

Clinical practice guidelines on the diagnosis and management of insomnia in family practice: Part 2

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Abstract: This is the second of a two part article on a problem based approach to insomnia. The first article provided the general practitioner with the background and methodology of the guideline formulation process. It also included recommendations on diagnosis and differential diagnosis of insomnia. In this article, the guideline covers recommendations on the diagnostic and therapeutic options for patients with insomnia.

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Key words: algorithmic approach, diagnosis, guidelines, insomnia, sleep disorders, treatment.

Introduction

The general practitioner was presented with the diagnosis and differential diagnosis of insomnia in a previous article. Having established the burden of illness and the effects of insomnia on quality of life, the need to manage this problem effectively is recognized. The general practitioner being at the frontline of health care, should be equipped with strategies for treatment of this problem.

This second part of the article aims to provide the primary care physician with some guidelines on the diagnostic and therapeutic interventions that can be used for patients with insomnia.

Table 1 summarizes the guideline recommendations covered in this article.

Diagnostic examinations for patients with insomnia

Recommendation

Among patients with insomnia, a sleep diary for 1–2 weeks should be kept to serve as a baseline assess-

ment of the sleep problem and to monitor the effectiveness of treatment (grade C).

Summary of evidence

A sleep diary kept for a period of 2 weeks is helpful for patients who have insomnia.¹ The diary includes the patients' usual bedtime, the total sleep time, the time until onset of sleep, number of awakenings in the night, medications used, quality of sleep rating and daytime consequences of poor sleep.² Table 2 is an example of a sleep diary adapted from the National Heart Lung and Blood Institute (NHLBI) Working Group on Insomnia. This record, although subjective, reflects the patient's perception of the amount and quality of sleep he or she is getting.³

This sleep diary would help the physician in determining the severity of the sleep disturbance, the medications being used, the duration of its use and provide a glimpse into the effectiveness of the present treatment regimens.

Recommendation

Insomnia involves daytime consequences such as fatigue, lack of energy, difficulty concentrating and irritability that cause marked distress or impairment in social, occupational or other important areas of functioning (grade B). As such, among patients with insomnia, there should be an assessment of daytime consequences using the scales available in the locality (grade C).

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Table 1 Summary of recommendations included in this article

Category	Recommendation
Diagnostic examinations	<p>Step 1: Among patients with insomnia, a sleep diary for one to two weeks should be kept to serve as a baseline assessment of the sleep problem and to monitor the effectiveness of treatment (grade C).</p> <p>Step 2: Insomnia involves daytime consequences such as fatigue, lack of energy, difficulty concentrating and irritability that cause marked distress or impairment in social, occupational or other important areas of functioning. (grade B). As such, among patients with insomnia, assessment of daytime consequences using the scales available in the locality should be done (grade C).</p> <p>Step 3: Among patients with chronic insomnia, polysomnography must be considered if one of the following clinical conditions is present:</p> <ul style="list-style-type: none"> • unsuccessful treatment • precipitous arousal or violent behaviors during sleep • initial diagnosis is uncertain • underlying cause might be either a sleep-related breathing disorder or a periodic limb movement disorder (grade B-C). <p>Step 4: Among patients with chronic insomnia, evaluation for depression is recommended (grade B).</p>
Therapeutic options for acute insomnia	<p>Among patients with acute insomnia, appropriate action against the inciting cause would often reverse the condition but short term pharmacologic therapy together with behavioral intervention should be initiated when the sleep disturbance persists and causes marked daytime impairment (grade C).</p>
Therapeutic options for chronic insomnia	<p>Option 1: Among patients with chronic insomnia, educational or behavioral intervention combined with pharmacologic agents is more beneficial than either therapy alone (grade A).</p> <p>Option 2: The following non-pharmacologic treatment options may be employed for patients</p> <ul style="list-style-type: none"> • stimulus control • relaxation techniques • cognitive behavior therapy • sleep hygiene education (grade A)with insomnia: <p>Option 3: Among patients with chronic insomnia, rational prescribing of medications is of utmost importance and should follow these principles:</p> <ul style="list-style-type: none"> • start with the lowest effective dose • use intermittent dosing • prescribe medications for short-term use • discontinue the medications gradually • be alert for rebound insomnia (grade C) <p>Option 4: Among patients with chronic insomnia, the following drug regimens may be considered: (i) benzodiazepines, (ii) zolpidem, (iii) antidepressants; and (iv) melatonin (grade A)</p>

Summary of evidence

According to the 1984 report of the National Institutes of Mental Health, insomnia is a cause of significant morbidity and mortality in the USA.³ Stoller states that it costs the American public about \$100 billion annu-

ally in medical expenses, ramifications of accidents, and reduced productivity due to absenteeism and decreased work efficiency.⁴

In a preliminary study done by Vgontzas *et al.* a positive correlation was found between objective sleep disturbance and activity on both limbs of the stress

