

Executive Summary

Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015

An American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine Clinical Practice Guideline

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Introduction

Since the publication of the initial position statement by the American Academy of Sleep Medicine (AASM) in 1995, the clinical use of oral appliances (OAs) for the treatment of snoring and obstructive sleep apnea (OSA) has markedly increased. The most recent AASM practice parameters on the treatment of snoring and OSA with oral appliances was published in 2006 as "Practice Parameters for

the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005” with the accompanying systematic review paper “Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review.”^{1, 2} Since these publications, the scientific literature on OAs has grown considerably, particularly related to clinical outcomes after use of OAs. The purpose of this guideline is therefore to replace the recommendations in the 2006 guideline for the use of OAs in the treatment of OSA and snoring.

Methods

To develop this guideline, the AASM and American Academy of Dental Sleep Medicine (AADSM) commissioned a task force of seven members, three sleep medicine physicians and two dentists, with expertise in the use of OAs, and two AASM research staff members experienced in guideline development. None of the task force members had any conflicts that would preclude participation in this effort. Eleven PICO (Patient, Population or Problem, Intervention, Comparison, and Outcomes) questions were developed based on both the questions raised in the 2006 AASM review paper¹ and practice parameter² and review of systematic reviews, meta-analyses, and guidelines published since then (Table 1). The AASM Board of Directors approved the final list of PICO questions before the targeted literature search was performed.

The literature search was performed by the AASM research staff using the PubMed and Embase databases. Though the search yielded all types of articles with various study designs, for most PICO questions the analysis was limited to only randomized controlled trials (RCTs). The RCTs that were cited in the 2006 AASM review paper¹ and 2006 practice parameter paper² were included for data analysis if they met the study inclusion criteria. For PICO questions 7 and 11, due to lack of RCTs, we relied on prospective observational studies. The PubMed database was searched from January 1, 2004, through July 31, 2012, and was updated again on February 28, 2013, to capture the latest literature. A total of 324 citations were identified in PubMed and supplemented by pearling. A total of 53 citations were identified in Embase, yielding a total of 377 citations from both databases.

Meta-analysis was performed, with Review Manager 5.2 software, to compare various types of OAs used to treat snoring and OSA. Oral appliances were categorized into the following types: custom, titratable; custom, non-titratable; non-custom, titratable; and non-custom, non-titratable. Meta-analysis was performed for each PICO question by pooling data across studies for each outcome measure. All analyses were performed using the random effects model. The result of each meta-analysis is shown as a forest plot.

The assessment of evidence quality was performed according to a modified Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process.³ The final assessment, as defined in Table 2, was determined for each treatment and outcome measure. The results are reported as evidence profiles for each PICO question that include the number of studies, study design, limitations, inconsistency, indirectness, imprecision, and other considerations that went into determining the quality of evidence for each outcome of interest. The task force then developed recommendations for the efficacy of OA treatment for snoring and OSA. Strengths of recommendation

were assigned to these statements based on the quality of the evidence and counterbalanced by an assessment of the relative benefits of the treatment versus the potential risks as delineated in Table 3.

This guideline refers to a “qualified dentist” as the dental provider of choice to provide oral appliance therapy. The successful delivery of oral appliances requires technical skill, acquired knowledge, and judgment regarding outcomes and risks of these therapies. The need to append the word “qualified” stems from two things: (1) all of the studies conducted to evaluate the efficacy and risks of oral appliances were conducted by dentists with considerable experience in dental sleep medicine, and (2) the unfortunate fact that training in dental sleep medicine is uncommon. Therefore, not all dentists have the training or experience required to deliver knowledgeable care, and application of the literature to practice dental sleep medicine.

The American Academy of Dental Sleep Medicine (AADSM) is one of several organizations that has begun to address this issue over the past decade via the development and delivery of educational programs in dental sleep medicine along with the development of a certifying examination in dental sleep medicine that is now administered and maintained by the American Board of Dental Sleep Medicine (ABDSM). As physicians diagnose and subsequently refer patients with OSA to select dentists to evaluate for delivery of oral appliance therapy, they should seek qualified dentists who have a valid state license and proof of liability coverage and possess additional training or experience in this area of care. Although not all-inclusive, desirable qualifications include that the dentist have at least one of the following: certification in dental sleep medicine by a non-profit organization, designation as the dental director of a dental sleep medicine facility accredited by a non-profit organization, or a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school in the last two years.

