

Oral Appliance therapy in Obstructive Sleep Apnea-Hypopnea syndrome - A clinical study on therapeutic outcomes

A Hoekema

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Background: Oral-appliance therapy is emerging as an alternative to continuous positive airway pressure (CPAP) as therapy for the obstructive sleep apnea-hypopnea syndrome (OSAHS). In clinical practice, however, oral appliances are used primarily for patients who do not respond to CPAP therapy. We hypothesized that an oral appliance is not inferior to CPAP in treating OSAHS effectively.

Method: We randomly assigned 103 OSAHS patients to oral-appliance or CPAP therapy. After eight weeks, treatment effect was assessed with polysomnography. Follow-up review was extended for patients requiring adjustments to therapy and ended with a patient's final polysomnographic evaluation or when a patient discontinued treatment. We then determined the proportion of patients for whom oral-appliance or CPAP therapy was effective. For the difference in effectiveness (oral-appliance minus CPAP therapy), a 95% two-sided confidence interval was calculated. Non-inferiority of oral-appliance therapy was considered established when the lower boundary of this interval exceeded - 25%.

Results: Treatment was effective for 39 of 51 patients using the oral appliance (76.5%) and for 43 of 52 patients using CPAP (82.7%). The lower boundary

Conclusion: In this randomised parallel trial, oral-appliance therapy was not inferior to CPAP as effective treatment of OSAHS. Subgroup analysis suggested that an oral appliance is particularly indicated for patients with non-severe disease.