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Editorial

Oral appliance in obstructive sleep apnea syndrome

Among “modern” diseases, obstructive sleep apnea syndrome (OSAS) has become the subject of many studies, although there has been great scientific interest in this condition for many years prior. In 400 B.C., Aristotle stated that the function of sleep was to make sensory perception and wakefulness possible. However, much of what is currently known now was discovered over the past 60 years.

Since Hans Berger's first paper in 1929 (Berger was the first to record electroencephalography in humans), many other researchers have studied the physiology of the sleep cycle [1]. In 1937, Loomis, Harvey, and Hobart observed by using EEG that the sleep cycle was characterized by distinct stages [2]. In 1968, and with a review in 1971, a committee composed of many physiology and sleep disorder experts published guidelines to help comprehend sleep cycle staging and polysomnographic techniques, and also created a standard staging process for children. Major developments in understanding sleep disorders have been achieved over the last 25 years. The most significant among these concepts is OSAS, which is a chronic evolutionary condition with high morbidity and mortality rates that presents many signs and symptoms that lead to severe hemodynamic, neurological, and behavioral repercussions. Treatment of OSAS presents great complexity and also requires a multidisciplinary approach [3].

Non-surgical and surgical treatments for OSAS have been proposed. Among the non-surgical treatments, continuous positive airway pressure (CPAP), oral appliances for mandibular advancement, and myofunctional therapy can be highlighted. The gold-standard treatment for OSAS is CPAP, but although its efficacy has been demonstrated in short-term evaluations, significantly lower rates of efficacy have been shown in long-term studies. This may be related to low adherence to CPAP treatment (CPAP is usually better tolerated by patients presenting moderate to severe apnea [4]).

When patients present less severe complaints, the likelihood of tolerating CPAP seems to be lessened. In such circumstances, oral appliances appear to be more attractive. Nonetheless, oral appliances for mandibular advancement are usually a second-choice treatment to be considered after attempting to use CPAP. These appliances are designed for dealing with mild and moderate snoring by making the mandible protrude and stabilizing it. This maintains the patency of the airways during sleep, with results that are similar to those of CPAP [5].

Since the mandibular advancement technique was first introduced, many oral appliances have become available for purchase. While the efficacy of prefabricated oral appliances has been questioned, customized models are frequently tested and have been validated for use in many studies [5,6]. Illustrating this, the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) cited 165 studies in their first guidelines, and more than 370 studies in the updated version in 2015 [6]. However, the level of evidence of these studies is limited because of the many different types of oral appliances used in them.

Pierre Robin was the first to document the use of an oral appliance in 1923 for mandibular advancement for treating nocturnal airway obstruction. In 1982, Cartwright and Samelson reported using a novel tongue retainer [7]; research on this subject has increased exponentially since then. The efficacy of these appliances depends on a number of factors, including: materials used, severity of the sleep-disordered breathing, degree of protrusion, fabrication method, and adjustability. Much creativity and ingenuity have gone into developing various oral appliance design features, but the lack of accepted standards for the designs of such appliances hinders comparison and interpretation of research findings. In order to address these deficiencies, a consensus conference was held to develop an evidence-based definition of an effective oral appliance for treating OSAS, and to establish a standardized benchmark for both research and clinical practice.

Following the conference, the draft definition was presented to and approved by the AADSM Board of Directors in March 2013 [4,6]. The final approved definition can be summarized as follows:

1. The purpose of an oral appliance is to treat mild to moderate OSAS, primary snoring and associated symptoms.
2. Oral appliances are intended to decrease the frequency and/or duration of apneas, hypopneas, respiratory effort-related arousals (RERAs) and/or snoring events.
3. Oral appliances have been demonstrated to improve nocturnal oxygenation as well as the adverse health and social consequences of OSAS and snoring.
4. Oral appliances are accepted therapy for patients with severe OSAS, who do not respond to, or are unable or unwilling to tolerate CPAP therapy. Although oral appliances are typically used as standalone therapy, they can serve as an adjunct to CPAP therapy and/or other treatment methods for managing OSAS.

For this definition, oral appliances refer to mandibular advancement devices (MAD) because they are the most effective and most widely used type in clinical practice. These oral appliances are customized using physical impressions and models of an individual patient's oral structures. As such, they are not primarily prefabricated items that have been trimmed, bent, realigned, or otherwise modified. They are made of biocompatible materials and engage both the maxillary and mandibular arches. These oral appliances have a mechanism that allows the mandible to be advanced in

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increments of 1 mm or less, with a protrusion adjustment range of at least 5 mm. In addition, reversal of the advancement needs to be possible, and the protrusion settings verifiable. It needs to be possible for the patient or caregiver to put such appliances into place and remove them. Retention of the appliance in relation to the teeth, implants or edentulous ridge must remain stable and the prescribed setting needs to be maintained during use. The structural integrity of oral appliances has to remain intact for a minimum of three years [4,6].

However, some questions remain unanswered regarding the use and efficacy of oral appliances. For instance, how much mandibular advancement is necessary to reach the desired effect? What are the side effects of this procedure?

In this issue of *Sleep Medicine*, the study by Anitua et al. aimed to analyze the effect on the evolution of the apnea–hypopnea index (AHI) of gradually incrementing the mandibular advancement of the oral appliance every two weeks [8]. The 36 patients (22 males) selected for this study presented improvement of AHI by using the oral appliance. Notably, 10 out of the 26 patients who presented reductions in AHI of more than 50% had zero advancement. They also reported having side effects consisting of temporomandibular joint pain, mouth dryness, and, in one case, a subjective bite alteration.

This topic continues to be important, yet controversial. The clarity of the guidelines becomes nebulous, given the multitude of variables that have to be considered in selecting treatments for patients with OSAS. Therefore, oral appliances play a crucial role in treatment selection.

Conflict of interest

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: http://dx.doi.org/10.1016/j.sleep.2017.01.011.

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