Complete Summary

GUIDELINE TITLE

Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders.

BIBLIOGRAPHIC SOURCE(S)

Kushida CA, Littner MR, Hirshkowitz M, Morgenthaler TI, Alessi CA, Bailey D, Boehlecke B, Brown TM, Coleman J Jr, Friedman L, Kapen S, Kapur VK, Kramer M, Lee-Chiong T, Owens J, Pancer JP, Swick TJ, Wise MS, American Academy of Sleep Medicine. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. Sleep 2006 Mar 1;29(3):375-80. [94 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Sleep-related breathing disorders including obstructive sleep apnea (OSA)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Treatment

CLINICAL SPECIALTY

Critical Care
Internal Medicine
Neurology
Psychiatry
Pulmonary Medicine
Sleep Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders
- To provide recommendations that add to the previously published guidelines and practice parameters on the diagnosis and management of obstructive sleep apnea (OSA)

TARGET POPULATION

Adults with sleep-related breathing disorders including obstructive sleep apnea (OSA)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Treatment based on prior diagnosis of obstructive sleep apnea using appropriate standards
2. Continuous positive airway pressure (CPAP) treatment
3. Bi-level positive airway pressure (BPAP) treatment
4. Addition of heated humidification and usage monitors
5. Polysomnography for titration (full-night or split-night, diagnostic titration studies)
6. Follow-up for usage and problems with devices
7. Patient education programs

MAJOR OUTCOMES CONSIDERED

- Clinical signs and symptoms of obstructive sleep apnea OSA
- Quality of life
- Optimal positive airway pressure (PAP)
- PAP utilization
- Daytime hypercapnea
- Adverse events
- Patient compliance/adherence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches in the English language literature (Medline 1966 - early 2005) of major topics relevant to positive airway pressure (PAP) treatment during sleep-related breathing disorders (SRBDs) were conducted. The initial literature search was done in April of 2001 followed by an update in April of 2002. A final literature search for just Level I studies was done in January of 2005 in order to keep the review as timely as possible and to avoid omission of potentially high impact studies published in the interim. The decision to limit the final search and some entire sections to Level I or II evidence was decided upon by the Task Force for the purposes of simplification and brevity. The Task Force did not feel this would detract from the overall conclusions made within the body of this review. The search focused on peer-reviewed clinical studies, including case-series and controlled trials, which contained information regarding PAP treatment outcomes, methods for polysomnographic titration, factors affecting adherence and side effects. Major search terms are included as Table 2 in the accompanying review paper (see the "Availability of Companion Documents" field). Review papers, commentary, case reports, pediatric populations, and studies pertaining to automatic adjusting positive airway pressure (APAP) were excluded, except where parenthetical comments are specifically noted.

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

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

Level II: Randomized trials with high alpha and beta error*

Level III: Nonrandomized concurrently controlled studies

Level IV: Nonrandomized historically controlled studies

Level V: Case series

*Alpha error refers to the probability (generally set at 95% or greater) that a significant outcome (e.g., $p<0.05$) is not a result of chance occurrence. Beta error refers to the probability (generally set at 80% to 90% or greater) that a nonsignificant result (e.g., $p>0.05$) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis to project the size of the study

population necessary to ensure that significant differences will be observed if actually present.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The level of evidence for the data in each paper relevant to the evaluation is listed in evidence tables specific for each question. Each paper was analyzed independently by 2 task force members. The level of evidence was rated using the American Academy of Sleep Medicine (AASM) classification of evidence for intervention studies, an adaptation of the Sackett criteria (See Rating Scheme for the Strength of the Evidence field in this summary). Disagreements between the 2 raters were adjudicated by a vote of the task force members.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Standards of Practice Committee (SPC) of the American Academy of Sleep Medicine (AASM) reviewed the accompanying review (see the "Availability of Companion Documents" field) and cited literature to develop the recommendations. These recommendations pertain to adults and in most cases are based on evidence published in peer-reviewed journals. However, where scientific data are absent, insufficient, or inconclusive, recommendations are based upon committee consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendation

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 over whelming 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

An outside review of these recommendations was performed and the American Academy of Sleep Medicine Board of Directors affirmed approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

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

Treatment with continuous positive airway pressure (CPAP) must be based on a prior diagnosis of obstructive sleep apnea (OSA) established using an acceptable method **(Standard**).

