Sleep Science 9 (2016) 221–224

HOSTED BY

ELSEVIER

Contents lists available at ScienceDirect

Sleep Science

journal homepage: www.elsevier.com/locate/ssci

Full length article

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

Emma García-Campos[1], Alberto Labra, Lourdes Galicia-Polo, Francisco Sánchez-Narváez, Reyes Haro, Ulises Jiménez, Adrián Poblano*

Clinic of Sleep Disorders, National University of Mexico (UNAM), Mexico City, Mexico

ARTICLE INFO

Keywords:
Obstructive sleep apnea
Mandibular advancement device
Polysomnography

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 forward [10]. They can be fixed or adjustable advancement, and given

Peer review under responsibility of Brazilian Association of Sleep.

* Corressponding author.
E-mail address: dra_emmagarcia@yahoo.com.mx (E. García-Campos).
[1] Dr. Balmis 148, Col. Doctores, Deleg. Cuauhtémoc, postal code 06726, México City, México.

http://dx.doi.org/10.1016/j.slsci.2016.10.003
Received 22 June 2016; Received in revised form 9 September 2016; Accepted 14 October 2016
Available online 28 October 2016

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 (AHI), 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.

Table 1
Comparison of Splint night polysomnography (SNP) variables before and after use of Mandibular advancement device (MAD).

	Before MAD	After MAD	*p*
Snoring index	159.95 ± 30.46/h	32.46 ± 7.92/h	0.001
Apnea-hypopnea index	22.45 ± 6.14/h	4.63 ± 0.98/h	0.006
Obstructive apnea index	13.20 ± 3.70/h	3.5 ± 1.62/h	0.01
Hypopnea index	59.23 ± 9.29/h	16.46 ± 4.39/h	0.001
Oxygen saturation in no-Rapid eye movements sleep	89.98 ± 0.84%	91.39 ± 0.43%	0.001
Oxygen saturation in Rapid eye movements sleep	89.66 ± 0.67%	90.91 ± 0.58%	0.001

2.5. Statistics

For a study of 80% of power and significance of 5%, a sample size of 28 patients was calculated. With data obtained from the questionnaires, a frequency analysis was performed. Central tendency measures were also performed. Results were analyzed comparing the PSG response in the same night before and during the use of MAD, with a Student's *t* test, using SPSS 16.0 for Windows. Significance was determined with value of $p \leq 0.05$.

3. Results

Thirty patients were enrolled in this study, 16 men and 14 women, with an average of 49.7 ± 12.45 years of age, and an average of body mass index (BMI) of 27.84 ± 9.98 kg/m^2. Median hours MAD use at night was of 6 h (range 5–7 h). The results of SNP show significant changes with the use of MAD in the following variables (see Table 1): SI, AHI, AI, and HI, showed a significant decreased with the use of MAD. Instead, O_2 saturation during REM sleep and in no-REM sleep showed a significant increase. In ESS score, we found a significant improvement after patients used MAD for three months (see Table 2). In the Bed partner questionnaire completed after the use of MAD, we found that in all but one patient, snoring decreased, and in one third, disappeared at all (see Table 3). Regarding side effects with the use of MAD, the main complaints manifested by patients were excessive drooling and dental pain, in the half, and in the quarter of the sample respectively (see Table 4).

4. Discussion

4.1. Main findings

The main contribution from this research was to show that MAD careful selected in treatment of OSAHS was a reliable alternative in their treatment, which was quantitatively verified by means of SNP in a short-time prospective research. There is a controversy on MAD use in literature, but our data showed significant decrease in SI, AHI, AI, and HI, and increase of O_2 saturation in REM and no-REM sleep, and improvement of other measurements, such as ESS and the Bed partner questionnaire. Clinicians and patients will have the benefit, provided by have more tools for OSAHS treatment.

4.2. Comparison with other studies

SNP is commonly used in the diagnostic evaluation of OSAHS patients and for titration of CPAP devices, watching the therapeutic response during the same night. SNP gives the opportunity of an assessment of efficacy, while expenses and times are optimized, by getting a basic diagnosis and therapeutic improvement in only one night with the MAD.

We found a significant decrease in the respiratory variables of sleep, such as AHI, as well as it happened when SI, AI and HI who were measured separately. Oxygen saturation showed a significant increase when using MAD, both, in REM and in non-REM sleep. Our data confirm results from other studies [28–30]. This fact supports our approach of using the SNP as an important measurement tool. In this study, we found that the levels of O_2 saturation improved when using MAD and this was not related to any sleep stage.

ESS showed a decrease in day-time somnolence of the patients, after 3 months using MAD, this data was significant too. Regarding the responses reported by the Bed partner questionnaire, only one case showed lack of improvement of snoring, but in 9 cases the bed partner reported total absence of respiratory noise during sleep after MAD use, as was reported previously [31,32].

