Valuation of orthoapnea device effectiveness in patients with obstructive sleep apnea syndrome. Preliminary study

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Aim

The mandibular advancement device (MAD) is employed in the treatment of obstructive sleep apnoea syndrome (OSAS) as an alternative in patients with mild or moderate OSAS or even in severe patients who do not tolerate the Continuous Positive Airway Pressure (CPAP) or refuse surgery. The main objectives of this study are to evaluate the effectiveness and tolerance of the MAD designed by Orthoapnea in the treatment of OSAS in adults, and determine whether there is an improvement or not in the airway area patency and volume and if the number of respiratory events and desaturations decreases.

Methods

The Orthoapnea device is a mandibular advancement device that allows lateral and vertical jaw movement during sleep, as well as a controlled regulation of the millimetre-exact adjustment of the advance.

In the prospective study, patients diagnosed with mild or moderate OSAS by respiratory polygraphy in Virgen de la Victoria Hospital (Málaga) were included. Mild OSAS is considered so when the apnoea-Hypopnoea index by sleep monitoring is from 5 to <15; moderate between 15 and <30 and severe if 30 or more. The following cases were excluded from the study: patients with severe comorbidity, severe obesity, anatomic problems which make MAD placing impossible, pregnant women and patients suffering from excessive daytime sleepiness due to other diseases (e.g. narcolepsy or restless legs syndrome). A basal polygraphy was performed and repeated after four weeks of MAD treatment. The following variables were recorded: sex, age, apnoea-hypopnoea index (AHI) in supine and prone position, total number of apnoeas, number of obstructive apnoeas, number of hypopnoeas, number of oxygen desaturations per hour and the percentage of time that the saturation was under 90 (CT90). During the treatment period, two 3D i-CAT CT scans were performed with and without MAD to measure airway area and volume, defined by Dolphin 3D imaging airway analysis tool. The treatment was considered effective when the AHI was significantly reduced or less than 5. The results were analysed by paired Student's T-test, Wilcoxon signed-rank test and McNemar's test.

A total of 100 patients were recruited for the study. At the present time, a total of 43 patients have completed the treatment: 32 men (74.4%) and 11 women (25.6%). The average age is 44.7 ± 19.2; the average body mass index, 27.1 ± 5.6 kg/m^2.

Results

The airway area patency and volume increased positively after using the device: area from 256 to 308 mm^2; volume from 4533 to 6356 mm^3 (Figure 1). The trial section presented in figure 2 shows that the Orthoapnea MAD therapy increased the airway area patency and volume in the velo/-oropharynx portion.

	P		Mean	Standard Deviation	Perc 25	Median	Perc 75
AREA (mm2)	**0,0004**	without	**256**	**242**	**0**	**313**	**471**
		with	**308**	**301**	**0**	**360**	**582**
VOLUME (mm2)	**0,000**	without	**4533**	**4531**	**0**	**4394**	**8485**
		with	**6356**	**6486**	**0**	**7571**	**10580**

Figure 1. – Airway area dimensions before and after MAD placing.

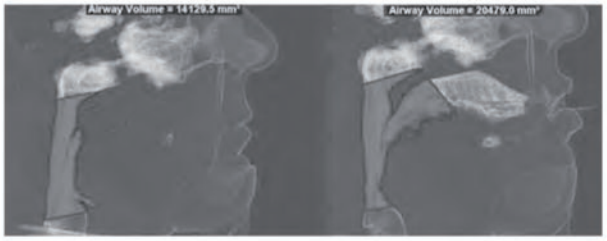

Figure 2. – 3D i-CAT CT image of a patient's airway before and after MAD placing.

When comparing the respiratory parameters before and after using the MAD, (Figure 3) statistically significant decreases (P<0.05) were obtained in the following variables: average AHI (from 16.2 to 6), both in supine and prone position; average of total apnoeas (from 69.2 to 9.8); average of obstructive apnoeas (from 34 to 8.7); average of hypopnoeas (from 70.1 to 24.8); oxygen desaturations per hour index (from 13.7 to 5.5); average CT90 (from 1.6 to 0.6).
In 69% of the cases the AHI is reduced to 50% and in 51,58% of the cases, an AHI under 5 was reached after using MAD.

As to the snoring subjective appraisal (Figure 4), all patients responded positively to the treatment. Here, the higher improvement scores were reached. 97 % of subjects suffered from chronic snoring, defined as 3-5 d/week or more without treatment.
83% of the patients used the device during all sleeping hours. The majority of side effects caused by MAD use were minor. In 86% of the cases the device was well tolerated. Only a 14% of the patients did not tolerate the treatment.

