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Mandibular Advancement Device vs CPAP in the Treatment of Obstructive Sleep Apnea: Are they Equally Effective in Short Term Health Outcomes?

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Source

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Abstract

QUESTION:

Is the treatment of obstructive sleep apnea (OSA) with mandibular advancement device (MAD) similar in health outcomes to continuous positive airway pressure (CPAP) in the short term (one month health outcomes)?

DESIGN:

Randomized, open labeled, cross over, non-inferiority trial; Clinical trial registered with https://www.anzctr.org.au (ACTRN 12607000289415).

ALLOCATION:

Patients randomized to both the treatment acclimatization and treatment arm orders, resulting in 4 randomized sequences for MAD (M) and CPAP (C): MCMC, MCCM, CMMC and CMCM. Each sequence was generated by a computer program using random permuted blocks. The acclimatization periods for each treatment were generally between 4-6 weeks. Treatment periods were for 1 month each.

BLINDING:

The investigators and participants were not blinded to study arm assignment.

FOLLOW-UP PERIOD:

1 month.

SETTING:

The study was conducted at three sleep centers in Sydney, Australia.

SUBJECTS:

126 adults, mean age 49.5 years, 81% male, mean AHI 25.6 events/h, were randomized. Inclusion Criteria: patients with newly diagnosed OSA, AHI > 10 events/h, age ≥ 20 years, ≥ 2 symptoms of OSA (snoring, fragmented sleep, witnessed apneas, or daytime sleepiness), and a willingness to use both treatments. Exclusion Criteria: previous OSA treatment or a need for immediate treatment, central sleep apnea, a coexisting sleep disorder, regular use of sedatives or narcotics, preexisting lung or psychiatric disease, and any contraindication for oral appliance therapy (e.g., periodontal disease or insufficient dentition).

INTERVENTION:

Patients meeting eligibility criteria were randomized to a 4-6 week each, acclimatization to CPAP and MAD. A 2 week wash out period was then followed by initial assignment to CPAP or MAD treatment and subsequent cross over. During each of the 4-6 weeks of acclimatization with each device, all patients were asked to use their device for as long as they could tolerate it on a nightly basis.

OUTCOMES:

The primary outcome was the difference in 24-hour mean arterial pressure (24MAP) between CPAP and MAD determined by 24-hour ambulatory blood pressure (BP) monitoring. Secondary outcome measures were central BP and arterial stiffness measurements, neurobehavioral function, and quality of life (QOL) using the Functional Outcomes of Sleep Questionnaire (FOSQ), the Short Form-36 (SF-36), the Epworth Sleepiness Score (ESS), and the AusEd driving simulator. Daily diaries were also used to monitor treatment side effects and determine subjective compliance. The sample size was calculated to show the non-inferiority of MAD relative to CPAP in the 24MAP after 1 month of therapy, using an a priori determined non-inferiority margin of 1.6 mmHg, assuming 90% power and a true difference between treatment means of zero. The primary hypothesis was tested by comparing the upper limit of the 95% confidence interval for the MAD-CPAP difference in 24MAP with the a priori non-inferiority margin using the paired t-test.

PATIENT FOLLOW-UP:

18 patients (14%) withdrew after randomization, leaving 108 (86%) who completed the study. Two patients withdrew because of treatment intolerance (one CPAP and one both CPAP and MAD). Analyses were limited to the 108 subjects who completed the trial, regardless of compliance with their assigned treatment.

MAIN RESULTS:

There was no statistically significant difference between the groups in the primary outcome. MAD was non-inferior to CPAP with a CPAP-MAD 24MAP difference, 0.2 mmHg (95% confidence interval, -0.7 to 1.1 mmHg). However, ultimately neither treatment lowered BP from baseline in the entire group, after 1 month of therapy. In the subgroup of patients with baseline hypertension (n = 45), there were consistent treatment-related 24MAP improvements ($p < 0.05$) of 2.5 mmHg (CPAP) and 2.2 mmHg (MAD), with neither treatment having a superior effect. There were no differences in secondary outcome measures between groups, except MAD performed better than CPAP in improving four of eight SF-36 general QOL domains, and the overall mental component score ($p < 0.05$). Subjective reports of nightly compliance were less for CPAP compared with MAD (mean compliance 5.2 ± 2.0 vs. 6.5 ± 1.3 h/night, $p < 0.0001$).Treatment preference results showed that 55 patients (51%) preferred MAD, 25 (23%) preferred CPAP, 23 (21%) preferred either, and 5 (4.6%) preferred neither.

CONCLUSION:

In adults with predominately moderate to severe OSA, the short term (one month) use of an adjustable MAD was not inferior to CPAP in its impact on 24 hour mean ambulatory blood pressure, daytime sleepiness, disease specific and general quality of life.

SOURCES OF FUNDING:

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[The use of mandibular advancing devices in the treatment of snoring and mild to moderate obstructive sleep apnoea syndrome].

[Article in Romanian]

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Source

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Abstract

Mandibular advancing devices (MAD) are a therapeutic option for snoring, mild obstructive sleep apnoea (OSA) and some patients with moderate or severe OSA non compliant to CPAP.

AIM:

evaluating the efficacy of MAD in the treatment of snoring and mild OSA.

MATERIALS AND METHOD:

MAD were applied in 26 patients (23 men) with a polysomnographic record (PSG) performed in the Polisomnography Lab II, Clinical Pneumophthysiology Hospital Iasi between 15 February-15 October 2007. Nineteen patients were included (the rest were excluded for various reasons). Each patient was examined ENT. PSG used a Weinmann, Germany, device, SomnoManager 12.7 software. MAD were installed. After one month patients were checked with polygraph Weinmann SomnoCheck effort for evaluating the treatment efficacy.

RESULTS:

All included patients snored in over 30% of total sleeping time (TST), having over 30 snorring episodes per sleep hour. The mean of snoring episodes per hour was 40.42 +/- 7.15 at diagnosis and at evaluation after a month it was reduced to 20.64 +/- 5.66 episodes per sleep hour. Mean value of AHI (apnoea-hypopnoea index) at diagnosis was 12.78 +/- 3.95 and after 1 month of MAD was 6.35 +/- 2.84 events per sleep hour. Mean body mass index (BMI) was 27.7 kg/m2 +/- 2.89 and wasn't changed at check-up. Desaturation index was 19.15 +/- 6.4 at diagnosis and improved to 7.94 +/- 3.39 desaturation episodes per sleep hour after 1 month of treatment. The side effects reported were transient, consisting in discomfort of the temporo-mandibular joint and

mild tooth ake. Most patients (16 subjects) use the device every night, displaying a high complianace to treatment.

CONCLUSIONS:

The use of MAD proves to be efficient in snoring patients, reduce AHI and associate a good compliance.

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