Introduction

This guideline was developed by a Clinical Practice Guidelines Working Group to assist physicians in the management of primary insomnia in adults. A companion guideline for the assessment of patients with insomnia accompanies this document. This guideline does not address the assessment and management of excessive daytime sleepiness (EDS) or the management of other primary sleep disorders (i.e.; obstructive sleep apnea, movement disorders in sleep or parasomnias).

Exclusions

- Children under the age of 18
- Pregnant and/or lactating women
- Geriatric patients: While the general principles of the management of primary insomnia apply to all adult patients it is important to note that "late life insomnia" requires specific interventions not addressed in this guideline[1]

Recommendations

- The management of primary insomnia is based on the foundation of behavioural and cognitive non-pharmacologic strategies. Pharmacologic interventions are adjunctive to the nonpharmacologic strategies. Adjunctive pharmacotherapy is used on a short-term (less than 7-14 days on a nightly basis) or intermittent (2-3 nights per week) for the sole purpose of preventing an exacerbation of the primary insomnia
- The patient must be an active participant in treatment process. Primary insomnia is a chronic illness that requires regular follow-up and monitoring to evaluate the patient's response to treatment and motivation to resolve the problem
- The goal of management is to provide the patient with the tools necessary to manage the chronic nature of the illness and minimize dependence on sedative medications.

Non-pharmacologic

Non-pharmacologic therapies are effective in the management of primary insomnia especially when behavioural and cognitive techniques are used in combination.[2] Behavioural techniques include sleep hygiene, sleep consolidation, stimulus control, and relaxation therapies. Cognitive techniques include cognitive behavioural therapy (CBT).[3,4]

Behavioural Therapies

Sleep hygiene[3]

The following recommendations should be individualized to address patient needs/situation.

PRACTICE POINTS

Initially, review of sleep behaviors and sleep hygiene advice with recommendations to adhere strictly to the principles of sleep hygiene will providea the clinician with an indication of the patient's **motivation to change the behaviors** that are perpetuating the insomnia.

Toward Optimized Practice

The above recommendations are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They should be used as an adjunct to sound clinical decision making.

Sleep Hygiene Advice:

- Avoid caffeine after lunch and alcohol within 6 hours of bedtime
- Avoid nicotine close to bedtime or during the night
- Engage in moderate physical activity but avoid heavy exercise within 3 hours of bedtime
- Avoid consuming excessive liquids or a heavy evening meal before bedtime
- Maintain a quiet, dark, safe, and comfortable sleep environment. Minimize noise and light
- Avoid a bedroom that is too hot or too cold
- Avoid watching/checking the clock

PRACTICE POINTS

Educate the patient about the following issues:

- Alcohol helps with sleep initiation, it impairs sleep maintenance and can exacerbate other sleep disorders
- Nicotine is a potent stimulant with a short half-life that induces awakenings as a result of withdrawal during the sleep period
- Smoking cessation aids (nicotine replacement products and bupropion) can cause insomnia

Sleep consolidation[4]

Some insomnia patients spend excessive time in bed trying to attain more sleep. Sleep consolidation is accomplished by compressing the total time in bed to match the total sleep need of the patient. This improves the sleep efficiency.

- Devise a "sleep prescription" with the patient: a fixed bedtime and wake time
- Determine the average total sleep time
- Prescribe the time in bed to current total sleep time plus 30 minutes
- The minimum sleep time should be no less than 5 hours.
- Set a consistent wake time (firmly fixed 7 days/week)
- The bed time is determined by counting backwards from the fixed wake time (For example: a patient estimates the total sleep time to be 5-6 hours/night, the total time in bed is 8 hours/night for a sleep efficiency of 5.5/8 = 68%. The prescribed total sleep time would be 6.5-7 hours/night, if the wake time is 6AM then the prescribed bedtime is 11-11:30 PM)
- For the first 2-4 weeks these times should remain consistent and the clinician should monitor the patients adherence to the program with sleep logs (see sleep log attachment)
- Advise the patient that napping will reduce the depth and restorative quality of sleep the following night
- Once the patient is sleeping for >85 to 90 percent of the time spent in bed for two consecutive weeks, then the amount of time spent in bed is slowly increased by 15- 30 minute every week.[5] If sleep efficiency of 90 percent is maintained, then therapy is successful. The average total sleep time for most people is between 6 and 8 hours a night.

PRACTICE POINTS

1. Advise patients that the goal of treatment is to improve the continuity and restorative quality of sleep, not to make them "8-hour sleepers". More often than not the total sleep time will be less than 8 hours per night.
2. Advise patients that they may suffer from daytime sleepiness in the initiation phase of compressing their sleep schedule.