Discussion

The most successful treatment in patients with OSAS is continuous positive airway pressure (CPAP), although the patients do not always tolerate it. In those cases, MAD poses an effective alternative to CPAP, as multiple studies endorse.[1-6] This research presents our experience with Orthoapnea MAD in patients diagnosed with mild and moderate OSAS, in line with SEPAR and National Consensus on OSAS Diagnosis and Treatment recommendations.[7, 8] In this study, it has been proved that Orthoapnea MAD therapy increases the airway area patency and volume in the velo/-oropharynx portion. Discordance between the snoring subjective appraisal after using MAD and

	P		Average	Real Desviation	Perc 25	Median	Perc 75
AHI supine	0,0001	Before	25,1	16,5	13,5	22,1	30,8
		After	6,9	7,0	1,9	4,6	10,5
AHI non-supine	0,005	Before	7,8	6,2	3,3	7,8	11,4
		After	3,9	5,9	1,0	1,9	3,6
Epworth Test	0,003	Before	12,0	5,0	9,0	12,0	16,0
		After	10,1	4,1	7,0	10,0	12,5
AHI	0,0001	Before	16,2	6,6	11,0	13,9	23,0
		After	6,0	5,4	2,4	4,9	7,7
No. of apneas	0,0001	Before	69,2	55,2	21,0	66,0	93,0
		After	9,5	12,0	2,0	5,0	12,0
No.of obstructive apneas	0,0001	Before	34,0	35,4	9,0	21,0	42,0
		After	8,7	11,3	1,5	5,0	12,0
No. of hypopneas	0,0001	Before	70,1	31,7	50,0	60,0	94,0
		After	24,8	21,6	9,5	19,0	35,0
No. of central apneas	0,461	Before	1,1	2,8	,0	,0	1,0
		After	2,5	11,1	,0	,0	,0
No. of mixed apneas	0,024	Before	1,4	4,0	,0	,0	,0
		After	,1	,3	,0	,0	,0
Desaturation Index/hour	0,0001	Before	13,7	6,7	8,2	12,1	18,2
		After	5,5	5,8	1,4	3,8	8,1
CT90	0,0001	Before	1,6	2,2	,1	,5	2,8
		After	,6	1,4	,0	,1	,6
No. of snorings	0,911	Before	177,4	113,6	75,0	169,0	282,0
		After	172,2	67,4	130,0	173,0	217,0

Figure 3. – Main respiratory parameters before and after MAD treatment.

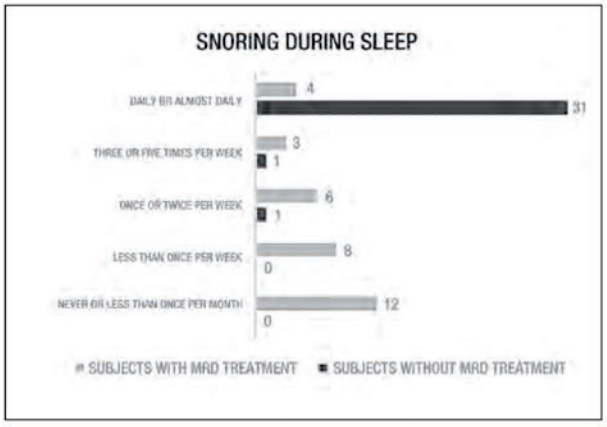

Figure 4. – Snoring subjective appraisal.

the results obtained by polygraphy has been observed. In this study, sound measurement was recorded using a nasal cannula, thus not measuring snoring intensity. Sounds recorded as snores in the polygraphy may have a lower intensity than those perceived by human ear.

Using MAD also determines a significant reduction ($P<0.05$) in the number of apnoeas-hypopnoeas at the expense of both obstructive and mixed apnoeas, and also hypopnoeas. Another significant reduction is observed in the oxygen desaturation index, compared to basal period ($P<0.05$). In 69% of the cases the AHI is reduced to 50% and in 51,58% of the cases, an AHI under 5 was reached after using MAD, which may be considered a positive result.

Conclusion

The use of Orthoapnea MAD proves to be an efficient therapeutic alternative, increasing airway area patency and volume, thus reducing the AHI on patients with mild and moderate OSAS, and improving some of its pathophysiologic consequences, such as nocturnal desaturation.

References

1. Lim J, Lasserson TJ, Fleetham J, Wright JJ. Oral appliances for obstructive sleep apnoea (Review). The Cochrane Library 2009;3:1-40.
2. Hoffstein V. Review of oral appliances for treatment of sleep-disordered breathing. Sleep Breath 2007;11:1-22.
3. Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman J Jr *et al.* American Academy of Sleep. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. Sleep 2006; 29:240-3.
4. Hoekema A, Stegenga B, de Bont LG. Efficacy and co-morbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systematic review. Critical Reviews in Oral Biology & Medicine 2004;15:137-55.
5. Marklund M, Stenlund H, Franklin KA. Mandibular advancement devices in 630 men and women with obstructive sleep apnea and snoring. Tolerability and predictors of treatment success. Chest 2004;125:1270-8.
6. Hoffstein V. Review of oral appliances for treatment of sleep-disordered breathing. Sleep Breath 2007;11:1-22.
7. Marín Trigo JM, Arán Corbella X, Barbé Illa F, Biurrum Unzué O, Fiz Fernández JA, Jiménez Gómez A *et al.* Normativa sobre el diagnóstico y tratamiento del síndrome de apnea obstructiva durante el sueño (SAOS).Recomendaciones de la Sociedad Española de Neumologia y Cirugía Torácica (SEPAR). Barcelona: Doyma; 1993.
8. Consenso nacional sobre Síndrome de Apneas-Hipopneas del sueño (SAHS). Arch Bronconeumol 2005;41(Suppl 4):1-80.