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Decrease of respiratory events in patients with obstructive sleep apnea-hypopnea syndrome using a mandibular advancement device assessed with split night polysomnography☆

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ABSTRACT

Introduction: Mandibular advancement device (MAD) may represent a feasible choice in the treatment of obstructive sleep apnea-hypopnea syndrome (OSAHS), in well selected patients.
Objective: The aim of this study is to assess the efficacy of MAD in patients with OSAHS, using split night polysomnography (SNP)
Method: We performed an auto controlled clinical trial to assess the efficacy of MAD in 30 patients with snoring and OSAHS. Clinical evaluation was made every 2 weeks to adjust treatment and observe changes in clinical symptoms. Three-months after placement of the MAD, a SNP was performed, using the MAD in the second half of the night, in order to compare the respiratory results.
Results: SNP show significant changes with use of MAD ($p < 0.05$) such as: Decrease in Snore index (from 159.95 to 32.46/h) and in Apnea-hypopnea index (AHI, from 22.45 to 4.63/h), increase in oxygen saturation (SaO_2, from 89.98% to 91.39%) and somnolence improvement, using the Epworth Sleepiness Scale (from 14.4 to 4.6 points).
Conclusion: Our data supports that the use of MAD is an alternative in the management of OSAHS, in well selected patients, used in a multidisciplinary fashion, and evaluated using a SNP.

1. Introduction

In recent years there has been an increase in the prevalence of Sleep breathing disorders (SBD), such as snoring and Obstructive sleep apnea-hypopnea syndrome (OSAHS) in worldwide [1]. For example, a recent research study in Mexico City, the prevalence of OSAHS was 3.2% (2.4% females and 4.4% males). Similar to the prevalence observed in the America population [2]. However, not all authors had been found similar prevalence, Tufik et al., found a higher frequency of OSAHS, around 32% in one population of Sao Paulo, Brazil [3].

OSAHS has a strong predominance in overweight and obese patients, contributing to the risk of cardiovascular disease. Recent assessments have shown, first in obesity, there is an increasing the prevalence of this pathology, this has attracted the attention of physicians [4], with the recognizing of the need of a multidisciplinary management of sleep breathing disorders such as snoring and OSAHS [5–8].

The contemporary physicians have more knowledge about this condition, and in the diagnosis and in therapeutic choices, given that the treatment should be individualized for each patient. The high costs of the treatments, the lack of therapeutic adherence as well as inadequate compliance of the patients, lead them to abandon their treatment. For this reason, there is a need for therapeutic alternatives which go beyond being efficient, have lower prices, and increase the possibility of long term success in the control of snoring and OSAHS [3,7]. Among these alternatives, the Mandibular advancement device (MAD) represent a less expensive choice in the management of SBD, as they might be used as isolated treatment or along with other treatment modalities, in well selected patients, by a multidisciplinary team, including the otolaryngologist, the sleep medicine specialist and the dentist [5,6,9].

MAD are oral appliances which are adapted to each dental arch, upper and lower, and due to their shape, they displace the mandible

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forward [10]. They can be fixed or adjustable advancement, and given that the genioglossus muscle is inserted in the genni process, in the anterior aspect of the mandible, with its protrusion, the retrolingual space is increased, due to the genioglossus traction, which pulls the tongue forward, avoiding collapse [11–13].

MAD are indicated in patients with snoring and with mild/moderate sleep apnea, and in patients who do not tolerate the treatment using Continuous positive airway pressure (CPAP) devices, or those who are not good candidates for surgical management [14,15]. The obstruction area should be located at the retrolingual space. Secondary effects that some patients experience include: excessive drooling, periodontal and dental disease, muscular pain and articular discomfort. All these complaints decrease during the first 2 weeks of treatment [16–18].

MAD showed their efficacy in a number of studies [19–22] but there are few specialists who are able to manage this therapeutic alternative. For this reason, there is not enough clinical evidence about their results in several populations [23]. In many cases, MAD is not adequately indicated, for a bad selection of patients, the lack of a multidisciplinary approach, or for the lack of a proper clinical following, leading to therapeutic fail. The international medical literature regarding patients treated with MAD and assessed with this diagnostic tool is underreported.

The aim in this study, was to test the proposed multidisciplinary management of patients with OSAHS, with MAD, and an alternative evaluation for their clinical following using a split night polysomnography (SNP).

2. Methods

2.1. Subjects

This was an auto-controlled clinical trial in 30 patients with OSAHS from the Clinic of sleep disorders of the National University of Mexico (UNAM), aimed to determine the therapeutic efficacy of MAD in the management of OSAHS, using a SNP. This study was approved by the Ethics Committee of the Clinic of sleep disorders of UNAM.