This recommendation is based on previous American Academy of Sleep Medicine (AASM) practice parameters for the indications for polysomnography and related procedures (2005 update).

CPAP is indicated for the treatment of moderate to severe OSA **(Standard)**.

This recommendation is based on 24 randomized controlled trials meeting Level I or II evidence-based medicine criteria.

CPAP is recommended for the treatment of mild OSA **(Option)**.

This recommendation as an option is based on mixed results in 2 Level I and 3 Level II outcome studies in patients with mild OSA.

CPAP is indicated for improving self-reported sleepiness in patients with OSA **(Standard)**.

This recommendation is based on 10 randomized controlled trials in which CPAP reduced sleepiness more than control procedures in patients with OSA.

CPAP is recommended for improving quality of life in patients with OSA **(Option)**.

This recommendation as an option is based on inconsistent results from 2 Level I studies and 4 Level II studies with placebo control, and 1 Level II study with conservative therapy as the control.

CPAP is recommended as an adjunctive therapy to lower blood pressure in hypertensive patients with OSA **(Option)**.

This recommendation as an option is based on 9 clinical trials, 6 of which did not find changes in mean arterial pressure compared to placebo.

Full-night, attended polysomnography performed in the laboratory is the preferred approach for titration to determine optimal positive airway pressure; however, split-night, diagnostic-titration studies are usually adequate **(Guideline)**.

This recommendation is based on 1 Level II and 6 Level IV studies.

CPAP Usage should be objectively monitored to help assure utilization **(Standard)**.

This recommendation is based on overwhelming evidence at all levels indicating patients with OSA overestimate their positive airway pressure. Level I and Level II studies indicate that objectively-measured nightly CPAP "time on" ranges from 3.5 hours/night in minimally symptomatic new patients to 7.1 hours/night in established users.

Close follow-up for positive airway pressure (PAP) usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of PAP use **(Standard)**.

This recommendation is based on 61 studies that examined management paradigms and collected acceptance, utilization, and adverse events; 17 of these studies qualified as Level I.

The addition of heated humidification is indicated to improve CPAP utilization **(Standard)**.

This recommendation is based on 3 Level I studies. There was 1 Level II study that did not find increased utilization with heated humidification. Three additional studies favored heated humidification over unheated or non-humidified CPAP.

The addition of a systematic educational program is indicated to improve PAP utilization **(Standard)**.

This recommendation is based on 4 Level I studies, 1 Level II study, and 1 Level III study.

After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is indicated yearly and as needed to troubleshoot PAP mask, machine, or usage problems **(Option)**.

This recommendation as an option is based on task force and SPC member consensus.

CPAP and bi-level positive airway pressure (BPAP) therapy are safe; side effects and adverse events are mainly minor and reversible **(Standard)**.

This recommendation is based on more than 23 published reports.

While the literature mainly supports CPAP therapy, BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present **(Guideline)**.

This recommendation is based on 2 Level I studies which yielded no evidence that BPAP improves efficacy or adherence in the management of OSA compared to CPAP.

BPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with daytime hypercapnia **(Option)**.

This recommendation as an option is based on 11 studies all graded at Level III or better that overall found improvement associated with BPAP therapy.

Definitions:

Levels of Recommendations

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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.

