PRACTICE PARAMETER

Practice Parameters for the Psychological and Behavioral Treatment of Insomnia: An Update. An American Academy of Sleep Medicine Report

An American Academy of Sleep Medicine Report

Standards of Practice Committee of the American Academy of Sleep Medicine

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Abstract: Insomnia is highly prevalent, has associated daytime consequences which impair job performance and quality of life, and is associated with increased risk of comorbidities including depression. These practice parameters provide recommendations regarding behavioral and psychological treatment approaches, which are often effective in primary and secondary insomnia. These recommendations replace or modify those published in the 1999 practice parameter paper produced by the American Sleep Disorders Association. A Task Force of content experts was appointed by the American Academy of Sleep Medicine to perform a comprehensive review of the scientific literature since 1999 and to grade the evidence regarding non-pharmacological treatments of insomnia. Recommendations were developed based on this review using evidencebased methods. These recommendations were developed by the Standards of Practice Committee and reviewed and approved by the Board of Directors of the American Academy of Sleep Medicine. Psychological and behavioral interventions are effective in the treatment of both chronic primary insomnia (Standard) and secondary insomnia (Guideline). Stimulus control therapy, relaxation training, and cognitive behavior therapy are individually effective therapies in the treatment of chronic insomnia (Standard) and sleep restriction therapy, multicomponent therapy (without cognitive therapy), biofeedback and paradoxical intention are individually effective therapies in the treatment of chronic insomnia (Guideline). There was insufficient evidence to recommend sleep hygiene education, imagery training and cognitive therapy as single therapies or when added to other specific approaches. Psychological and behavioral interventions are effective in the treatment of insomnia in older adults and in the treatment of insomnia among chronic hypnotic users (Standard).

Keywords: Practice guidelines, practice parameters, insomnia primary, insomnia secondary, treatment, behavioral, psychological, non-pharmacological, stimulus control therapy, relaxation training, sleep restriction, cognitive behavior therapy, multicomponent therapy, paradoxical intention, sleep hygiene education.

Citation: Morgenthaler T; Kramer M; Alessi C et al. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American Academy of Sleep Medicine report. *SLEEP* 2006;29(11): 1415-1419.

Disclosure Statement

This was not an industry supported study. Dr. Morgenthaler has received research support from Itamar Medical, LTD. and ResMed, Inc. Dr. Alessi is a consultant for Prescription Solutions, Inc. Dr. Coleman is on the medical advisory board of Influent Medical; and is a consultant and speaker/instructor for Acclarent. 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 Cephalon, Lilly, and Sepracor; is a consultant for Lilly, Cephalon, and Shire; and is a speaker for Johnson & Johnson, Cephalon, and Lilly. Dr. Swick has received research support from Sanofi-Aventis, Takeda Pharmaceuticals, Merck, Jazz Pharmaceuticals, Pfizer, Somaxon, Astellas-Pharmaceuticals, and Cephalon; and is a member of the speakers' bureau for GlaxoSmith-Kline, Jazz Pharmaceuticals, Sepracor, Cephalon, and Boehringer Ingelheim. Drs. Kramer, Friedman, Boehlecke, Brown, Lee-Chiong, and Pancer have indicated no financial conflicts of interest.

Submitted for publication April 20, 2006 Accepted for publication April 30, 2006

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1.0 INTRODUCTION

INSOMNIA IS A COMMON CONDITION, REPORTED TO OCCUR IN ONE THIRD OF THE ADULT POPULATION.¹ CHRONIC INSOMNIA IS ASSOCIATED WITH A reduced quality of life, impaired daytime functioning, increased loss of time from work and higher health costs. Chronic insomnia is also associated with an increased risk of depression and chronic use of hypnotic medication.²⁻⁴

The diagnosis of insomnia is based on subjective complaints of difficulty falling asleep or staying asleep, or non-restorative sleep associated with marked distress or significant daytime impairment. Insomnia-related complaints may include reports of daytime fatigue, problems with memory and concentration and mood disturbance. Insomnia can be a primary disorder, as in primary insomnia (e.g. psychophysiological insomnia, paradoxical insomnia, idiopathic insomnia, physiological insomnia-unspecified, etc.), or (what we term here as) secondary insomnia, where insomnia is a symptom of or associated with other conditions including medical or psychiatric illness, substance abuse disorder or another sleep disorder. It is often difficult to distinguish the cause of insomnia in patients with concurrent medical disorders. However, insomnia, whether primary or secondary to a comorbid illness, merits attention. Indicators of the severity of insomnia

include intensity, frequency and duration of the sleep difficulty. Insomnia is said to be persistent if it lasts from 1 to 6 months, and chronic if it lasts more than six months.