Table 2 Sample sleep diary*

	First day	Second day	Third day
Complete upon awakening	Bedtime		
	Rise-time		
	Time to fall asleep (in minutes)		
	Estimated number of awakenings and total time awake (in hours)		
	Estimated amount of sleep obtained		
Complete before bedtime	Number of naps		
	Number of alcoholic drinks and caffeinated drinks		
	Rate how you felt today:		
	1 very tired/sleepy		
	2 somewhat tired		
	3 fairly alert		
	4 wide awake		
	Irritability level:		
	1 none		
	2 some		
	3 moderate		
	4 fairly high		
	5 high		
	Medications used		

*NHLBI Working Group on Insomnia. Insomnia: Assessment and Management in Primary Care. American Academy of Family Physicians. 1999 June.

system (i.e., the hypothalamic pituitary adrenal axis and the sympathetic system) in a group of patients with chronic insomnia.⁵

In a retrospective cohort study done by Simon and VonKorff it was found that by using the Social Disability Schedule, patients with insomnia had an odds ratio of 1.9 of having severe occupational role disability compared to those without the symptom. The number of days of restricted activity due to illness and days spent in bed because of illness were two times more common in the insomnia group. There was also an observed 60% increase in the mean total health services cost (cost of care, medications, physician follow up) in the insomnia group.⁶

Despite all of these, Holbrook *et al.* in the article entitled *The Diagnosis and Management of Insomnia in Clinical Practice: A Practical Evidence-Based Approach*, states that information on the prognosis of insomnia is still scant. Complications associated with insomnia are presumed to be limited to impairments related to sleep deprivation, both actual and perceived, and to medications taken to augment sleep or increase alertness.⁷

However, according to the American Association of Sleep Medicine, it is still recommended that assessment be made of daytime consequences using the different scales including a neuropsychological assessment such as vigilance/concentration tests, motor speed and accuracy, memory and reasoning.⁸

Recommendation

Among patients with chronic insomnia, polysomnography must be considered if one of the following clinical conditions is present:

- Unsuccessful treatment
- Precipitous arousal or violent behaviors during sleep
- Initial diagnosis is uncertain
- Underlying cause might be either a sleep-related breathing disorder or a periodic limb movement disorder (grade B-C)

Summary of evidence

Polysomnography refers to the collective findings of the electroencephalography, eye movements, electromyography readings, airflow findings, limb, chest and abdominal movements recorded during sleep.^{3,9}

Polysomnography is not routinely indicated in the evaluation of all patients with chronic insomnia.^{8,9} A summary of the different guidelines that have been published regarding the use of polysomnography has stated any of the following as an indication for the use of this test among patients with insomnia:

- Symptoms of sleep disordered breathing
- Violent sleep related behaviors that may cause injury to the patient
- Snoring associated with observed apneas and/or excessive daytime sleepiness

- Failure of treatment
- Periodic limb movement disorders^{8,9}

Recommendation

Among patients with chronic insomnia, evaluation for depression is recommended (grade B).

Summary of evidence

Insomnia may be a prodrome of a psychiatric illness particularly depression.¹⁰ An office based survey of patients with insomnia seen by physicians in the USA (1993), showed that 30% of this population had also been diagnosed with depression.¹¹ In another epidemiologic survey by Simon and Vonkorff, the prevalence of patients with a major depressive disorder was significantly higher among patients with insomnia compared to patients without (31 vs 4%).⁶

In an article by Mendelson *et al.*, it was stated that one third of patients with insomnia and daytime dysfunction appeared to be at risk for major depressive events.¹² Rajput and Bromley in another article stated that chronic insomnia especially in the elderly can be a symptom of depression.¹³

Insomnia related to major depression can be characterized as repeated awakenings in the night and premature morning awakenings accompanied by an uncomfortable mood in the morning.¹⁴

Therapeutic options for acute insomnia

Recommendation

Among patients with acute insomnia, appropriate action against the inciting cause would often reverse the condition but short-term pharmacologic therapy together with behavioral intervention should be initiated when the sleep disturbance persists and causes marked daytime impairment (grade C).

Summary of evidence

The NHLBI guidelines for insomnia assessment and management in primary care (1998) state that the cause of acute insomnia can often be traced to a particular inciting event. However, even brief episodes of acute insomnia should be treated appropriately when daytime sequelae are severe. They further added that it is important to note that untreated acute insomnia might lead to chronic insomnia.²

The recommended pharmacologic and non-pharmacologic treatment options are similar for those with chronic insomnia and will be discussed in greater detail in the recommendations that follow.

Therapeutic options for chronic insomnia

Recommendation

Among patients with chronic insomnia, educational or behavioral intervention combined with pharmacologic agents is more beneficial than either therapy alone (grade A).

Summary of evidence

As chronic insomnia is often due to a myriad of factors, a patient may need multiple treatment modalities.

In a randomized controlled trial conducted by Morin *et al.* patients receiving cognitive behavior therapy (CBT) alone or CBT with temazepam rated themselves as significantly less impaired than those receiving drug treatment alone or placebos. They concluded that drug therapy gradually lost its clinical benefits over time but behavioral therapy had more lasting effects.¹⁵

Kupfer and Reynolds in a review article stated that to achieve treatment goals for patients with insomnia, educational, behavioral and pharmacologic interventions should be combined.¹ Attarian concurred with this statement when he noted that the best management for insomnia is a combination of hypnotic medication and behavioral methods.³ Holbrook *et al.* also advocates a three step approach to treatment in primary care: (i) look for reversible underlying causes; (ii) non-pharmacologic therapy; and (iii) pharmacologic therapy.