Classification of Evidence

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

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Level III: Nonrandomized concurrently controlled studies

Level IV: Nonrandomized historically controlled studies

Level V: Case series

*Alpha error refers to the probability (generally set at 95% or greater) that a significant outcome (e.g., $p<0.05$) is not a result of chance occurrence. Beta error refers to the probability (generally set at 80% to 90% or greater) that a nonsignificant result (e.g., $p>0.05$) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis to project the size of the study population necessary to ensure that significant differences will be observed if actually present.

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 the recommendations (See "Major Recommendations"). These recommendations, in most cases, are based on evidence published in peer-reviewed journals. However, where scientific data are absent, insufficient, or inconclusive, recommendations are based upon committee consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Increased correct patient utilization of positive airway pressure (PAP) devices
- Improved clinical management of obstructive sleep apnea (OSA)
- Identification of appropriate indications for bilevel positive airway pressure (BPAP) as a second-line therapy

POTENTIAL HARMS

While sinusitis, mask leaks, and dermatitis are not infrequent, tinnitus and dyspnea occur more rarely. A listing of adverse events associated with positive airway pressure (PAP) therapy is presented in Table 3 of the accompanying review paper (see "Availability of Companion Documents" field).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not 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 the propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient and the availability of diagnostic and 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
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Kushida CA, Littner MR, Hirshkowitz M, Morgenthaler TI, Alessi CA, Bailey D, Boehlecke B, Brown TM, Coleman J Jr, Friedman L, Kapen S, Kapur VK, Kramer M, Lee-Chiong T, Owens J, Pancer JP, Swick TJ, Wise MS, American Academy of Sleep Medicine. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. Sleep 2006 Mar 1;29(3):375-80. [94 references] PubMed

ADAPTATION

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

DATE RELEASED

2006 Mar

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

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

This was not an industry supported study. Dr. Kushida has received research support from GlaxoSmithKline, Boehringer-Ingelheim, XenoPort, Inc., Schwarz Pharmaceuticals, and Kyowa Pharmaceuticals; and has participated in speaking engagements supported by GlaxoSmithKline. Dr. Littner has received research support from GlaxoSmithKline, AstraZeneca, Boehringer-Ingelheim, Dey Pharmaceuticals, and Altana Pharmaceuticals; has participated in speaking engagements supported by Pfizer, Glaxo-SmithKline, and Boehringer-Ingelheim; and is a member of the advisory boards for Novartis, Pfizer, and Dey Pharmaceuticals. Dr. Hirshkowitz has received research support from Sanofi, Merck, Takeda, Somaxon, and Cephalon; is on the speakers' bureaus for Cephalon, Sanofi, Takeda, and Sepracor; and has received research equipment from ResMed, Respironics, and Sunrise. Dr. Morgenthaler has received research support from Itamar Medical, ResMed, and ResMed Research Foundation; and has received research equipment from Olympus, Inc. Dr. Alessi is a consultant for Prescription Solutions, Inc. Dr. Kapur has received research support from the Washington Technology Center and Pro-tech Services, Inc.; and has received research equipment from Respironics. Dr. Owens has received research support from Eli Lilly, Cephalon, Sepracor, and Johnson & Johnson; and is a speaker or consultant for Eli Lilly, Cephalon, Johnson & Johnson, Shire, and Select Comfort. Dr. Swick has received research support from Orphan Medical (Jazz Pharmaceuticals), Cephalon, Sanofi-Aventis, Merck, and Takeda Pharmaceuticals; and has participated in speaking engagements supported by Orphan Medical (Jazz Pharmaceuticals), Cephalon, Takeda Pharmaceuticals, and GlaxoSmithKline. Dr. Coleman has participated in speaking engagements supported by Aventis; and is an investor in the Murphysboro Imaging Leasing Company. Drs. Bailey, Boehlecke, Brown, Friedman, Kapen, Kramer, Lee-Chiong, Pancer, and Wise 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:

- Gay P, Weaver T, Loube D, Iber C; Positive Airway Pressure Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine. Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. Sleep 2006 Mar;29(3):381-401.

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

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