The present paper replaces the previous practice parameters⁸ for the non-pharmacologic treatment of chronic insomnia. These updated recommendations are based on the accompanying review paper² prepared by a taskforce appointed by the Standards of Practice Committee (SPC) of the American Academy of Sleep Medicine (AASM).

2.0 METHODS

A task force of content experts was appointed by the AASM in January, 2004 to review and grade evidence in the peer-reviewed scientific literature regarding the behavioral and psychological treatment of insomnia, including both primary and secondary insomnia. Recommendations are based on evidence from studies evaluated in this literature review.

The Board of Directors of the AASM approved these recommendations. All members of the AASM SPC and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of interest with regard to this subject.

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.

The AASM expects these guidelines to have a beneficial impact on professional behavior, patient outcomes, and, possibly, health care costs. These practice parameters reflect the state of knowledge at the time of publication and will be reviewed, updated, and revised as new information becomes available. This practice parameter paper is referenced, where appropriate, using square-bracketed numbers to the relevant sections and tables in the accompanying review paper, or with additional references at the end of this paper. As described in the accompanying review paper, reviewed articles were assigned an evidence classification based on criteria listed in Table 1. Definitions for varying levels of recommendations (reflecting the strength of the available evidence) used by the AASM appear in Table 2. For some parameters there were no studies meeting inclusion criteria that specifically addressed the clinical issue. In these cases (Parameters 3.10-3.13) the parameter is provided since we believe it refers to an important clinical question, but no specific recommendation level is provided.

3.0 RECOMMENDATIONS

Although the focus of the prior practice parameters⁸ were primarily limited to the effectiveness of specific individual therapies in the treatment of chronic primary insomnia in adults, these updated parameters will also address use of behavioral therapies in secondary insomnia, and in special populations. New recommendations, as well as those that are the same as, similar to, or an expansion of recommendations in the prior practice parameters are noted in the text. The recommendations in this paper are sup-

Table 1—AASM Classification of Evidence

Evidence Study Design

Levels

I Randomized well-designed trials with low alpha and beta

II Randomized trials with high alpha and beta error*
III Nonrandomized concurrently controlled studies
IV Nonrandomized historically controlled studies

V Case series

Adapted from Sackett9

*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%).

Table 2—AASM Levels of Recommendations

| Term | Definition |
|-----------|--|
| rerm | Delinition |
| Standard | This is a generally accepted patient-care strategy, which |
| | reflects a high degree of clinical certainty. The term stan- |
| | dard 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. |
| | |

ported by Level I to Level V evidence.

Adapted from Eddy¹⁰

Each of the 37 articles presented in Table 2 of the accompanying review paper¹¹ was evaluated using the evidence-based approach outlined by the SPC in Table 1 of this paper. Recommendations were developed by the SPC and the level of supporting evidence (Standard, Guideline, or Option) assigned according to the scheme shown in Table 2. The following are recommendations of the SPC approved by the Board of Directors of the AASM.

RECOMMENDATIONS ACCORDING TO TYPE OF INSOMNIA

3.1 Psychological and behavioral interventions are effective and recommended in the treatment of chronic primary insomnia. [4.2] (Standard)

This is a new recommendation that was implied, but not specifically stated in the prior practice parameters. There were 17 studies identified in the current review that evaluated the effects of treatment for primary insomnia, including 5 randomized controlled trials with Level I evidence that demonstrated the effectiveness of psychological and behavioral interventions.¹²⁻¹⁶

3.2 Psychological and behavioral interventions are effective and recommended in the treatment of secondary insomnia. [4.3, 4.4] (Standard)

This is a new recommendation (evidence relating to secondary insomnia was not included in the earlier review). There were 11 studies identified in the current review that evaluated the effects of treatment for insomnia associated with another medical or psychiatric disorder, including four randomized controlled trials with either Level I^{15,17} or Level II^{18,19} evidence demonstrating the effectiveness of psychological and behavioral interventions.

