Complete Summary

GUIDELINE TITLE

Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders.

BIBLIOGRAPHIC SOURCE(S)

Morgenthaler TI, Lee-Chiong T, Alessi C, Friedman L, Aurora RN, Boehlecke B, Brown T, Chesson AL Jr, Kapur V, Maganti R, Owens J, Pancer J, Swick TJ, Zak R, Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. Sleep 2007 Nov 1;30(11):1445-59. [133 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 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)

Circadian rhythm sleep disorders (CRSDs)

- Exogenous CRSDs, including shift work disorder (SWD) and jet lag disorder (JLD)
- Endogenous CRSDs, including advanced sleep phase disorder (ASPD), delayed sleep phase disorder (DSPD), irregular sleep-wake rhythm (ISWR), and the non–24-hour sleep-wake syndrome (nonentrained type) or free-running disorder (FRD)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology
Pediatrics
Psychiatry
Sleep Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations for the assessment and treatment of circadian rhythm sleep disorders

TARGET POPULATION

Children and adults (sighted and unsighted) with exogenous and endogenous circadian rhythm sleep disorders (CRSDs)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Polysomnography (PSG)
2. Morningness-Eveningness Questionnaire (MEQ) (insufficient evidence to recommend)

3. Circadian phase markers
4. Actigraphy for diagnosis and response to therapy
5. Sleep log or diary

Treatment

1. Planned sleep and nap schedules
2. Timed light exposure
3. Timed melatonin administration
4. Hypnotics (benzodiazapine receptor agonists)
5. Stimulants/alerting agents (modafinil, caffeine)
6. Keeping home based sleep hours when traveling (for jet lag)
7. Shifting sleep schedules (for jet lag prevention)
8. Chronotherapy
9. Mixed modality approaches

MAJOR OUTCOMES CONSIDERED

- Changes in timing of circadian phase markers (core body temperature, melatonin secretion)
- Adverse effects of medications
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search

The Guideline Developers searched MEDLINE through October 2006 to identify citations of potential relevance for this review. The most relevant search term, Sleep Disorders, Circadian Rhythm, became a MESH heading in the year 2000, and the search term, Chronobiology Disorders, became a MESH heading in 2001. Several Circadian Rhythm Sleep Disorders (CRSDs) are not yet included in the MESH headings list. Consequently, to identify relevant articles, especially those published prior to 2000, the terms were searched both as MESH headings and as keywords. Also, broader search terms were used and then limited by including sleep as a search co-term. An iterative process was used to remove duplicates; that is, as each term was searched, only articles that had not been previously identified were added to the citation list. In addition, the bibliographies of review articles were examined by Task Force members in order to find articles that were missed in the initial search.

After the large set of potentially relevant citations was identified, the titles and abstracts were reviewed by at least two members of the task force who voted for or against inclusion in a final set of articles to be reviewed in more detail and

scored. When the two reviewers were in disagreement, the Chair of the Task Force acted as a tiebreaker.

Inclusion and Exclusion

The medical literature was searched for studies of patients with a presumptive or diagnosed CRSD, and an evidence table constructed. Searches were limited to articles published in the English language involving human subjects. Abstracts, theoretical papers and editorials were excluded. Review articles were excluded from the evidence table, but were incorporated into the report where appropriate for background. Because unequivocal cases of advanced sleep phase disorder (ASPD) and free running disorder (FRD) are quite rare, single case reports were accepted for these categories; otherwise, studies were required to include at least eight subjects. The guideline developers did not include studies of disorders that may have a circadian component but are not considered CRSDs; e.g., restless legs syndrome, seasonal affective disorder (winter depression), and extended duty/acute sleep deprivation. Also, guideline developers did not review studies of treatments that might affect circadian rhythms if the study did not aim to correct a circadian abnormality (e.g., melatonin administration for psychophysiological insomnia). No age range was imposed; in other words, studies that involved children, young adults, and older adults were included. Some of the studies were used as evidence on more than one relevant question; i.e., risk, assessment, and treatment.

