Complete Summary

GUIDELINE TITLE

Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005.

BIBLIOGRAPHIC SOURCE(S)

Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman J Jr, Friedman L, Hirshkowitz M, Kapen S, Kramer M, Lee-Chiong T, Owens J, Pancer JP. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. Sleep 2006 Feb 1;29(2):240-3. [8 references] PubMed

GUIDELINE STATUS

This is the current release of this guideline.

This guideline updates a previous version: Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. Sleep 1995 Jul;18(6):511-3.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Snoring
- Obstructive sleep apnea (OSA)

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Dentistry
Internal Medicine
Neurology
Pediatrics
Psychiatry
Pulmonary Medicine
Sleep Medicine

INTENDED USERS

Dentists
Physicians

GUIDELINE OBJECTIVE(S)

To reissue, modify, and, if necessary, replace recommendations for the use of oral appliances in the treatment of snoring and obstructive sleep apnea based on the scientific literature published since 1995.

TARGET POPULATION

- Patients with primary snoring or mild to moderate obstructive sleep apnea (OSA) who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep position change
- Patients with mild to moderate OSA who prefer oral appliances to continuous positive airway pressure (CPAP) therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with continuous positive airway pressure

Note: The recommendations are restricted to adolescents and adults.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Oral appliances
2. Nasal continuous positive airway pressure (CPAP)
3. Upper airway surgery
4. Polysomnography
5. Attended cardiorespiratory sleep study

MAJOR OUTCOMES CONSIDERED

- Snoring level
- Clinical signs and symptoms of obstructive sleep apnea
- Apnea-hypopnea index and oxyhemoglobin saturation
- Respiratory distress index
- Adverse events

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The data for this review were assembled by searching PubMed for English language peer-reviewed publications containing the key words "oral appliance," "obstructive sleep apnea," "orthodontic appliances," and related terms. The search was restricted to adult patients. Of the 112 articles produced by this search, 45 were rejected because they did not report original investigations, did not describe investigative methods adequately, were not studies of oral appliance therapy, or reported data on fewer than 8 patients. Articles known to task force members that met the selection criteria but did not appear in the original search were added to the list. By this means 64 additional articles were added before January 2004, creating a list of 131 articles (Online Evidence Table). The same search process was repeated in July 2004 yielding 10 additional papers included for this review.

NUMBER OF SOURCE DOCUMENTS

141 articles

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level I (Grade A Recommendation): Randomized well-designed trials with low-alpha and low-beta errors*

Level II (Grade B Recommendation): Randomized trials with high-beta errors*

Level III (Grade C Recommendation): Nonrandomized controlled or concurrent cohort studies

Level IV (Grade C Recommendation): Nonrandomized historical cohort studies

Level V (Grade C Recommendation): Case series

*Alpha (type 1 error) refers to the probability that the null hypothesis is rejected when in fact it is true (generally acceptable at 5% or less, or $p<0.05$). Beta (Type II error) refers to the probability that the null hypothesis is mistakenly accepted when in fact it is false (generally trials accept a beta error of 0.20). The estimation of Type II error is generally the result of a power analysis. The power analysis

takes into account the variability and the effect size to determine if sample size is adequate to find a difference in means when it is present (Power generally acceptable at 80-90%).

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The task force first developed an abstract form in order to create a standardized database for the review, for the subsequent parameter development, and for the critical scrutiny of readers. The elements of this Evidence Table were selected to address the questions in the task force's charge. These data are contained in an Evidence Table, available in an online supplement and as a companion to this summary. In addition, each paper was graded for research quality and evidentiary strength by reference to a scale advocated by Sackett (see "Rating Scheme for the Strength of the Evidence" field in this summary). The studies and papers graded as Level I or II evidence are listed in Appendix 1 of the original guideline document (Evidence Table, selected studies, Level I-II). This evidence table can be accessed on the web at http://www.aasmnet.org.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Standards of Practice Committee of the American Academy of Sleep Medicine (AASM), in conjunction with specialists and other interested parties, developed these practice parameters based on the accompanying review paper. A Task Force of content experts was appointed by the AASM to review and grade evidence in the scientific literature regarding the clinical use of oral appliances in the treatment of snoring and obstructive sleep apnea (OSA). In most cases, recommendations are based on evidence from studies published in the peer-reviewed literature.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendations

Standard: This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.

