Randomised controlled trial

A mandibular advancement device did not affect daytime sleepiness and quality of life in obstructive sleep apnoea

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Commentary on: Marklund M, Carlsberg B, Forsgren L, *et al.* Oral appliance therapy in patients with daytime sleepiness and snoring or mild to moderate sleep apnea: a randomized clinical trial. *JAMA* 2015;175:1278–85.

Context

Obstructive sleep apnoea (OSA) is a sleep-related breathing disorder, characterised by (intense) snoring and recurrent obstructions of the upper airway during sleep. Among other things, OSA is associated with cardiovascular complications and increased mortality.¹ Oral appliances that move the mandible into a more anterior position, commonly known as mandibular advancement devices (MAD), have gained popularity as an alternative to continuous positive airway pressure (CPAP) therapy. It aims at relieving upper airway obstruction by positioning the mandible and its attached soft tissue structures in a forward and downward position during sleep. In this clinical trial, Marklund and colleagues examined the objective and subjective effects of MAD therapy on daytime sleepiness and quality of life (QOL) compared with placebo therapy.

Methods

Ninety-six adult patients with reported daytime sleepiness and an apnoea-hypopnea index (AHI) lower than 30 were included and computer randomised to a MAD or a placebo oral appliance. Ninety-one patients completed the study from May 2007 through August 2011. The MAD tested was an individually made elastomer appliance with an adjustable Herbst mechanism. It was individually titrated to an optimal mandibular advancement. The placebo upper jaw device consisted of only a bilaminar splint which did not advance the mandible during sleep. Subjective primary outcomes regarding daytime sleepiness and QOL were assessed with validated questionnaires. Objective secondary

outcomes such as AHI and sleep quality were derived from overnight polysomnography (PSG) at baseline and after 4 months of follow-up.

Findings

MAD therapy was not associated with improvements in daytime sleepiness (Epworth Sleepiness Score and Karolinska Score) and QOL (Short-Form 36 (SF-36), Functional Outcomes of Sleep Questionnaire (FOSQ)) from baseline to follow-up when compared with the placebo device. Although, subjectively several parameters improved with MAD, none of those parameters were significantly better improved compared to placebo.

Interestingly, the placebo device was so successful that 52% of the placebo patients were interested in continuing placebo treatment. Furthermore, the authors showed a significant reduction in AHI, snoring and symptoms of restless legs with use of an MAD compared with the placebo device.

Commentary

In this clinical trial, Marklund and colleagues focused on a difficult group of patients—those who only snore or suffer from mild to moderate OSA but who also have impaired daytime performance and excessive daytime sleepiness. These patients do not always have a clear indication for treatment in terms of cardiovascular risk reduction or survival rate. Regarding the significant reduction in AHI, MAD therapy was effective in people with restless legs. Unfortunately, these patients did not experience significant improvements in daytime sleepiness and QOL.

In a study from Doff *et al*² it was shown that several subjective parameters (SF-36 and FOSQ) significantly improved with MAD therapy in the short-term (2 months) and long-term (2 years) follow-up. However, they also included patients with severe OSA in their trial. The hypothesis could be that more severe OSA is accompanied with more subjective OSA symptoms regarding daytime sleepiness and QOL.

It should also be considered that daytime sleepiness and a diminished QOL do not improve despite adequate treatment as there are many other factors (ie, other sleep disorders or underlying diseases) that affect those parameters. Nowadays, compliance monitoring is becoming more important as low compliance is related to poor clinical outcomes. It is also known that a positive effect of treatment on OSA symptoms will improve compliance as patients get more 'rewarded'.

In this study, compliance was only assessed subjectively by questionnaires and not objectively. Therefore, it was not possible to study the relationship between compliance and efficacy of MAD therapy. Statistical power may also have been limited to detect small differences in primary outcomes.

A strong point of this study is that efficacy was evaluated using PSG, validated questionnaires and even vigilance tests. The outcomes certainly improve our current understanding of MAD therapy in mild to moderate OSA.

Implications for practice

This study provides important information about treating mild to moderate OSA with a MAD. It also shows that objective improvement may not accompany subjective improvement.

Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.

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References

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