RECOMMENDATIONS FOR SPECIFIC THERAPIES

3.3 Stimulus control therapy is effective and recommended therapy in the treatment of chronic insomnia. [4.3, 4.4, 4.5] (Standard)

This recommendation is unchanged from the prior practice parameter. Since the prior review, there was 1 additional randomized controlled trial (Level II) supporting the effectiveness of stimulus control therapy.²⁰ The objective of stimulus control therapy is to train the insomnia patient to re-associate the bed and bedroom with sleep and to re-establish a consistent sleep-wake schedule.

3.4 Relaxation training is effective and recommended therapy in the treatment of chronic insomnia. [4.6] (Standard)

This recommendation represents a change from the prior practice parameter. Since the prior review, there were 4 additional randomized controlled trials, including 3 Level I^{12,21,22} and 1 Level II studies¹⁹ strengthening the support regarding the effectiveness of relaxation training. Relaxation training involves methods aimed at reducing somatic tension (e.g., progressive muscle relaxation, autogenic training) or intrusive thoughts at bedtime that interfere with sleep.

3.5 Sleep restriction is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.4, 4.6] (Guideline)

This recommendation is a change from the prior practice parameter. Since the prior review, there have been 2 additional randomized controlled trials, including 1 Level I²¹ and 1 Level II²³ study strengthening the support regarding the effectiveness of sleep restriction therapy. This form of therapy involves curtailing the amount of time in bed to the actual amount of time spent asleep, thereby creating a mild sleep deprivation, and then lengthening sleep time as sleep efficiency improves.

3.6 Cognitive behavior therapy, with or without relaxation therapy, is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.6](Standard)

This recommendation is a change from the prior practice parameter. Since the prior review, there have been 5 additional randomized controlled trials, including 4 Level I studies^{12,16,24,25} and 1 Level II study²⁶ strengthening the support regarding the effectiveness of cognitive behavior therapy. In addition, there have been 7 additional randomized controlled trials supporting the effectiveness of cognitive behavior therapy with relaxation therapy, including 4 level I studies^{14,17,27,28} and 3 level II studies.^{18,19,29} Cognitive behavior therapy includes various combinations of both cognitive as well as behavioral interventions. The cognitive component is

aimed at changing patients' beliefs and attitudes about insomnia. The behavioral component may include therapies such as stimulus control therapy, sleep restriction, or relaxation training. Sleep hygiene education is often also included.

3.7 Multicomponent therapy (without cognitive therapy) is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.8, 5.0] (Guideline)

This is a new recommendation. There were 3 randomized controlled trials supporting the effectiveness of multicomponent therapy without cognitive therapy including 1 Level I study combining stimulus control therapy, relaxation training and sleep hygiene education¹⁵; 1 Level II study combining stimulus control therapy, sleep restriction and sleep hygiene education³⁰; and 1 Level II study combining sleep restriction and stimulus control therapy.³¹

3.8 Paradoxical intention is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.6] (Guideline)

This recommendation is unchanged from the prior practice parameter. Since the prior review, there was 1 additional randomized controlled trial (Level II)³² supporting the effectiveness of paradoxical intention. This method of treatment involves instructing the patient to remain passively awake and avoid any effort (i.e., intention) to fall asleep. The goal is to eliminate performance anxiety, as it may inhibit sleep onset. This parameter is limited to sleep initiation insomnia, since studies supporting paradoxical intention were based on samples of sleep onset insomniacs and therefore findings may not generalize to sleep maintenance or mixed insomnia.

3.9 Biofeedback is effective and recommended therapy in the treatment of chronic insomnia. (Guideline)

This recommendation is unchanged from the prior practice parameter. There were no additional studies involving biofeedback since the prior review included in the current review. This form of therapy provides visual or auditory feedback to patients to help them control some physiologic parameters (e.g. muscle tension) in order to seek reduction in somatic arousal.