The developers also reviewed studies of simulated shift work disorder (SWD) or jet lag disorder (JLD) and included them in the evidence table if they provided evidence for important principles that could be applied clinically. These studies recruited subjects without a clinical diagnosis who participated in a phase shifting protocol designed to simulate a clinical condition. Given the constraints of space, these studies are summarized in the text, and not described in detail.

NUMBER OF SOURCE DOCUMENTS

63

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 1

Risk/Assessment: Validating[1] cohort with well-validated reference standards[2]

Treatment: High quality randomized controlled trial (RCT) on well-characterized subjects or patients

Level 2

Risk/Assessment: Smaller or "exploratory" cohort study or one that has incompletely validated reference standards[2]

Treatment: Cohort study or flawed clinical trial (e.g., small N, blinding not specified, possible assignment to treatment, incompletely validated reference standards[2])

Level 3

Risk/Assessment: Case control or cross sectional study

Treatment: Case control study

Level 4

Risk/Assessment: Case series (and poor quality cohort and case control studies)

Treatment: Case series (and poor quality cohort and case control studies)

Notes

1. Validating studies test the quality of a specific diagnostic test, based on prior evidence.
2. Reference standards: polysomnography (PSG), sleep logs, actigraphy, phase markers, validated self-reports.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Each article was abstracted either by a task force member or a paid professional. Each abstract contained four essential items that were placed in a Population, Intervention, Comparison, and Outcome (PICO) evidence table; namely, 1) A description of the Patient or Problem that was addressed, 2) The Intervention that was made, 3) A Comparison intervention (if necessary) and 4) The Outcome(s). These abstracts are posted in an evidence table on the American Academy of Sleep Medicine (AASM) website: www.aasmnet.org/.

In addition to being abstracted, the studies were graded using the Oxford System for Evidence-Based Medicine (see the "Rating Scheme for the Strength of the Evidence" field).

Final summaries of information from included articles are listed in an evidence table available at http://www.aasmnet.org/.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

On the basis of the evidence reviews and noted references, the Standards of Practice Committee (SPC) of the American Academy of Sleep Medicine, in conjunction with specialists and other interested parties, developed the recommendations included in this practice parameters paper related to the evaluation and therapy of circadian rhythm sleep disorders.

In most cases, the strength of the recommendation is based on evidence from studies published in peer-reviewed journals that were evaluated as noted in the evidence table of the companion review papers. However, when scientific data were absent, insufficient, or inconclusive, the recommendations are based upon consensus after review and discussion by the SPC. Those recommendations for which consensus formed the main basis for the recommendation are specifically indicated.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Standard: This is a generally accepted patient-care strategy that 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 that 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 that 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 (AASM) approved these recommendations.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (**1-4**) and levels of recommendation (**standard, guideline, option**) are defined at the end of the "Major Recommendation" field.

General Recommendations for Evaluation of Circadian Rhythm Sleep Disorders (CRSD)

1. Use of a sleep log or diary is indicated in the assessment of patients with a suspected CRSD. **(Guideline)**
2. Actigraphy is indicated to assist in evaluation of patients suspected of CRSDs, including irregular sleep-wake disorder (ISWR), free-running disorder (FRD) (with or without blindness) **(Option)**, and in advanced sleep phase disorder (ASPD), delayed sleep phase disorder (DSPD), and shift work disorder (SWD). **(Guideline)**
3. Actigraphy is useful as an outcome measure in evaluating the response to treatment for CRSDs. **(Guideline)**
4. There is insufficient evidence to recommend the routine use of the Morningness-Eveningness Questionnaire (MEQ) for the clinical evaluation of CRSDs. **(Option)**
5. Circadian phase markers are useful to determine circadian phase and confirm the diagnosis of FRD in sighted and unsighted patients but there is insufficient evidence to recommend their routine use in the diagnosis of SWD, jet lag disorder (JLD), ASPD, DSPD, or ISWR. **(Option)**
6. Polysomnography (PSG) is indicated to rule out another primary sleep disorder in patients with symptoms suggestive of both a CRSD and another primary sleep disorder, but is not routinely indicated for the diagnosis of CRSDs. **(Standard)**

