Complete Summary

GUIDELINE TITLE

Practice parameters for the medical therapy of obstructive sleep apnea.

BIBLIOGRAPHIC SOURCE(S)

Morgenthaler TI, Kapen S, Lee-Chiong T, Alessi C, Boehlecke B, Brown T, Coleman J, Friedman L, Kapur V, Owens J, Pancer J, Swick T, Standards of Practice Committee, American Academy of Sleep Medicine. Practice parameters for the medical therapy of obstructive sleep apnea. Sleep 2006 Aug 1;29(8):1031-5. [65 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- October 24, 2007, Provigil (modafinil): Cephalon has agreed to include additional labeling revisions to the WARNINGS, CLINICAL PHARMACOLOGY, PRECAUTIONS, and PATIENT PACKAGE INSERT sections.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Obstructive sleep apnea (OSA), including OSA related consequences:
  - Excessive daytime sleepiness (EDS)
  - Cognitive disturbances
  - Depression
  - Hypertension
  - Cardiovascular disease
  - Cerebrovascular disease
- Obesity

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Internal Medicine
Otolaryngology
Pulmonary Medicine
Sleep Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations regarding the use of medical therapy (defined as therapies other than modification of upper airway patency with devices or surgical interventions) for the treatment of obstructive sleep apnea (OSA)

TARGET POPULATION

Adults with obstructive sleep apnea

INTERVENTIONS AND PRACTICES CONSIDERED

1. Dietary weight loss
2. Combination of dietary weight loss with primary treatment for obstructive sleep apnea (i.e., positive airway pressure, dental devices, surgery)
3. Weight loss by bariatric surgery
4. Treatment with modafinil
5. Treatment with topical nasal corticosteroids
6. Use of positional therapy

Note. The following interventions were considered by the authors, but not recommended:

- Selective serotonergic uptake inhibitors (ssris)
- Protriptyline (not recommended as a primary treatment for OSA)
- Methylxanthine derivatives (aminophylline and theophylline)
- Estrogen therapy (estrogen preparations with or without progesterone)
- Oxygen supplementation (not recommended as a primary treatment for OSA)
- Short-acting nasal decongestants

MAJOR OUTCOMES CONSIDERED

- Incidence of obstructive sleep apnea (OSA)
- Apnea-hypoxia index (AHI)
- Oxygen desaturation indices
- Incidence and severity of excessive daytime sleepiness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evidence was collected by the authors of the companion document, Medical Therapy for Obstructive Sleep Apnea: A Review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine.

A PubMed search (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi) was conducted for key words: sleep apnea or obstructive sleep apnea with bariatric surgery, diet, therapy, oxygen, supplemental oxygen, drug therapy, pharmacotherapy, medical, endocrine, position, weight reduction, weight loss, rhinitis, nasal symptoms, nasal therapy. Literature searches were limited to clinical studies published in the English language between 1985 and January 2005. A search update in April 2005 was conducted on PubMed for "obstructive sleep apnea" and "therapy" with screening of abstracts to ensure completeness of review. Inclusion criteria for the articles included: English language, clinical trials, polysomnography end-points of apnea and/or hypopnea indices and adult subjects. Exclusion criteria included case reports, subjects <20 years of age and use of non-United States Food and Drug Administration-approved medications. In addition to reviewing pertinent findings in the studies meeting the inclusion/exclusion criteria, the authors of the companion document presented data from additional studies, where further insight has been gained.

Of the 1750 abstracts identified by the key word search, 135 studies were identified as qualifying for the above inclusion and exclusion criteria and relevant to the categories of weight loss, pharmacotherapies, delivery of supplemental oxygen and positional therapy. Overall, most of the qualifying studies identified provided Level II or Level III evidence for the effectiveness of an intervention (see

Rating Scheme for the Strength of the Evidence) on improving the apnea-hypopnea index (AHI) Very few studies presented data on neurobehavioral, metabolic or cardiovascular outcomes. In addition, very few of the papers compare medical therapies to continuous positive airway pressure (CPAP) outcomes.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

American Academy of Sleep Medicine Classification of Evidence

Level I Randomized well-designed trials with low alpha and beta levels*

Level II Randomized trials with high alpha and beta levels*

Level III Nonrandomized concurrently controlled studies

Level IV Nonrandomized historically controlled studies

Level V Case series

*Alpha (type I 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

Studies described in this report have each been characterized with evidence levels using criteria listed in Table 2 of the review paper accompanying the original guideline document (see "Availability of Companion Documents" field).