Snoring and/or OSAHS patients were seen in the Otolaryngology department. During clinical consultation, the OSAHS diagnosis was made based on history, physical examination and diagnostic polysomnography (PSG) [24]. Patients who were candidates for MAD included those who had collapse at the retrolingual space, determined by examination, and the response watched on the mandibular protrusion maneuver. Patients who required management for nasal pathology were treated by the specialist. Patients were referred then to the Dentistry department to continue with their evaluation, using dental and skeletal tests, selecting only those cases who met the dentistry criteria for MAD collocation.

During the first appointment with the dentist, the tests included: weight measurement, dental and articular evaluation, assessment of the snoring noise according to the protrusion maneuver, and using a temporal MAD. Measurements were taken for the evaluation of the required advancement. We also used the Epworth Sleepiness Scale (ESS) [25], and the evaluation of the Bed partner questionnaire after Johnstone et al. of the snoring noise [26]. A second ESS and Bed partner questionnaire was made 3 months after MAD use.

Odontological evaluation included soft and hard tissues examination of the oral cavity, looking for absence dental mobility, adequate periodontal health and temporomandibular function, and taking care of the absence of discomfort during mandibular movements. Patients were excluded for any cranial disorder, so radiographic studies such as cephalometric or dental studies could be needed.

Inclusion criteria were the presence of symptoms: snoring, daytime sleepiness, fragmented sleep, witnessed apneas, and with diagnosis of OSAHS (IAH < 30 events/h) in PSG. Patients were excluded if there was edentulous, periodontal disease, or pain with protrusion maneuver.

The scores of Epworth sleepiness scale were also evaluated. Institutional ethics committee approval was obtained and informed consent was obtained from all patients according to Declaration of Helsinki.

2.2. Principles for the placement of MAD

The patient must have good oral hygiene and six teeth on each arch, with healthy posterior on each quadrant, that keep the splint on place. There will be no discomfort when doing movement border to border or for mandibular protrusion (maximum protrusive < 6 mm). This is important, because this will be the final splint position. Once the patients were enrolled, they came next week for the splint collocation. For this device, to be effective, the obstruction area must be located on the posterior aspect of the pharynx and caused by the base of the tongue.

2.3. Adjustment and placement of MAD

In this study Somnofit (OCSIMED Swiss) MAD device was used. This is a thermoplastic, adjustable MAD, with 6 levels of advancement. We used advancement bands that can be gradually adapted and avoids joint damage during the process of getting to the required advancement level on each case (50–70% of the maximum protrusive). Patients were informed also about the possible secondary effects when using this device and all signed a consent form.

The maximum level of advancement was independently assessed for each case. One month after MAD collocation, patients were asked about the event of side effects for the use of MAD. Three months after MAD collocation, once the patient and his bed partner reported an evident clinical improvement, the next step was the PSG evaluation with a SNP and MAD at the adequate advancement level.

2.4. Polysomnography

Patients were connected according to the International 10–20 system for electrodes placement for electroencephalography (EEG), and the guidelines for the performance of respiratory polygraphy. Registered variables were: electroencephalography, electrooculography, electromyography, electrocardiography, thorax and abdominal respiratory movements, air flux by thermistor, oxygen saturation, body position and lower extremities movements. PSG records were performed using a Cadwell EEG-PSG equipment (Cadwell Industries, Kennewick, WA).

During the first 4 h, the patient was instructed not to use the MAD. After 4 h, the patient was instructed to use it. PSG studies were evaluated according to the American Academy of Sleep Medicine Manual for the Scoring of sleep and Associated Events: Rules, Terminology and Technical Specifications [27]. The following variables were studied, before and during the use of MAD: Snoring index (SI), Apnea-Hypopnea Index (AHÍ), Apnea index (AI), Hypopnea index (HI) and oxygen (O_2) saturation during Rapid eye movements sleep (REM) and no-REM sleep.

We performed a SNP, half of night without MAD, and the other half with MAD, because we wanted to know how much it could AHI change to evaluate the patient for a full night, and during the 4 h of the divided night. On the other hand, the SNP was consider an ideal tool in this study, because besides not spend great resources, on a night it brings help in diagnosis and therapeutic, allowing us to control changes in important variables such weight, clinical characteristics, such as obstruction of the airway by turbinate hypertrophy, temperature, allergies, that during the diagnostic study did not show, getting more realistic results.