Guideline: This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

Option: This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Board of Directors of the American Academy of Sleep Medicine approved these recommendations.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of recommendations (Standard, Guideline, and Option) and levels of evidence (I-V) are defined at the end of the "Major Recommendations" field.

Diagnosis

The presence or absence of obstructive sleep apnea (OSA) must be determined before initiating treatment with oral appliances to identify those patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment. Detailed diagnostic criteria for OSA are available and include clinical signs, symptoms, and the findings identified by polysomnography. The severity of sleep related respiratory problems must be established in order to make an appropriate treatment decision. **(Standard)**

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper. However, there is a higher level of evidence that severity of OSA is predictive of response to oral appliances.

Appliance Fitting

Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion, and associated oral structures. Dental management of patients with oral appliances should be overseen by practitioners who have undertaken serious training in sleep medicine and/or sleep related breathing disorders with focused emphasis on the proper protocol for diagnosis, treatment, and follow up. **(Option)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to specify the training of the personnel responsible for fitting the oral appliances. It is based on committee consensus.

Although cephalometric evaluation is not always required for patients who will use an oral appliance, appropriately trained professionals should perform these examinations when they are deemed necessary **(Option)**.

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

Treatment

Treatment Objectives

For patients with primary snoring without features of OSA or upper-airway resistance syndrome, the treatment objective is to reduce the snoring to a subjectively acceptable level **(Standard)**.

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

For patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the apnea-hypopnea index and oxyhemoglobin saturation **(Standard)**.

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

Oral appliances are appropriate for use in patients with primary snoring who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep-position change. **(Guideline)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to exclude mild OSA patients; these latter patients are discussed in the next practice parameter. This recommendation is based on 1 level I study and 2 level V studies.

Although not as efficacious as continuous positive airway pressure (CPAP), oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. **(Guideline)**

This is a new recommendation. It is based on 11 level I, 3 level II, and 16 level III-V studies that used stringent criteria for defining success.

Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral

appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. **(Guideline)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to clarify treatment of patients with severe OSA. It is based on 1 level II study and 2 lower level studies.

Follow-up

Follow-up sleep testing is not indicated for patients with primary snoring. **(Guideline)**

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

To ensure satisfactory therapeutic benefit from oral appliances, patients with OSA should undergo polysomnography or an attended cardiorespiratory (Type 3) sleep study with the oral appliance in place after final adjustments of fit have been performed. **(Guideline)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to generalize therapeutic evaluation to all patients with OSA, not only patients with moderate to severe OSA. This recommendation is based on 2 level I and 5 level V studies. The reader is also referred to the recent practice parameter paper regarding indications for polysomnography (see National Guideline Clearinghouse [NGC] summary of American Academy of Sleep Medicine guideline Practice parameters for the indications for polysomnography and related procedures: an update for 2005.

Patients with OSA who are treated with oral appliances should return for follow-up office visits with the dental specialist. Once optimal fit is obtained and efficacy shown, dental specialist follow-up at every 6 months is recommended for the first year, and at least annually thereafter. The purpose of follow up is to monitor patient adherence, evaluate device deterioration or maladjustment, evaluate the health of the oral structures and integrity of the occlusion, and assess the patient for signs and symptoms of worsening OSA. Intolerance and improper use of the device are potential problems for patients using oral appliances, which require patient effort to use properly. Oral appliances may aggravate temporomandibular joint disease and may cause dental misalignment and discomfort that are unique to each device. In addition, oral appliances can be rendered ineffective by patient alteration of the device. **(Option)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to generalize follow-up to all patients with OSA, to specify frequency of follow-up visits, and to expand upon the reasons for the follow-up visit. It is based upon committee consensus on factors described in the accompanying review paper.

Patients with OSA who are treated with oral appliances should return for periodic follow-up office visits with the referring clinician. The purpose of follow up is to assess the patient for signs and symptoms of worsening OSA. Close

communication with the dental specialist is most conducive to good patient care. An objective reevaluation of respiration during sleep is indicated if signs or symptoms of OSA worsen or reoccur **(Option)**

This recommendation is a modification of the recommendation of the previous practice parameter paper to consolidate the reasons for follow-up with the referring clinician into a single practice parameter.