Recommendations for Evaluation and Treatments of Circadian Rhythm Sleep Disorders

Shift Work Disorder

1. Both the Morningness-Eveningness Questionnaire (MEQ) and measurement of circadian phase markers (e.g., core body temperature nadir or timing of melatonin secretion) are at present of unproved usefulness in evaluation of patients with suspected SWD. **(Option)**
2. Planned napping before or during the night shift is indicated to improve alertness and performance among night shift workers. **(Standard)**
3. Timed light exposure in the work environment and light restriction in the morning, when feasible, is indicated to decrease sleepiness and improve alertness during night shift work. **(Guideline)**
4. Administration of melatonin prior to daytime sleep is indicated to promote daytime sleep among night shift workers. **(Guideline)**
5. Hypnotic medications may be used to promote daytime sleep among night shift workers. Carryover of sedation to the nighttime shift with potential adverse consequences for nighttime performance and safety must be considered. **(Guideline)**
6. Modafinil is indicated to enhance alertness during the night shift for SWD. **(Guideline)**

   Caffeine is indicated to enhance alertness during the night shift for SWD. **(Option)**

Jet Lag Disorder

1. There is insufficient evidence to recommend the routine use of actigraphy, polysomnography, or measurement of circadian phase markers in the evaluation of jet lag disorder. **(Option)**
2. When time at destination is expected to be brief (i.e., two days or less), keeping home-based sleep hours, rather than adopting destination sleep hours, may reduce sleepiness and jet lag symptoms. **(Option)**
3. The combination of morning exposure to bright light and shifting the sleep schedule one hour earlier each day for three days prior to eastward travel may lessen symptoms of jet lag. **(Option)**
4. Melatonin administered at the appropriate time is indicated to reduce symptoms of jet lag and improve sleep following travel across multiple time zones. **(Standard)**
5. Short-term use of a benzodiazepine receptor agonist hypnotic is indicated for the treatment of jet lag-induced insomnia, but potential adverse effects must be considered, and effects on daytime symptoms of jet lag disorder have not been adequately addressed. **(Option)**
6. Caffeine is indicated as a way to counteract jet lag-induced sleepiness, but may also disrupt nighttime sleep. **(Option)**

Advanced Sleep Phase Disorder

1. There is insufficient evidence to recommend the use of the MEQ for the routine diagnosis of ASPD. **(Option)**
2. Polysomnography is not routinely indicated for the diagnosis of ASPD. **(Standard)**
3. There is insufficient evidence to recommend the use of circadian markers for the routine diagnosis of ASPD. **(Option)**
4. Prescribed sleep/wake scheduling, timed light exposure, or timed melatonin administration are indicated as treatments for patients with ASPD. **(Option)**

Delayed Sleep Phase Disorder

1. Polysomnography is not indicated in the routine assessment of DSPD. **(Standard)**
2. Morning light exposure is indicated in the treatment of DSPD. Optimal timing, duration, and dosing of morning light treatment for DSPD remain to be determined. **(Guideline)**
3. Chronotherapy (i.e., prescribed progressive delay in the schedule of sleep time until the desired sleep schedule is reached) may be useful for DSPD. **(Option)**
4. Properly timed melatonin administration is indicated as a therapy for DSPD. **(Guideline)**
5. Vitamin B12 is not indicated in the treatment for DSPD. **(Guideline)**
6. There is insufficient evidence supporting the use of hypnotic medications to promote sleep or the use of stimulant medications to promote alertness for DSPD. **(Option)**

Free-Running Circadian Rhythm Sleep Disorder

1. Sleep logs are useful for assessment in FRD patients. **(Option)**

2. Circadian phase markers are useful to determine circadian phase and confirm the diagnosis of FRD in sighted and unsighted patients. **(Option)**
3. Prescribed sleep/wake scheduling as a method to improve circadian rhythms may be useful for therapy of FRD in sighted individuals. **(Option)**
4. Circadian phase shifting by timed light exposure may be used to treat FRD in sighted individuals. **(Option)**
5. Circadian phase shifting by timed melatonin administration may be used to treat FRD in sighted individuals. **(Option)**
6. Timed melatonin administration is indicated for the therapy of FRD in blind individuals. **(Guideline)**
7. There is insufficient evidence to support using vitamin B12 in treating FRD in sighted individuals. **(Option)**

