A Preliminary Study on the Short-Term Outcomes of a Titratable Prefabricated Mandibular Advancement Device in the Treatment of Patients with Obstructive Sleep Apnea-Hypopnea Syndrome

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BACKGROUND AND PURPOSE

Non invasive therapy through the use of an intraoral mandibular advancement device (MAD) is a common therapeutic option for obstructive sleep apnea-hypopnea syndrome (OSAHS) as accepted by the American Academy of Sleep Medicine standards [1].

A prefabricated monoblock MAD has been associated with a poor clinical outcome compared with a custom made device [2]. Although there is some recent data about the beneficial role of titratable prefabricated MADs [3] definitive evidence is still lacking.

The aim of this prospective study was to assess the short-term effect on sleep apneas, sleep structure and daytime sleepiness of a titratable, prefabricated mandibular advancement device (TP-MAD) in patients with mild to moderate OSAHS.

SAMPLE AND METHODS

Nine patients diagnosed with OSAHS were treated with TP-MADs. Polysomnographic and questionnaires-based control was done at baseline and after a mean of 10±3 weeks.

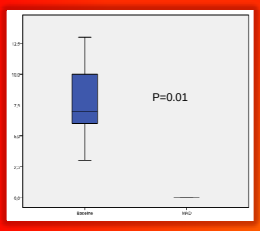
Subjective Sleepiness was evaluated by Epworth Sleepiness Scale (ESS), Stanford Sleepiness Scale (SSS) and Visual Analogue Scale (VAS).Snoring was assessed by the Thornton Snoring Scale (TSS), Pittsburgh Sleep Quality Index (PSQI) was used in order to evaluate subjective sleep quality and the compliance was assessed by a diary of use of the oral appliance.

Comparisons at successive time points were performed by Wilcoxon matched pairs test. Significance was assumed for p≤0.05.

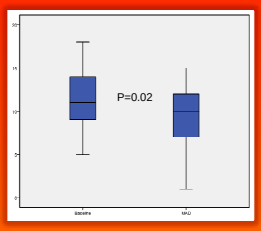
Baseline Variables	Mean	Standard Deviation	Min	Max
Mean Age (years)	48.8	7.3	36	57
BMI (Kg/m2)	28.9	3.6	26.8	34.5
Neck Diameter (cm)	37.0	2.5	33.5	40.0
ESS (Epworth Sleepiness Scale)	11.1	4.2	5	18
TSS (Thornton Snoring Scale)	8	3	3	13

Photos

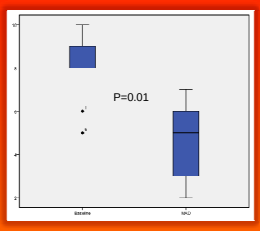
1. Patient without Oral Appliance
2. Patient with Oral Appliance
3. Oral Appliance used in this study (Somnofit from Oscimed SA)