OSA is a chronic disorder and therefore would be best diagnosed and followed by a sleep physician in cooperation with any other healthcare providers the patient may be going to for treatment (their primary care physician, a qualified dentist, ENT, etc.). For the purposes of this guideline, a sleep physician is defined as a physician who is either sleep board-certified or sleep board-eligible. A multicenter, prospective, comparative effectiveness study showed that board-certified sleep physicians and accredited centers improved patient-centered outcomes for OSA patients.⁴ Also, most of the RCTs that were reviewed to develop the recommendations in this current guideline were conducted by sleep physicians and investigators as defined by the above criteria.

Results

Our assessment of the efficacy of different OAs, as compared to each other and to PAP for different levels of OSA severity (mild, moderate, and severe), was based on very limited evidence. Most of the studies accepted for inclusion in this guideline did not provide sub-analyses of results based on different levels of OSA severity. Therefore, the recommendations presented below do not provide guidance for

treating OSA patients with specific levels of severity. Meta-analyses performed using the limited available evidence indicates that OAs can significantly reduce the apnea hypopnea index/respiratory disturbance index/ respiratory event index (AHI/ RDI/ REI) across all levels of OSA severity in adult patients. There was no statistically significant difference in the mean reduction in AHI before and after treatment using OAs versus CPAP across all levels of OSA severity. Moreover, there was no significant difference between OAs and CPAP in the percentage of mild OSA patients achieving their target AHI/ RDI/ REI (<5, <10, >50% reduction) after treatment. For patients with moderate to severe OSA, however, the odds of achieving the target AHI were significantly greater with CPAP than with OAs.

Our assessment of factors that may be used to predict treatment success in adults with OSA was also based on very limited evidence. We found that treatment success was usually defined as a reduction in the AHI/ RDI/ REI to a specific level (e.g., post-treatment AHI/ RDI/ REI <5, >50% reduction in AHI/ RDI/ REI). However, there were no reported factors that consistently predicted treatment success. Specifically, there was conflicting evidence for the use of age, gender, neck circumference, body mass index (BMI), and cephalometric measurements to predict treatment success. Patient preference for OA versus CPAP should be considered by the treating sleep physician before therapy is prescribed. The strength of each recommendation was not only made based on the quality of evidence, but also incorporated patient preference along with other factors such as cost, value, and other patient-related factors.

Summary of Recommendations

1. We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). (STANDARD)

Quality of Evidence: High

Values and Trade-Offs: Oral appliances (OAs) reduce the frequency and intensity of snoring, improve sleep quality for both patients who snore and their bed partners, and improve quality of life (QOL) measures. Though the available evidence on these outcomes is limited, we gave this a STANDARD strength of recommendation, as the possible benefits from treatment of primary snoring clearly outweigh the risk. Insufficient evidence exists to conclude that treatment of primary snoring improves other health-related outcomes, or to compare objective sleep quality during use of oral appliances versus other treatments. Therefore, OAs should be recommended for patients who snore who fail conservative measures (such as weight loss, positional therapy, and avoiding alcohol) and request further treatment. Diagnosis of primary snoring should be rendered by a sleep physician and not a dentist, as snoring is frequently accompanied by OSA, and misdiagnosis can have serious implications for the patient.

2. When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: The overall grade for the body of evidence exploring the impact of custom vs. non-custom OAs to treat OSA varies between low and moderate depending on the physiologic sleep outcome measures. A systematic review of the evidence has shown that custom, titratable OAs reduce the AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation to a greater extent than do non-custom OAs. The evidence supports the use of custom, titratable OAs over other types of appliances. Although the reduction in AHI and ODI are similar for both custom, titratable and custom, non-titratable OAs, the confidence interval for the effect of the custom, titratable OAs is considerably smaller than for the custom, non-titratable appliances. Both types of custom appliances are more effective than non-custom OAs.