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) developed the recommendations based on the companion document, Medical Therapy for Obstructive Sleep Apnea: A Review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine. A Task Force of content experts was appointed by the AASM to review and grade evidence in the scientific literature regarding therapies for obstructive sleep apnea not covered by previous practice parameters.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

American Academy of Sleep Medicine 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

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

Each recommendation is rated based on the level of the recommendation. Definitions of the levels of the evidence (levels I-V) and levels of the recommendations (Standard, Guideline, Option) are presented at the end of the "Major Recommendations" field.

Weight Reduction

Successful dietary weight loss may improve the apnea-hypopnea index (AHI) in obese obstructive sleep apnea (OSA) patients. **(Guideline)**

This parameter is based on one Level I, one Level II, and 2 Level III papers.

Dietary weight loss should be combined with a primary treatment for OSA. (Kushida et al., 2005; Kushida et al., 2006; American Sleep Disorders Association, 1996) **(Option)**

Bariatric surgery may be adjunctive in the treatment of OSA in obese patients. **(Option)**

There are no Level I-III studies of bariatric surgery for OSA specifically. However, many non-randomized, uncontrolled investigations are now available, show improvements in AHI with weight loss, and therefore there is consensus among members of the Task Force and the Standards of Practice Committee that bariatric surgery may play a role in the treatment of morbidly obese OSA patients as an adjunct to less invasive and rapidly active first-line therapies such as positive airway pressure (PAP).

Pharmacologic Agents

Selective serotonergic uptake inhibitors (SSRIs) are not recommended for treatment of OSA. **(Standard)**

The above recommendation is derived from 2 Level II publications and one level V using paroxetine and fluoxetine.

Protriptyline is not recommended as a primary treatment for OSA. **(Guideline)**

Three Level II and one Level V papers form the basis of this recommendation.

Methylxanthine derivatives (aminophylline and theophylline) are not recommended for treatment of OSA. **(Standard)**

For this recommendation, there are 3 Level II publications, all of which report similar negative findings.

Estrogen therapy (estrogen preparations with or without progesterone) is not indicated for the treatment of OSA. **(Standard)**

This recommendation is based on the results of 4 Level I, 3 Level II, and one Level V publications.

Modafinil is recommended for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective positive airway pressure (PAP) treatment and who are lacking any other identifiable cause for their sleepiness. **(Standard)**

All five studies included in the review (3 Level I, one Level II, and one Level V) attest to the partial effectiveness of modafinil in the management of residual sleepiness in patients with treated OSA who have no other identifiable reason for hypersomnolence.

Supplemental Oxygen

Oxygen supplementation is not recommended as a primary treatment for OSA. **(Option)**

There are 2 Level II and 2 Level III studies that show oxygen administration improves oxygenation parameters in patients with OSA.

Medical Therapies Intended To Improve Nasal Patency

Short-acting nasal decongestants are not recommended for treatment of OSA. **(Option)**

One level II study showed little additive effect of oxymetazoline to positional therapy in improving AHI.

Topical nasal corticosteroids may improve the AHI in patients with OSA and concurrent rhinitis, and thus may be a useful adjunct to primary therapies for OSA. **(Guideline)**

This recommendation is based upon the results of one level I study that demonstrated an improvement in mean AHI from 20 to 12 events/hr using fluticasone nasal spray.

Positional Therapies

Positional therapy, consisting of a method that keeps the patient in a non-supine position, is an effective secondary therapy or can be a supplement to primary therapies for OSA in patients who have a low AHI in the non-supine versus that in the supine position. **(Guideline)**

Patients who normalize their AHI when they sleep in a nonsupine position tend to have less severe OSA, to be less obese, and to be younger. Three Level II studies form the basis for this practice parameter, one of which compared supine with an upright position.