Stimulus control[3]

Stimulus control is designed to re-associate the bed/bedroom with sleep and to re-establish a consistent sleep-wake schedule. This is achieved by limiting activities that serve as cues for staying awake. The treatment consists of the following behavioural instructions:

- Eliminate non-sleep activities in the bedroom. Remove the TV and computer from the bedroom
- Use the bed and bedroom only for sleep and sex
- Go to bed only when sleepy, even if later than prescribed sleep schedule
- Get out of bed if not able to sleep within 15-20 minutes - go to another room and relax. Return to bed only when sleepy
- Set alarm for agreed upon wake time
- Avoid excessive napping during the day - a brief nap (15-30 minutes) during the mid-afternoon can be refreshing and is unlikely to disrupt nocturnal sleep[5]

Anxiety Reducing Strategies and Relaxation therapies

Relaxation therapy is designed to reduce physiological and psychological arousal to promote sleep. Recommended relaxation therapies must be individualized and include:

- Avoid arousing activities before bed (late night phone calls, work, watching TV
- Designate at least one hour before bedtime to help unwind from the day's stresses - dim light exposure and engage in relaxing activities
- Relaxation techniques such as deep breathing, light exercise, stretching, yoga and relaxation CDs can help promote sleep
- Stress management skills training and relaxation therapies such as progressive muscle relaxation, biofeedback, hypnosis, meditation, imagery training, are usually provided by a trained professional (through books, videos, or face-to-face sessions)[a]
- Techniques for managing worry can be useful for some patients. This may include keeping a worry journal, scheduling worry time, challenging worried thinking, or seeking professional help

Cognitive Therapies[3,4]

Cognitive behavioral therapy (CBT) addresses the inappropriate beliefs and attitudes that perpetuate the insomnia. The goal of this technique/process is to identify dysfunctional sleep cognitions, challenge the validity of those cognitions, and replace those beliefs and attitudes with more appropriate and adaptive cognitions. Common faulty beliefs and expectations that can be modified include:

- Unrealistic sleep expectations (e.g., "I need to have 9 hours of sleep each night")
- Misconceptions about the causes of insomnia (e.g., "I have a chemical imbalance causing my insomnia")
- Amplifying the consequences (e.g., "I cannot do anything after a bad night's sleep")
- Performance anxiety and loss of control over ability to sleep (e.g., "I am afraid of losing control over my ability to sleep")

Pharmacologic

Pharmacotherapy should be considered an adjunctive therapy to cognitive and behavioural therapies in the comprehensive management of primary insomnia.

Principles of Treatment

Pharmacotherapy is generally recommended at the lowest effective dose as short-term treatment lasting less than 7 days. Although long-term use of hypnotic agents is discouraged due to the potential for tolerance and dependence, there are specific situations and circumstances under which long term use of hypnotics may be appropriate.

- Short term (<7 consecutive nights)[6]:
  - Initially used to break the cycle of chronic insomnia and allow the patient to adapt to cognitive and behavioural interventions
  - Used to manage an exacerbation of previously controlled primary insomnia
- Long term intermittent[7] (self administered therapy to decrease arousal and prevent relapse):
  - Used on a limited PRN basis (<3 times/week) for occasional bouts of insomnia
  - Used on a scheduled basis (i.e., <3 times/week) to ensure consistent adequate sleep in a patient with chronic primary insomnia where the goal of therapy is to prevent relapse

Therapeutic Options

First-line Pharmacotherapy: Highest level of evidence supporting efficacy and safety

Agents	Recommended Dose	Comments
Zopiclone	3.75-7.5 mg	• Short half-life provides lower risk of morning hang-over effect • Metallic after-taste most common adverse reaction
Temazepam	15-30 mg	• Intermediate half-life carries a low-moderate risk of morning hang-over effect

Second-line Pharmacotherapy: Moderate level of formal evidence. Extent of current use and favorable tolerability support use as second-line agents

Agents	Recommended Dose	Comments
Trazodone	25-50 mg	• Shorter half-life carries lower risk of morning hang-over effect

Variable Evidence

Agents	Recommended Dose	Comments
L'Tryptophan	500 mg-2 gm	• Evidence supporting efficacy is variable and insufficient. May be requested by individual patients looking for a "natural source" agent. Taken 60 minutes before bedtime
Melatonin	0.3-5 mg	
Valerian	400-900 mg	

Other Non-Prescription Products

Agents	Usual Dose	Comments
Diphenhydramine - Benadryl® - Sleep Eze - Simply Sleep - Nytol® - Unisom®	25-50 mg hs	Potential for serious side effects arising from anticholinergic properties (especially in elderly); residual daytime sleepiness, diminished cognitive function, dry mouth, blurred vision, constipation, urinary retention, etc. These products are not intended for long term use and tolerance to sedative effects likely develops rapidly (3 days) Gravol not approved in Canada as a sleep aid
Dimenhydrinate - Gravol	25-50 mg hs	
Doxylamine - Unisom 2	25-50 mg hs	

Not Recommended

The following agents are not recommended for the management of conditioned insomnia except in cases where the agent is being used specifically to mange a co-morbidity such as depression.