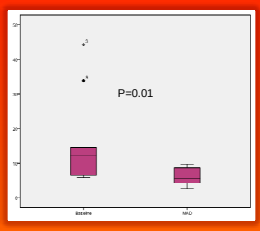
TSS before and after OA therapy



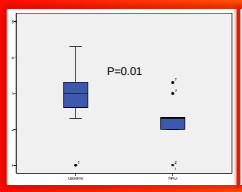
ESS before and after OA therapy



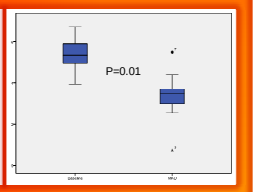
PSQI before and after OA therapy



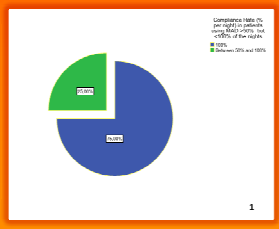
Arousal Index before and after OA

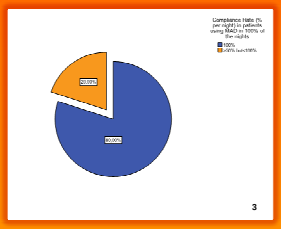


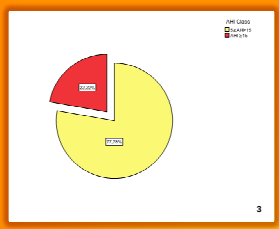
SSS before and after OA therapy

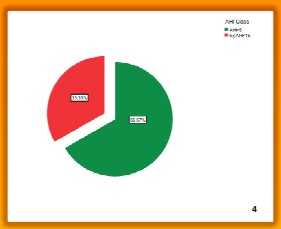


VAS before and after OA therapy









Pie Charts: Compliance rates (1,2) ; AHI diistribution before and after OA therapy (3,4)

PSG Respiratory Status	BASELINE Mean	BASELINE SD	MAD Mean	MAD SD	Sig. (p value)
AHI (events/h)	11.6	8.6	4.8	4.0	0.02
OEI (events/h)	15.4	16.5	4.4	4.0	0.05
AI (events/h)	7.1	9.1	1.5	1.8	0.02
MeanO2Sat (%)	95.0	1.0	94.8	2.1	0.67
MinO2Sat (%)	83.6	6.5	81.9	12.7	0.86
ODI (events/h)	9.4	5.2	4.4	4.0	0.03

PSG Sleep Microstructure	BASELINE Mean	BASELINE SD	MAD Mean	MAD SD	Sig. (p value)
Arousals	16.3	13.6	6.0	2.8	0.01
PLMi	13.9	28.8	4.1	7.8	0.62

PSG Sleep Structure	BASELINE X	BASELINE SD	MAD X	MAD SD	Sig. (p value)
Total Sleep Time (min)	417	54	409	49	0.95
Sleep Eficiency (%)	83	9	84	8	0.44
Sleep Latency (min)	29	24	16	8.1	0.09
SLR (min)	158	72	96	51	0.14
N1 Sleep Stage (%)	15	10	9	3	0.14
N2 Sleep Stage (%)	55	15	49	9.1	0.26
N3 Sleep Stage (%)	14	7.4	21	8.3	0.05
R Sleep Stage (%)	15	7.7	21	7.7	0.09

Tables Legend: AHI – Apnea Hipopnea Index; OEI – Obstructive Events Index; AI – Apnea Index; ODI – Oxygen Dessaturation Index; PLMi – Periodic Limb Movement Index; SLR – Latency to REM Sleep

RESULTS AND CONCLUSIONS

Snoring was abolished or became inaudible in all patients as witnessed by their bed partners. Six of the 9 patients (67%) had treatment success and one patient had partial therapeutic response from TP-MAD. Slow-wave sleep increased from 14% of total sleep time at the baseline to 21% after therapy with TP-MAD. Arousal index was lower after therapy (6/hr) than at the baseline (16/hr). All sleepiness scales scores and sleep complaints as well as sleep quality improved (p<0.05). 55.6% of the patients were fully compliant to the treatment (using TP-MAD for 100% of the nights) whereas 44.4% used TP-MAD for at least 50% of the nights during the study.

In this preliminary study, a titratable prefabricated mandibular advancement device was effective on sleep apneas and sleep in the short term. The results encourage more studies with this type of device in larger samples and during longer follow-up periods.

References:

1. Kushida CA; Morgenthaler TI; Littner MR et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: An Update for 2005. *SLEEP* 2006; 29(2): 240-243; 2. Vanderveken OM, Devolder A, Marklund M, Boudewyns AN, Braem MJ, Okkerse W, et al. Comparison of a custom-made and a thermoplastic oral appliance for the treatment of mild sleep apnea. Am J Respir Crit Care Med. 2008 Jul 15;178(2):197-202; 3. Friedman M, Pulver T, Wilson M. Otolaryngology office-based treatment of obstructive sleep apnea-hypopnea syndrome with titratable and non-titratable thermoplastic mandibular advancement devices. Otolaryngology-Head and Neck Surgery. 2010; 143:78-84