Neither custom nor non-custom OAs have been shown to significantly affect sleep architecture and sleep efficiency. However, the overall improvement in other physiologic sleep parameters with the use of custom OAs in adult patients with OSA should result in an improvement in daily function and quality of life.

The available data also suggest that OAs effectively improve daytime sleepiness. The mean change in the Epworth Sleepiness Scale (ESS) with custom, titratable OAs is moderate. The reduction in subjective daytime sleepiness achieved with custom titratable OAs is not inferior to that reported with CPAP therapy. In contrast, very limited data suggest that custom, non-titratable OAs do not produce a significant change in ESS. Insufficient data are available to assess objective measures of sleepiness or wakefulness following OA therapy.

The evidence indicates that OAs are also effective in improving QOL. Specifically, custom, titratable OAs provide moderate improvement in QOL outcomes. The data on QOL is very limited for custom, non-titratable OAs, and therefore their use cannot be recommended to improve QOL.

3. We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)

Quality of Evidence: Moderate

Values and Trade-Offs: A review of the evidence suggests that adherence rates using OAs are greater than those observed with CPAP. However, no randomized controlled trials have assessed objective OA adherence rate as compared with CPAP. The subjective reporting of adherence rate is prone to bias, and needs to be interpreted with caution as patients may overestimate their OA use. However, a patient whose OSA does not improve with the use of CPAP or is intolerant to CPAP may benefit from the use of an OA. Overall, the discontinuation of therapy due to side effects occurs less when using OAs versus

CPAP to treat adult patients with OSA.

The overall grade for the body of evidence on the impact of OAs to treat obstructive sleep apnea (OSA) varies between low and moderate depending on the physiologic sleep outcome measures. A systematic review of the evidence has shown that OAs reduce AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation. However, OAs have shown no significant effect on sleep architecture and sleep efficiency. The overall improvement in physiologic sleep parameters with the use of OAs in adult patients with OSA should result in an improvement in daily function and quality of life. Although OAs have been shown to improve physiologic sleep parameters, continuous positive airway pressure (CPAP), in our meta-analyses, was found to be superior to OAs in reducing the AHI, arousal index, and oxygen desaturation index and improving oxygen saturation, and therefore, should still generally be the first-line option for treating OSA. The improvement in QOL produced by custom, titratable OAs is not inferior to that reported with CPAP therapy. The quality of evidence for the use of these OAs to improve QOL is moderate, whereas the quality of evidence comparing OAs to CPAP is low. The custom, titratable OAs improve QOL, but as with CPAP, reduced QOL may persist despite otherwise adequate therapy.

The available data regarding the impact of OAs on blood pressure are more limited (overall grade for the body of evidence is low) than the data addressing blood pressure change with CPAP. For example, the role of OAs in patients with resistant hypertension has not yet been evaluated. However, the available data suggest that OAs may be as effective as CPAP in at least select patient populations to lower blood pressure and therefore should not preclude the use of either therapy or diminish the other established benefits that accrue from treatment of OSA. Of note, no RCTs have assessed the impact of OA therapy on other cardiovascular endpoints.

In summary, OAs may be effective in improving sleep parameters and outcomes of OSA, and there is little likelihood of harm. Although they are not as efficacious as PAP therapy, the benefits of using OAs outweigh risks of not using OAs. Thus, a STANDARD strength of recommendation to use OAs was provided.

4. We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: Beneficial treatment effects may be reduced by treatment-related side effects, and most OA therapy side effects are dental. A wide range of devices made from a variety of materials and having different characteristics are utilized in clinical practice. Literature on dentists performing interventions to prevent failure of OA therapy is limited, although the topic is mentioned in the results and discussion sections of some publications. Therefore, the overall evidence in support of the above recommendation was considered low. Nevertheless, minimization of side effects may improve adherence and thereby patient outcomes. Several studies demonstrated dental interventions to mitigate side effects. Additionally, knowledge of dental materials and a variety of dental devices including the knowledge of the patients' dental status will likely ensure fewer side effects. A qualified

dentist will be able to screen for many problems and choose and/ or build the OA with features to minimize the side effects of the therapy. A qualified dentist will have the skills to choose the proper OA and make necessary modifications to accommodate patients who, among other things, may have allergies to metals or acrylics, are strong teeth grinders, or have anatomical deviations. The patient's history and exam, appliance preference, and review of any side effects should be taken into account to avoid device breakage, allergic reactions, or discomfort that leads to frustration or discontinuation of the therapy.