Based on this information, we can say that success in the use of MAD rely greatly on an accurate evaluation of the site of obstruction, as well as the multidisciplinary approach and management. Follow up of these patients is equally important, and SNP is a useful tool in the accurate assessment of these patients.

In our study, we determined the efficacy of MAD used in a Mexican population, and we propose the use of SNP as a technique that allow us to decrease expenses to both; the hospitals and the patients, getting in only one night the chance to find a basal result and therapeutic results as well. This allows the proper clinical following of these patients. The use of MAD in well selected patients, and its assessment with SNP should be considered in a regular basis, as it would allow to a larger number of patients and follow them taking in mind the decrease of expenses in diagnosis and treatment.

Finally, the most commonly found side effect was excessive drooling, which lasted for about a month and then disappeared with no treatment. The second most frequent side effect was dental pain, which was also self-limited. Four patients reported no side effects. These alterations had been reported previously in other investigations [33–36].

4.3. Limitations of the study

These included the sample size, in futures studies we will increase the number of studied patients. We are aware that SNP is not the only one study to assess these patients, however, the high costs of complete

Table 2
Results of Epworth sleepiness scale before and after 3 months of Mandibular advancement device (MAD) use.

	Before MAD (points)	After MAD (points)	*p*
Epworth sleepiness scale	14.4 95 ± 4.18	4.6 95 ± 1.77	0.001

Table 3
Results from the Bed partner questionnaire after use of Mandibular advancement device (MAD).

	Snoring disappearing	Persisted mild snoring	Persisted moderate snoring	No changes in snoring
Bed partner answer	9 cases (30%)	11 cases (36%)	9 cases (30%)	1 case (3%)

Table 4
Temporal side effects after use of Mandibular advancement device (MAD).

Side effects	Number of cases	%
Excessive drooling	16	53
Dental pain	8	26
Articular pain	1	3
Muscular pain	1	3
No side effects	4	13

PSG or two, the few resources of our population, the awaiting for the final report, and not enough spaces in specialized clinics, led us to use a simplified method such as SNP. With the resources available for this study, it was less cost prohibitive to perform SNP for a two night study. It has been demonstrated that the results in both modalities of studies are comparable, when using CPAP therapy, and working like this, we can save money and time, helping to improve waiting times that are commonly found in sleep clinics.

5. Conclusions

The results of this study showed that split night polysomnography is a useful tool for the use of alternatives such as oral devices, thus allowing us to decrease expenses of both, in diagnosis and management of this demographic of patients.