3.10 Insufficient evidence was available for sleep hygiene education to be an option as a single therapy. Whether this therapy is effective when added to other specific approaches could not be determined from the available data. [4.6, 4.7] (No recommendation level)

This recommendation is unchanged from the prior practice parameter. This form of behavioral intervention aims to make patients more aware of health practices (e.g. diet, exercise, substance abuse) and environmental factors (e.g. light, noise, temperature) that may be either detrimental or beneficial for sleep. Sleep hygiene education is often included with other forms of behavioral interventions; however, in some studies, sleep hygiene education was used as the control condition. Data are insufficient to assess the effectiveness of sleep hygiene education as a single therapy.

3.11 Insufficient evidence was available for imagery training to be an option as a single therapy. Whether this therapy is effective when added to other specific approaches could not be determined

from the available data. [4.7] (No recommendation level)

This recommendation is unchanged from the prior practice parameter. This treatment involves a visualization technique to focus on some pleasant or neutral images to block out unwanted thoughts before sleep. There were no new studies involving imagery training, either alone or in combination with other therapies, in the current review.

3.12 Insufficient evidence was available for cognitive therapy to be recommended as a single therapy. [4.6] (No recommendation level)

This recommendation is unchanged from the prior practice parameter. There were no new studies involving cognitive therapy as a single therapy in the current review. This form of therapy seeks to change misconceptions about sleep and faulty beliefs and attitudes about insomnia and its perceived daytime consequences. Although, as described above, there is extensive evidence for the effectiveness of cognitive therapy used in combination with other therapies (e.g., within cognitive behavior therapy), there remains limited evidence to recommend cognitive therapy as a single therapy.

3.13 Insufficient evidence was available to recommend one single therapy over another, or to recommend single therapy versus a combination of psychological and behavioral interventions. [4.6, 4.7] (No recommendation level)

This is a new recommendation. Few studies compared 1 single therapy with another. In addition, over half (21 out of 37) of the studies identified in the accompanying review paper combined 2 or more psychological and/or behavioral methods when treating insomnia. However, there was insufficient evidence from the current review to evaluate the effectiveness of one therapy over another, or to recommend single versus combination therapy.

RECOMMENDATIONS RELEVANT TO SPECIFIC PATIENT GROUPS

3.14 Psychological and behavioral interventions are effective and recommended in the treatment of insomnia in older adults. [4.4] (Standard)

This is a new recommendation. There were 8 studies conducted in adults with an average age of greater than 60 years, including studies of primary, secondary and mixed insomnia. Seven of these studies were randomized controlled trials, including 5 studies with Level I evidence^{15,16,21,25,28} and 2 studies with Level II evidence^{23,33} demonstrating the effectiveness of psychological and behavioral interventions in older adults.

3.15 Psychological and behavioral interventions are effective and recommended in the treatment of insomnia among chronic hypnotic users. [4.5] (Standard)

This is a new recommendation. There were 4 studies identified in the current review that examined psychological and behavioral interventions among chronic hypnotic users. Three of these were randomized controlled trials, of which 2 provided Level I^{25,28} and 1 provided Level II evidence²⁰ of the effectiveness of psychological and behavioral interventions among chronic hypnotic users.

4.0 AREAS FOR FUTURE RESEARCH

- 4.1 Studies are needed that evaluate the effectiveness of psychological and behavioral treatments not only in reducing insomnia symptoms but also in improving measures of clinical significance, such as daytime function, quality of life and morbidity. This issue has also been raised in the 2005 National Institutes of Health State of the Science Conference Statement³⁴ regarding chronic Insomnia.
- 4.2 In studies of secondary insomnia, research is needed to determine whether targeting sleep symptoms leads to an improvement in sleep, regardless of whether or not there is improvement in the underlying condition.
- 4.3 Further research is needed comparing the effectiveness of different single psychological and behavioral therapies for insomnia.
- 4.4. Further research is also needed to address whether there is an added benefit of providing a combination of psychological and behavioral therapies over a single therapy, and to identify patient groups where combination or single therapy is most appropriate.
- 4.5 Studies are needed that compare pharmacologic and psychological/behavioral treatments of insomnia, as well as combined therapies in terms of their short and long-term effectiveness, risks/benefits, costs and patient satisfaction.

ACKNOWLEDGMENTS

The AASM and the SPC would like to thank Sara Seaquist and Maria DeSena for coordinating the work on this practice parameter and to Richard Rosenberg, PhD, Andrew L. Chesson, MD, and Max Hirshkowitz, PhD for their contributions to the preparation of the manuscript.

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