5. We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: The overall grade of evidence for support of follow-up evaluations and testing by sleep physicians is low due to a lack of evidence. However, the discussion sections in most research studies report significant improvement in OA efficacy when changes were made to the appliances based on data obtained either during or after the sleep studies. While insufficient evidence exists to produce a meta-analysis, the available data suggest that subjective feedback is not sufficient to determine the optimal setting of the OA in the management of OSA. Without objective data the patient may, unnecessarily, remain sub-optimally treated. Follow-up sleep testing by sleep physicians should also be considered for OA-treated patients who develop recurrent symptoms, show substantial weight changes, or receive diagnoses of comorbidities relevant to OSA.

6. We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: A review of the evidence suggests that patients may benefit from periodic follow-up visits with a physician and with a qualified dentist. Several studies have demonstrated that adjustments made to the OA by a dentist, based on data obtained from PSGs and home sleep apnea tests conducted by a physician, may result in greater long-term improvement in OSA. The absence of periodic follow-up visits may result in suboptimal improvement in OSA or side effects that increase risk for discontinuation of therapy.

Table 1. PICO Questions

1. In adult patients with primary snoring, do oral appliances (OAs) improve snoring, sleep quality, including the bed partner's sleep quality, and/ or quality of life measures compared to other therapies or no treatment?
2. In adult patients with obstructive sleep apnea (OSA) (irrespective of underlying severity of OSA, and for each mild, moderate, or severe OSA), do oral appliances improve the apnea hypopnea index (AHI)/ respiratory disturbance index (RDI)/ respiratory event index (REI), oxygen saturation, arousal index, and/ or sleep architecture compared to other therapies or no treatment?
3. In adult patients with OSA, do OAs improve cardiovascular endpoints, such as hypertension, coronary artery disease, myocardial infarction, and/ or arrhythmias, as compared to other therapies or no treatment?
4. In adult patients with OSA, do OAs improve quality of life measures, and/ or objective and subjective daytime sleepiness, as compared to other therapies or no treatment?
5. In adult patients with OSA, do titratable OAs improve AHI/ RDI/ REI, oxygen saturation, arousal index, and/ or sleep architecture and do they improve long-term management of OSA with outcome measures such as AHI/ RDI/ REI, sleep quality, quality of life measures, cardiovascular endpoints, and/ or subjective/ objective measures of sleepiness compared to non-titratable OAs?)
6. In adult patients with OSA, do OAs lead to mild or serious side effects compared to those treated with other therapies or no treatment?
7. In adult patients with OSA, do follow-up oximetries, home sleep apnea tests, polysomnograms, or follow-up with a sleep physician improve long-term management with OAs as compared to no follow-up?
8. In adult patients with OSA, does follow-up with dentists/ sleep specialists improve adherence and reduce side effects associated with OAs compared to those who do not have follow-up?
9. In adult patients with OSA, does OA use show better adherence than that reported by subjective or objective measures for PAP therapy?
10. In adult patients with OSA, do different types of OAs have variable effectiveness in controlling sleep-disordered breathing as measured by the AHI/ RDI/ REI and/ or other outcome measures such as sleep quality, quality of life measures, cardiovascular endpoints, and/ or objective/ subjective daytime sleepiness?
11. In adult patients with OSA, what are the factors that predict success with OAs compared to other therapies or no treatment?

Table 2. Final Assessments of Level of Bodies of Evidence	
High: We are very confident that the true effect lies close to that of the estimate of the effect.	
Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.	
Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.	
Very low: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.	

Table 3. AASM strengths of recommendations

		Overall quality of evidence			
		High	Moderate	Low	Very Low
Assessment of benefits versus harms/burdens	Benefits clearly outweigh harms/burdens	Standard	Standard	Guideline	Option
	Benefits closely balanced with harms/burdens OR uncertainty in the estimates of benefits versus harms/burdens	Guideline	Guideline	Option	Option

	Harms/burdens clearly outweigh benefits	Standard	Standard	Standard	Standard
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