References

[1] Franklin KA, Lindberg E. Obstructive sleep apnea is a common disorder in the population-a review of the epidemiology of sleep apnea. J Thorac Dis 2015;7:1311–22.
[2] Torre-Bouscoulet L, Vázquez-García JC, Muciño A, Márquez M, López MV, Montes de Oca M, et al. Prevalence of sleep related symptoms in four Latin American cities. J Clin Sleep Med 2008;4:579–85.
[3] Tufik S, Santos-Silva R, Taddei JA, Bittencourt RL. Obstructive sleep apnea syndrome in the Sao Paulo Epidemiologic Sleep Study. Sleep Med 2010;11:441–6.
[4] Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman JJr, et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. Sleep 2006;29:240–3.
[5] Lavigne GJ, Goulet JP, Zuconni M, Morrison F, Lobbezoo F. Sleep disorders and the dental patient: an overview. Oral Surg Oral Med Oral Pathol Oral Radio Endod 1999;88:257–72.
[6] Kornegay EC, Brame JL. Obstructive sleep apnea and the role of dental hygienists. J Dent Hyg 2015;89:286–92.
[7] Grunstein RR, Hedner J, Grote L. Treatment options for sleep apnoea. Drugs 2001;61:237–51.
[8] Deacon NL, Jen R, Li Y, Malhotra A. Treatment of obstructive sleep apnea prospects personalized combined modality therapy. Ann Am Thorac Soc 2016;13:101–8.
[9] Jaiswal M, Srivastava GN, Pratap CB, Sharma VK, Chaturvedi PT. Effect of oral appliance for snoring and sleep apnea. Int J Orthod Milwaukee 2015;26:67–71.
[10] Jayesh SR, Bhat WM. Mandibular advancement device for obstructive sleep apnea: an overview. J Pharm Bioallied Sci 2015;7(Suppl. 1):223–5.
[11] Ferguson KA, Love LL, Ryan CF. Effect of mandibular and tongue protrusion on upper airway size during wakefulness. Am J Respir Crit Care Med 1997;155:1748–54.
[12] Losert-Bruggner B. Determining the optimal position for snoring splints. Forced mandibular advance is not always required. HNO 2000;48:955–9.
[13] Lyons MF, Cameron DA, Banham SW. Snoring, sleep apnoea and the role of dental appliances. Dent Update 2001;28:254–6.
[14] Ferguson KA, Cartwright R, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. Sleep 2006;29:244–62.
[15] Ng AT, Darendeliler NA, Petocz P, Cistulli PA. Cephalometry and prediction of oral appliance treatment outcome. Sleep Breath 2012;16:47–58.
[16] Perez CV, de Leeuw R, Okeson JP, Carlson CR, Li HF, Bus HM, et al. The incidence and prevalence of temporomandibular disorders and posterior open bite in patients receiving mandibular advancement device therapy for obstructive sleep apnea. Sleep Breath 2013;17:323–32.
[17] Yoshida K. Influence of sleep posture on response to oral appliance therapy for sleep apnea syndrome. Sleep 2001;24:538–44.
[18] Liu CY, Lu HY, Dong FS, Ma WS, Wang J, Hu XY, et al. Effects of a mandibular advancement device on genioglossus in obstructive sleep apnoea hypopnea syndrome. Eur J Orthod 2015;37:290–6.
[19] Bartolucco ML, Bortolotti F, Raffaelli E, 'Anto VD, Michelottii A, Alessandri Bonetti G. The effectiveness of different mandibular advacement amounts in OSA patients: a systematic review and meta-regression analysis. Sleep Breath 2016;20:911–9.
[20] Jaiswal M, Srivastava GN, Pratap CB, Sharma VK, Chaturvedi TP. Effect of oral appliance for snoring and obstructive sleep apnea. Int J Orthod Milwaukee 2015;26:67–71.
[21] Gjerde K, Lehmann S, Berge ME, Johansson AK, Johansson A. Oral appliance treatment in moderate and severe obstructive sleep apnoea patients non-adherent to CPAP. J Oral Rehabil 2016;43:249–58.
[22] Marty M, Lacaze O, Arreto CD, Pierrisnard L, Bour F, Cheliout-Heraut F, Simonneau G. Sleep and obstructive sleep apnea: objective efficacy and impact of a chairside fabricated mandibular advancement device. J Prosthodont 2015. http://dx.doi.org/10.1111/jopr.12401.
[23] Marklund M. Long-term efficacy of an oral appliance in early treated patients with obstructive sleep apnea. Sleep Breath 2016;20:689–94.
[24] American Academy of Sleep medicine. International classification of sleep disorders, 3ª ed. Darien: IL; American academy of sleep medicine; 2014.
[25] Jiménez-Correa U, Haro R, Poblano A, Arana-Lechuga Y, Terán G, González-Robles RO, et al. Mexican version of the Epworth Sleepiness Scale. Open Sleep J 2009;2:6–10.
[26] Johnstone CD, Gleadhill IC, Cinammond FJ, Gabbey J, Burden DJ. Mandibular advancement appliances and obstructive sleep apnea: a randomized clinical trial. Eur J Orthodon 2002;24:251–62.
[27] Berry RB, Brooks R, Gamaldo CE, Harding SM, Marcus CL, Vaughn BV for the American Academy of Sleep Medicine. The AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications, 2nd. ed. Darien, IL: American Academy of Sleep Medicine; 2012.
[28] Guimarães TM, Colen S, Cunali PA, Rossi R, Dal-Fabbro C, Ferraz O, et al. Treatment of obstructive sleep apnea with mandibular advancement appliance over prostheses: a case report. Sleep Sci 2015;8:103–6.
[29] Glos M, Penzel T, Schoebel C, Nitzche GR, Zimmermann S, Rudolph C, et al. Comparison of effects of OSA treatment by MAD and by CPAP on cardiac autonomic function during daytime. Sleep Breath 2016;20:635–46.
[30] Denolf PL, Vanderveken OM, Marklund ME, Braem MJ. The status of cephalometry in the prediction of non-CPAP treatment outcome in obstructive sleep apnea patients. Sleep Med Rev 2015;27:56–73.
[31] Otsuka R, Almeida FR, Lowe AA. The effects of oral appliance therapy on occlusal function in patients with obstructive sleep apnea: a short-term prospective study. Am J Orthod Dentofac Orthop 2007;131:176–83.
[32] Bailey DR. Dental management of sleep disorders. Dent Today 2002;21:88–93.
[33] Pantin CC, Hillman DR, Tennant M. Dental side effects of an oral device to treat snoring and obstructive sleep apnea. Sleep 1999;22:237–40.
[34] Pliska BT, Nam H, Chen H, Lowe AA, Almeida FR. Obstructive sleep apnea and mandibular advancement splints: occlusal effects and progression of changes associated with a decade of treatment. J Clin Sleep Med 2014;10:1285–91.
[35] Almeida FR, Lowe AA, Otsuka R, Fastlicht S, Farbood M, Tsuiki S. Long-term sequelae of oral appliance therapy in obstructive sleep apnea patients: Part 2. Study-model analysis. Am J Orthod Dentofac Orthop 2006;129:205–13.
[36] Rose EC, Schnegelsberg C, Staats R, Jonas IE. Occlusal side effects caused by a mandibular advancement appliance in patients with obstructive sleep apnea. Angle Orthod 2001;71:452–60.