An earlier article by Rajput and Bromley in 1999 stated the following:

- drug therapy may be beneficial for short-term improvement
- behavioral intervention may produce more sustained effects
- behavioral intervention combined with pharmacologic agents may be more effective than either approach alone.¹³

Wohlgemuth *et al.* after conducting a randomized controlled trial comparing CBT, relaxation training (RT) and placebo treatment recommended that considering the cost, side effects and temporary benefits of drug treatment, CBT as a first line therapy for chronic insomnia warrants consideration.¹⁶

Recommendation

The following non-pharmacologic treatment options may be employed for patients with insomnia:

- Stimulus control
- Relaxation techniques
- Cognitive behavior therapy
- Sleep hygiene education (grade A)

Summary of evidence

Behavioral interventions have been shown to produce sustained and reliable effects against insomnia. Several non-pharmacologic treatment options were published in the guidelines by the American Academy of Sleep Medicine.¹⁷ The following were among those that were highly recommended:

- Stimulus control
- Muscle relaxation
- Biofeedback
- Sleep restriction
- Multicomponent cognitive behavior therapy.

Other behavioral techniques based on these guidelines were recommended as adjuncts and include the following: (i) sleep hygiene education; (ii) imagery training; and (iii) pure cognitive therapy.

However, other studies yielded more favorable information regarding these non pharmacologic modalities. Wohlgemuth *et al.* reported a 54% reduction in wake time after sleep onset among patients treated with cognitive behavioral therapy alone.¹⁶

In another study conducted by Davidson *et al.* for cancer patients with insomnia, a six step program involving stimulus control therapy, relaxation training, cognitive emotional arousal was said to be associated with improved sleep, reduced fatigue and enhanced ability to perform activities.¹⁸

A review article by Kirkwood stated that non pharmacologic options including combinations of behavioral interventions, sleep restriction therapy and patient education provided longer lasting benefits.¹⁹

In a randomized controlled trial by Lichstein, patients who were allocated a combination of sleep hygiene instruction, stimulus control and relaxation showed better improvement in sleep quality than controls.²⁰

Another randomized controlled trial comparing structured sleep hygiene, structured sleep hygiene with moderate afternoon exercise and structured sleep hygiene with light early morning therapy showed that significant improvement resulted from the latter treatment regimen.²¹

Recommendation

Among patients with chronic insomnia, the rational prescription of medications is of utmost importance and should follow these principles:

- start with the lowest effective dose
- use intermittent dosing
- prescribe medications for short-term use
- discontinue the medications gradually
- be alert for rebound insomnia (grade C)

Summary of evidence

Rajput and Bromley in an earlier cited article emphasized the need to start with the lowest dose possible, on

a short-term basis, using an intermittent dosing regimen with gradual tapering.¹³ The NHLBI also warns that dosage is the single best predictor for the risk of side effects.² Other considerations are the pharmacodynamic and pharmacokinetic properties of these drugs. A good treatment regimen should be one that has a high efficacy and a wide margin of safety with the least possible adverse effects.

Recommendation

Among patients with chronic insomnia, the following drug regimens may be considered: (i) benzodiazepines; (ii) zolpidem; (iii) antidepressants; and (iv) melatonin (grade A).

Summary of evidence

Many authors have agreed that short term use of pharmacologic agents is useful for the optimal management of insomnia.

Benzodiazepines have been shown to be effective in inducing, maintaining and consolidating sleep when compared with placebos. The drug however, has side effects such as anterograde amnesia and for long acting benzodiazepines, residual daytime drowsiness.⁷ In a meta analysis by Holbrook *et al.* benzodiazepines were found to be superior than placebos in reduction of sleep latency and increasing sleep time.²² Concern however, with the use of this drug stems from the potential to develop dependence.

Zolpidem, an imidazopyridine has similar efficacy to benzodiazepines. It is said to cause less cognitive psychomotor side effects. Concern for dependence however, and risks for tolerance have been noted. In a study by Voderholzer *et al.*, it was concluded that zolpidem (10 mg) given for 4 weeks when compared with placebos only had slight (not significant) rebound effects on sleep continuity and that tolerance and dependence are low at this dosage.²³ Toner however, reported a series of cases in which patients developed delirium, nightmares and hallucinations after zolpidem treatment.²⁴ In a study by Ganzoni and Gugger, adverse events were reported in 8.9 and 7.2% of the study population who were treated with zolpidem. The adverse events included mild headache, confusion, somnolence and gastrointestinal disturbances.²⁵

Melatonin has been used to reset the biological clock and as a hypnotic for non circadian insomnia. In a clinical trial by Garfinkel *et al.*, it was concluded that 14 out of 18 subjects in the melatonin group compared with four out of 16 subjects in the placebo group, discontinued benzodiazepine therapy. Sleep quality scores were also better in the melatonin group. After 6 months on melatonin alone, 19 out of 24 patients still maintained good quality sleep.²⁶

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