Irregular Sleep-Wake Rhythm

1. The use of sleep logs and/or actigraphy are indicated to identify and monitor treatment outcomes in ISWR, including in older people with dementia and those living in nursing homes. **(Guideline)**
2. Daytime bright light exposure may improve circadian rest-activity rhythms and consolidation of sleep and wake in nursing home residents with dementia and ISWR. **(Option)**
3. Melatonin is not indicated for the treatment of ISWR in older people with dementia, but may be indicated for children with ISWR and severe psychomotor retardation. **(Option)**
4. Mixed modality approaches combining bright light exposure, physical activity, and other behavioral elements are indicated in treatment of ISWR among older people with dementia **(Guideline)**, including nursing home residents **(Guideline)**, and children with ISWR and moderate to severe mental retardation. **(Option)**

Definitions:

Level 1

Risk/Assessment: Validating[1] cohort with well-validated reference standards[2]

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Level 2

Risk/Assessment: Smaller or "exploratory" cohort study or one that has incompletely validated reference standards[2]

Treatment: Cohort study or flawed clinical trial (e.g., small N, blinding not specified, possible assignment to treatment, incompletely validated reference standards[2])

Level 3

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Risk/Assessment: Case series (and poor quality cohort and case control studies)

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Notes

1. Validating studies test the quality of a specific diagnostic test, based on prior evidence.
2. Reference standards: polysomnography (PSG), sleep logs, actigraphy, phase markers, validated self-reports.

Levels of Recommendation

Standard: This is a generally accepted patient-care strategy that 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 that 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 that 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

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

The appropriate treatment of patients with circadian rhythm sleep disorders may improve daytime sleep among night shift workers, alertness in jet lag disorder and shift work disorder, and circadian rest-activity rhythms and consolidation of sleep and wake in nursing home residents with dementia and irregular sleep-wake

rhythm; and reduce symptoms of jet lag and improve sleep following travel across multiple time zones.

POTENTIAL HARMS

- Hypnotic medications may be used to promote daytime sleep among night shift workers. Carryover of sedation to the nighttime shift with potential adverse consequences for nighttime performance and safety must be considered.
- Short-term use of a benzodiazepine receptor agonist hypnotic is indicated for the treatment of jet lag-induced insomnia, but potential adverse effects must be considered, and effects on daytime symptoms of jet lag disorder have not been adequately addressed.
- Caffeine is indicated as a way to counteract jet lag-induced sleepiness, but may also disrupt nighttime sleep.

CONTRAINDICATIONS

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The use of light treatment in patients using photosensitizing drugs or who have ongoing ocular or retinal pathology may be contraindicated.

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 expected to obtain the same results. The ultimate judgment regarding appropriateness of any specific therapy must be made by the clinician and patient, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, resources available, and other relevant factors.

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)

Morgenthaler TI, Lee-Chiong T, Alessi C, Friedman L, Aurora RN, Boehlecke B, Brown T, Chesson AL Jr, Kapur V, Maganti R, Owens J, Pancer J, Swick TJ, Zak R, Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. Sleep 2007 Nov 1;30(11):1445-59. [133 references] PubMed

ADAPTATION

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

DATE RELEASED

2007 Nov

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

The authors have indicated no financial conflict 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 are available:

- Sack RL, Auckley D, Auger RR, et al. Circadian rhythm sleep disorders: Part I, basic principles, shift work and jet lag disorders. Sleep 2007;30(11):1460-83. Electronic copies: Available in Portable document Format (PDF) from the American Academy of Sleep Medicine Web site.
- Sack RL, Auckley D, Auger RR, et al. Circadian rhythm sleep disorders: Part II, advanced sleep phase disorder, delayed sleep phase disorder, free-running disorder and irregular sleep-wake rhythm. Sleep 2007;30(11):1484-1501. 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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