Definitions:

Levels of Recommendations

Standard: This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.

Guideline: This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

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Classification of Evidence

Level I (Grade A Recommendation): Randomized well-designed trials with low-alpha and low-beta errors*

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (See "Major Recommendations").

In most cases, the recommendations are based on evidence from studies published in peer-reviewed journals. However, where scientific data are absent, insufficient, or inconclusive, recommendations are based upon task force consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Reduction of snoring to a subjectively acceptable level
- Resolution of the clinical signs and symptoms of obstructive sleep apnea
- Normalization of the apnea-hypopnea index and oxyhemoglobin saturation

POTENTIAL HARMS

Investigations show that there are many potential side effects and complications associated with oral appliance (OA) therapy but most are minor and temporary and do not significantly affect appliance use. Many of the minor side effects (discomfort or excessive salivation) improved even with continued appliance use. However, others are more significant and do not necessarily resolve over time and may lead to discontinuation of oral appliance treatment. Some of the bite changes did not resolve with cessation of therapy and more information is needed about the significance of these occlusal changes and the risks of long-term appliance use. Conceivably, these changes may be due to frank tooth movement, remodeling of the temporomandibular joint (TMJ) complex, or neuromuscular adaptation that may have an influence on the posture of the mandible. The response of some patients to exercises suggests that it may be related to a failure to reposition the mandible into the glenoid fossa. Additional cephalometric, radiographic, and clinical studies are needed to elucidate the importance of these changes.

For further details on adverse events, see the companion review document listed in the "Availability of Companion Documents" field.

CONTRAINDICATIONS

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Dental Contraindications

Patients need to have an adequate number of healthy teeth (not compromised by periodontal disease) in the upper and lower dental arch to use a mandible repositioning appliance (MRA). The exact number of teeth necessary for adequate

support of an MRA has not been identified but consensus holds that at least 6 to 10 teeth in each arch is desirable. Consensus opinion is that the patient should have the ability to protrude the mandible forward and open the jaw widely without significant limitation in order to be fitted with an MRA. Moderate to severe temporomandibular joint (TMJ) problems or an inadequate protrusive ability may be contraindications to oral appliance (OA) therapy. Not all TMJ problems are a contraindication to OA therapy--mild TMJ problems may be lessened by the forward jaw position. Significant bruxism may be a contraindication to OA therapy. Some patients may damage the appliance if they have severe bruxism or may have increased pain if the appliance rigidly holds them in a single fixed position. Patients with full dentures are generally unable to use an MRA but some of these patients may be treated with a tongue device (TD).

QUALIFYING STATEMENTS

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These practice parameters define principles of practice that should meet the needs of most patients in most situations. These guidelines should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding propriety of any specific care must be made by the physician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman J Jr, Friedman L, Hirshkowitz M, Kapen S, Kramer M, Lee-Chiong T, Owens J, Pancer JP. Practice parameters for the treatment of snoring and obstructive sleep apnea

with oral appliances: an update for 2005. Sleep 2006 Feb 1;29(2):240-3. [8 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2006)

GUIDELINE DEVELOPER(S)

American Academy of Sleep Medicine - Professional Association

GUIDELINE DEVELOPER COMMENT

This guideline has received recognition from the American Medical Association (AMA) for the process of development.

SOURCE(S) OF FUNDING

American Academy of Sleep Medicine

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the American Academy of Sleep Medicine Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest

statements and were found to have no conflicts of interest with regard to this subject.

GUIDELINE STATUS

This is the current release of this guideline.

This guideline updates a previous version: Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. Sleep 1995 Jul;18(6):511-3.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: www.aasmnet.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Oral appliances for snoring and obstructive sleep apnea: a review. Sleep 2006;29(2):244-262. Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site.
- Oral appliance review. Evidence tables. Sleep 2006;29(2). Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: www.aasmnet.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 25, 1999. The information was verified by the guideline developer on May 24, 1999. This NGC summary was updated by ECRI on March 29, 2006. The updated information was verified by the guideline developer on April 21, 2006.

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Date Modified: 9/29/2008