Agents	Comments
Antidepressants - mirtazapine, fluvoxamine, tricyclics	Relative lack of evidence
Amitriptyline	Relative lack of evidence and significant adverse effects (such as weight gain)
Antihistamines - chlorpheniramine	Relative lack of evidence or excessive risk of daytime sedation, psychomotor impairment and anticholinergic toxicity
Antipsychotics (Conventional or 1st-Generation) - chlorpromazine, methotrimeprazine, loxapine	Relative lack of evidence and unacceptable risk of anticholinergic and neurological toxicity
Antipsychotics (Atypical or 2nd-Generation) - risperidone, olanzapine, quetiapine	Relative lack of evidence and unacceptable cost and risk of metabolic toxicity
Benzodiazepines (Intermediate and Long-Acting) - diazepam, clonazepam, flurazepam, lorazepam, nitrazepam, alprazolam, oxazepam Benzodiazepines (Short-Acting) - triazolam	Excessive risk of daytime sedation and psychomotor impairment No longer recommended due to unacceptable risk of memory disturbances, abnormal thinking and psychotic behaviors

Cont'd

Chlorals - chloral hydrate, ethchlorvinyl	Excessive risk of tolerance, dependence and abuse as well as adverse gastrointestinal and CNS effects
Muscle relaxants - cyclobenzaprine, meprobamate	Relative lack of evidence and excessive risk of adverse CNS effects

PRACTICE POINTS

The foundation of the management of conditioned insomnia is behavioural and cognitive therapy. Ongoing evaluation of the patient's motivation to adhere to the behavioral and cognitive strategies is an important part of monitoring the patient's progress. Adherence to, and compliance with these strategies is usually effective and minimizes the potential for dependence on medication.

FIRST VISIT

- Prescribe behavioral and cognitive interventions
- Use sleep logs and diaries to monitor the patient's progress (see sleep log attachment)
- Consider pharmacotherapy based on the patient's sense of urgency, need for relief and willingness (motivation) to follow the behavioral and cognitive recommendations.

FOLLOW-UP AT 2 – 4 WEEKS

- Evaluate sleep efficiency and daytime symptoms
- Reinforce behavioral interventions
- Review or reconsider pharmacotherapy

3 MONTH FOLLOW-UP

- If there is no progress or limited improvement referral to sleep medicine program or psychologist may be warranted

Credibility

The insomnia guideline working group was comprised of family physicians, sleep medicine specialists, general internists, a psychiatrist, and a clinical pharmacist. The Alberta Medical Association Toward Optimized Practice (TOP) program guided the development process using the Appraisal of Guidelines For Research and Evaluation (AGREE) Instrument to evaluate the quality of the guideline.[9] An extensive review of the literature was performed and provided the following key documents as the foundation for the current state of the evidence:

1. "Current State Of The Science Of Chronic Insomnia", National Institutes of Health.[2]
2. "Manifestations and Management of Chronic Insomnia in Adults", The Agency for Healthcare Research and Quality, University of Alberta, Evidence-based Practice Center.[7]
3. "Guidance on the use of Zaleplon, Zolpidem and Zopiclone For The Short-Term Management of Insomnia", the British National Health Service, National Institute for Clinical Excellence.[5]
4. "Insomnia", Sleep Medicine Clinics, Volume 1, Number 3, September 2006.[4]

The results and recommendations of these documents have been reviewed by the guideline committee and form the basis of the evidence for the background material and recommendations. The clinical tools have been developed by the guideline committee based on Canadian expert and primary care physician consensus. Funding for this project has been provided by the TOP program and no members of the guideline committee have received pharmaceutical or industry funding or support in their role as a committee member.

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2. National Institutes of Health State-of-the-Science Conference Statement: Manifestations and Management of Chronic Insomnia in Adults. August 2005. http://consensus.nih.gov/2005/2005InsomniaSOS026html.htm
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8. Manifestations and Management of Chronic Insomnia in Adults", The Agency for Healthcare Research and Quality, University of Alberta, Evidence based Practice Center.
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Selected Readings

1. Morin. C.M. (1993). Insomnia: Psychological Assessment and Management. New York : The Guilford Press.
2. Reite, M., Ruddy, J., Nagel. K. (2002). Concise Guide To Evaluation and Management of Sleep Disorders (3rd Edition). Washington, DC : American Psychiatric Publishing, Inc.
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6. Lamberg. L. (2000). Bodyrhythms: Chronobiology and Peak Performance. New York : Asja Press.
7. Kryger. M. (2004). Can't Sleep, Can't Stay Awake : A Women's Guide To Sleep Disorders. Toronto: HarperCollins Publisher Ltd.

Toward Optimized Practice

Toward Optimized Practice (TOP) Program

Arising out of the 2003 Master Agreement, TOP succeeds the former Alberta Clinical Practice Guidelines program, and maintains and distributes Alberta CPGs. TOP is a health quality improvement initiative that fits within the broader health system focus on quality and complements other strategies such as Primary Care Initiative and the Physician Office System Program.

The TOP program supports physician practices, and the teams they work with, by fostering the use of evidence-based best practices and quality initiatives in medical care in Alberta. The program offers a variety of tools and outreach services to help physicians and their colleagues meet the challenge of keeping practices current in an environment of continually emerging evidence.

To Provide Feedback

The TOP Program encourages your feedback. If you need further information please contact:

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