±9.7</td>
<td>.054</td>
</tr>
<tr>
<td>Haverage</td>
<td>67.0±8.5</td>
<td>65.8±9.3</td>
<td>.253</td>
</tr>
</tbody>
</table>

Legend: TRT - total recording time; TST - total sleep time; Latency - time until falling asleep; N1% - N1 sleep stage (percentage of time spent in sleep); N2% - N2 sleep stage (percentage of time spent in sleep); N3% - N3 sleep stage (percentage of time spent in sleep); REM% - REM sleep stage (percentage of time spent in sleep); WASO – wake after sleep onset; SleepEff - sleep efficiency; AHI(NREM/REM) - apnea-hypopnea index (inNREM/REM sleep); AI - apnea index; HI - hypopnea index; ApMeanDur - mean duration of apneas; HypoMeanDur - mean duration of hypopneas; ArIndex - arousal index; SpO2mean - mean oxygen saturation; SpO2nadir - lowest oxygen saturation;

In the majority of cases, patients were diagnosed with severe OSA, based on baseline AHI values. The group presented with a disrupted sleep structure, represented by a prolonged sleep latency, decreased amount of deep and REM sleep, as well as increased number of awakenings during the night. The breathing disturbances included apneas and hypopneas, apneas being slightly prevalent during the diagnostic night. When OA was applied, a considerable increase in the TST was recorded, however, an increased number of awakenings during the night was registered, without any change in the sleep latency. Sleep structure was considerably improved, presenting with an increased amount of REM sleep (Fig. 7). AHI was significantly decreased with OA, with more pronounced reduction of the breathing disturbances during NREM sleep.
For the duration of the study, few patients reported mild and non-significant side effects after the introduction of the OA. These included excessive salivation (n=4) and transient discomfort or pain in the TMJ (n=6), which did not influence the overall compliance.

**DISCUSSION**

The specific design of the OA may possibly determine the degree of advancement of the mandible and therefore influence clinical efficacy and patient compliance. The results from our study demonstrate that OA set at 75% of the maximum protrusion capacity show satisfactory therapeutic effect. Although we did not investigate other protrusion positions, our results are consistent with other studies, which report "dose" dependent effect and best improvement of the condition at either 50% or 75% advancement of the mandible [18, 19, 20].

Several non-randomized uncontrolled studies report either normalization or a considerable reduction of AHI after the introduction of OA [21, 22, 23]. In a randomized study, Walker-Engström et al. found a mean normalization rate of 45% and compliance of 92% in a patient population of 77 OSA patients. Our results are in line with those cited, demonstrating a significant decrease in the number of respiratory events, as expressed by the AHI (33.4±31.1 vs 45.5±30.8, p<0.001, after therapy and at baseline, respectively), confirming the statement that OA could be a reasonable alternative for the treatment of patients with moderate and severe OSA. What is more, we found a significant curtailment of the mean residual apnea (20.9±6.9 vs 24.1±6.4sec, p=0.005) and hypopnea (27.9±7.4 vs 32.1±5.8 sec, p=0.042) duration and the associated changes of the oxygen saturation (Tabl. 2).

Our results showed a significant decrease in hypopneas with no effect on the apnea index. However, this does not necessarily mean that apneas are not affected by the oral appliance. We may speculate that the apneas were "reduced" to hypopneas and the hypopneas were successfully treated. Furthermore, the apnea length was decreased, which proves the device affects the apneas as well. On the other hand, Walker-Engström et al. reported a significant reduction in the apnea index (73.5±4.4) vs 9.4±5.0), p<0.001) after a 6-month follow up with 75% advancement of the device [24]. These results suggest that the longer duration of the OA use may lead to a further improvement of the respiratory parameters. Since treatment with the dental device is a persisting process, more long-term follow-ups are needed in order to establish the real therapeutic effects.

The use of the oral appliance has led to an increase in the percentage of REM sleep stage. This finding, combined with the decreased arousal index, resulted in an improved structure of nocturnal sleep and was in line with the reported resolution of the subjective sleepiness and a description of better sleep quality by the patients. Walker-Engström et al. found a significant decrease of excessive daytime sleepiness at baseline and at the 6-months follow-up, which weakly correlated with changes in the AHI of the group [24]. On the contrary, Aarab et al. reported a non-significant increase of REM sleep, but a considerable reduction in the number of respiratory arousals and almost no improvement of the daytime sleepiness in their group of OSA patients [18]. Similar results of persisting daytime somnolence were demonstrated in the studies of Engelman et al. [25] and Neill et al. [26]. These conflicting results could be explained by the fact that the assessment of sleepiness by means of a questionnaire is not a reliable method,

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**Fig. 7. Effect of the OA on the sleep efficiency and sleep structure in patients with OSA**

Legend: N1 sleep stage (percentage of time spent in sleep); N2% - N2 sleep stage (percentage of time spent in sleep); N3% - N3 sleep stage (percentage of time spent in sleep); REM% - REM sleep stage (percentage of time spent in sleep); SleepEff – sleep efficiency
but also that the improvement of the condition in our study, could be due to a “placebo effect”.

Side effects, related to OA use are not infrequently reported [27]. They are usually described as mild and transient, resolve with OA use and include the following: TMJ pain and locking, headache [24], excessive salivation, xerostomia [28]. The side effects, reported by the patients in the present study were minor and did not affect the overall compliance with the therapy.

CONCLUSION:
OA is a reasonable alternative for the treatment of patients with moderate and severe OSA, resulting in an improvement of the polysomnographic parameters and expressed by excellent patient compliance.

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