Definitions:

American Academy of Sleep Medicine Classification of Evidence

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Level III Nonrandomized concurrently controlled studies

Level IV Nonrandomized historically controlled studies

Level V Case series

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American Academy of Sleep Medicine Levels of Recommendations

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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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased incidence and severity of obstructive sleep apnea (OSA) and associated excessive daytime sleepiness, cognitive disturbances, depression, hypertension, cardiovascular disease, and cerebrovascular disease

POTENTIAL HARMS

- Use of modafinil: Blood pressure must be monitored because of mild elevations reported in some obstructive sleep apnea (OSA) patients using modafinil.
- Use of bariatric surgery: A cautionary note is warranted because of reports of recurrence of OSA after several years even without regaining of weight. Also, bariatric surgery is not without complications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Morgenthaler TI, Kapen S, Lee-Chiong T, Alessi C, Boehlecke B, Brown T, Coleman J, Friedman L, Kapur V, Owens J, Pancer J, Swick T, Standards of Practice Committee, American Academy of Sleep Medicine. Practice parameters for the medical therapy of obstructive sleep apnea. Sleep 2006 Aug 1;29(8):1031-5. [65 references] PubMed

ADAPTATION

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

DATE RELEASED

2006 Aug 1

GUIDELINE DEVELOPER(S)

American Academy of Sleep Medicine - Professional Association

SOURCE(S) OF FUNDING

American Academy of Sleep Medicine

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Timothy I. Morgenthaler, MD, Mayo Clinic, Rochester, MN; Sheldon Kapen, MD, Detroit VA Medical Center, Detroit, MI; Teofilo Lee-Chiong, MD, National Jewish Medical and Research Center, Denver, CO; Cathy Alessi, MD, UCLA/Greater Los Angeles VA Healthcare System, Sepulveda, CA; Brian Boehlecke, MD, University of North Carolina, Chapel Hill, NC; Terry Brown, DO, St. Joseph Memorial Hospital, Murphysboro, IL; Jack Coleman, MD, Murfreesboro, TN; Leah Friedman, MA, PhD, Stanford University, Stanford, CA; Vishesh Kapur, MD, University of Washington, Seattle, WA; Judith Owens, MD, Rhode Island Hospital, Providence, RI; Jeffrey Pancer, DDS, Toronto, Ontario, Canada; Todd Swick, MD, Houston Sleep Center, Houston, TX

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

This was not an industry supported study. Dr. Morgenthaler has received research support from Itamar Medical Ltd. and ResMed Research Foundation; and has received research equipment from Olympus. Dr. Alessi is a consultant for Prescription Solutions, Inc. Dr. Coleman is a member of the Medical Advisory Board for Influent and is a consultant and speaker/instructor for Acclarent. Dr.

Kapur has received research support from Pro-tech Services, Inc.; and has received research equipment from Respironics. Dr. Owens has received research support from Eli Lilly, Cephalon, and Sepracor; is a consultant for Eli Lilly, Cephalon, Shire, and Sanofi-Aventis; and has participated in speaking engagements supported by Eli Lilly, Cephalon, Sanofi-Aventis, and Johnson & Johnson. Dr. Swick has received research support from Sanofi- Aventis, Takeda Pharmaceuticals, Merck, Jazz Pharmaceuticals, Pfizer, Somaxon, Astellas-Pharmaceuticals, and Cephalon; and is on the speakers' bureau of GlaxoSmithKline, Jazz Pharmaceuticals, Sepracor, Cephalon, and Boehringer Ingelheim. Dr. Hirshkowitz has received research support from Sanofi-Aventis, Takeda, Merck, GlaxoSmithKline, Cephalon, Sepracor, Respironics, ResMed, and NBI; is on the speakers' bureau of Sanofi, Takeda, and Cephalon; is a consultant for Sanofi-Synthelabo, Takeda, and Cephalon; and has received research equipment from ResMed, Respironics, Sunrise, Puritan Bennett, Itamar, Nasal Aire, and Fisher-Paykel. Drs. Kapen, Lee-Chiong, Boehlecke, Brown, Friedman, and Pancer have indicated no financial conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

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 is available:

- Veasey, SC, Guilleminault C, Strohl KP, Sanders, MH, Ballard RD, Magalang UJ. Medical therapy for obstructive sleep apnea: a review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine. Sleep 2006 Aug;29(8):1036-44.

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine 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 NGC summary was completed by ECRI on September 22, 2006. This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Provigil (modafinil) Tablets.

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