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Mandibular advancement device therapy in obstructive sleep apnea

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Chapter 8

Summary

Obstructive sleep apnea (OSA) is characterized by recurrent collapse of the upper airway during sleep despite ongoing inspiratory efforts. As a consequence of their disturbed sleep condition, OSA patients often complain about daytime symptoms, such as excessive sleepiness and unrefreshing sleep. Continuous positive airway pressure (CPAP) is generally considered the “gold standard” treatment for OSA. Although CPAP is a highly efficacious treatment, there is a need for other treatment options, because the effectiveness of CPAP is often limited by poor patient acceptance and tolerance, as well as by a suboptimal compliance. Nowadays, mandibular advancement devices (MADs) are widely prescribed for the treatment of mild-to-moderate OSA. These oral appliances are often considered by patients to be a more acceptable treatment modality compared to CPAP. In 2002, when we started with our placebo-controlled randomized clinical trial (RCT), especially case series were published on the therapeutic efficacy of mandibular advancement devices (MADs) in OSA patients. Consequently, there was not enough scientific evidence for the efficacy of MADs. Therefore, we decided to investigate three important aspects of MAD therapy in an RCT: (1) the time-variant nature of the apnea-hypopnea index (AHI) and its consequences for diagnosis and therapy evaluation in OSA patients; (2) the influence of mandibular protrusion on OSA signs and symptoms; and (3) the short-term and long-term effects of both MAD and CPAP in the treatment of OSA.

When using the AHI in the diagnosis and therapy evaluation of OSA, it is of importance that the AHI is stable over time. Therefore, in **chapter 2** of this thesis, the AHI variability was determined during a 10-week period, and a mathematical technique was described to assess its possible consequences for diagnostic and therapy evaluation purposes. From this study, it can be concluded that recordings can only confirm or deny the presence of OSA when obtained AHI values lie outside a cut-off band surrounding the AHI cut-off point.

As a first step for the RCT described in this thesis, an adjustable MAD was developed with a constant vertical dimension at different mandibular positions. In **chapter 3** of this thesis, the initial efficacy of this MAD in the treatment of OSA was assessed in a pilot study. Further, it was aimed to evaluate the patients’ compliance to the MAD therapy and to determine the feasibility of the procedures of this pilot trial for

use in a future RCT. In **chapter 4** of this thesis, the influence of four mandibular protrusion positions, at a constant vertical dimension, on OSA signs and symptoms was assessed. On the basis of this study, it was recommended to start an MAD treatment in the 50% protrusion position as a result of a weighted compromise between efficacy and side-effects.

After the start of our RCT, several other RCTs have addressed the efficacy of MADs in the treatment of OSA. Their common control condition, CPAP, was usually found to be superior to MAD therapy. However, in these studies, only CPAP was titrated objectively. To enable an unbiased comparison between both treatment modalities, the MAD should be titrated objectively as well. Therefore, the aim of the study in **chapter 5** of this thesis was to compare the effects of an MAD with those of nasal CPAP (nCPAP), following polysomnographically controlled titration of both treatment modalities. Further, in the study in **chapter 6**, both modalities were followed over a one-year period. Based on both studies, it was concluded that there is no clinically relevant difference between MAD and nCPAP in the treatment of mild-to-moderate OSA.

Conclusions

The following conclusions can be drawn from this thesis:

- It should be taken into account that in the diagnosis and therapy evaluation of OSA, there is considerable intra-individual variability between AHI recordings (**chapter 2**).
- It is recommended to start an MAD treatment in the 50% protrusion position in the treatment of mild-to-moderate OSA (**chapter 3** and **chapter 4**).
- There is no clinically relevant difference between MAD and nCPAP in the treatment of mild-to-moderate OSA, neither at the short-term (**chapter 5**) nor at the long-term (**chapter 6**).

Samenvatting