# REVIEW ARTICLE

# INSOMNIA DIAGNOSIS AND MANAGEMENT: AN OSTEOPATHIC APPROACH

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#### **KEYWORDS:**

Insomnia

OMT

Osteopathic

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#### ABSTRACT:

Insomnia affects a large percentage of American adults and is among the most commonly treated medical conditions in the outpatient clinical setting. The psychological, medical and financial impact of insomnia is substantial. Research indicates that pharmacologic treatment is associated with significant risk, and clinicians should consider other modalities including cognitive behavioral therapy before prescribing medications for the treatment of insomnia. Other complementary treatments including yoga, stress management and traditional Chinese medical therapies are promising, but more research is needed.

The osteopathic family physician plays an important role in diagnosis and management. An osteopathic approach to patient care is highly beneficial and includes a multifaceted evaluation when taking a patient history and osteopathic manipulative treatment (OMT) to balance autonomic tone and correct associated somatic dysfunction.

### INTRODUCTION

At any given time, up to 15% of all adults struggle with insomnia.¹ The osteopathic family physician encounters such patients in clinical practice on a regular basis, and the appropriate diagnosis and management of insomnia disorder has a significant impact not only on individuals and families but also on system-level occupational and medical costs. It is estimated that 30%–45% of American adults suffer from acute or chronic insomnia over the course of a lifetime,¹ resulting in \$92.5 billion–\$106.5 billion in annual medical costs.² Aside from medical costs, chronic lack of sleep results in significant physical and mental consequences from loss of occupational productivity and missed work.

Insomnia disorder is more common in women, with a bimodal age distribution during the younger adult years<sup>3</sup> and after menopause.<sup>4</sup> There is often a familial pattern and insomnia may have genetic influences, though this has not been fully determined.<sup>1</sup> Numerous associations have been attributed to insomnia including: older age,<sup>2,5</sup> female sex,<sup>2,3,5</sup> mental illness,<sup>5</sup> poor general health,<sup>2,5</sup> lower socioeconomic status,<sup>3,5</sup> family history,<sup>2</sup> easy arousability,<sup>2</sup> and chronic pain.<sup>2</sup>

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As osteopathic family physicians, we have the unique capacity to diagnose and manage insomnia from a whole-patient perspective. Given the numerous bidirectional associations between poor sleep quality and chronic medical and behavioral health issues, the evaluating physician must take into consideration all aspects of a patient's general health and socioeconomic disparities. Additionally, the evidence is clear that pharmacology alone is rarely the best option for the treatment of insomnia<sup>2,4,5</sup>; however, nonpharmacologic interventions such as behavioral health modalities and osteopathic manipulative treatment (OMT) may be beneficial components of a comprehensive sleep restoration plan.

# Definition

The American Academy of Sleep Medicine defines insomnia as "the subjective perception of difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity for sleep, and that results in some form of daytime impairment."<sup>1,4</sup> According to the DSM-5 criteria (Table 1), sleep difficulty should be present at least 3 nights per week for 3 consecutive months and should occur despite adequate opportunity to obtain sleep. Insomnia can be characterized as *acute* (symptoms lasting 1–3 months), *chronic* (symptoms lasting 3 months or longer), or *recurrent* (2 or more episodes within 1 year). <sup>1,2,5</sup>

It is important to note that the DSM-5 outlines new diagnostic terminology and replaces primary and secondary insomnia with insomnia disorder. The terms "primary" and "secondary" are

no longer used considering recent research, which has shown that there is a bidirectional relationship between insomnia and associated physical or behavioral disorders.<sup>6</sup> For example, insomnia may occur as a result of underlying depression. Conversely, a patient who struggles with untreated or incompletely treated insomnia disorder may subsequently develop major depression. It is not necessary to determine temporal relationship or causality regarding medical or mental comorbid conditions. Rather, insomnia disorder should be identified as a separate clinical entity if it is severe enough to warrant treatment.<sup>7</sup> If the insomnia disorder occurs with another mental or medical comorbidity, it should be documented.<sup>7</sup>

Note that when coding for insomnia disorder, there is a singular code—G47.00—that encompasses all associated comorbidities. The comorbid diagnoses, if present, should be listed immediately after the insomnia disorder diagnosis to imply association. Medical complexity regarding coding does not escalate for insomnia disorder diagnoses (ie, Hierarchical Condition Category or HCC value) with the exception of insomnia related to substance use, which is beyond the focus of this paper.

### TABLE 1:

Diagnostic and Statistical Manual of Mental Disorders (DSM-5) Diagnostic Criteria for Insomnia Disorder<sup>7</sup>

- Dissatisfaction with sleep quantity or quality with <u>1 or more</u> of the following symptoms:
  - o Difficulty initiating sleep
  - o Difficulty maintaining sleep, characterized by frequent awakenings or trouble returning to sleep after awakenings
  - o Early-morning awakening with inability to return to sleep
  - o The sleep disturbance causes significant distress or impairment in daytime functioning, as evidenced by at least 3 of the following:
    - Fatigue or low energy
    - Daytime sleepiness
    - Impaired attention, concentration, or memory
    - Mood disturbance
    - Behavioral difficulty
    - Impaired occupational or academic function
    - Impaired interpersonal or social function
    - Negative effect on caregiver or family functioning
- The sleep difficulty occurs <u>at least 3 nights per week</u>, is present for <u>at least 3 months</u>, and occurs despite adequate opportunity for sleep.

## Diagnosis

Insomnia disorder is a clinical diagnosis and is best identified after careful questioning of the patient, as well as a bed partner, if applicable. Historical questions should include timing of sleep, daytime effects, sleep schedule, sleep environment and sleep habits. It is also important to identify any contributing factors, including behavioral health diagnoses, comorbid medical conditions, medications and substance use.<sup>2</sup> Some clinicians recommend the use of a 2-week sleep diary before treatment, during treatment and after any relapse.2 Wrist actigraphy may be a helpful adjunct and is a readily available tool for many patients, but it is not an alternative to a sleep diary. Additionally, there are several validated sleep quality rating scales that may be used to gather subjective information regarding a patient's sleep habits and resulting level of impairment.1 Commonly used tools include the Epworth Sleepiness Scale, the Pittsburgh Sleep Quality Index and the Insomnia Severity Index.

Determining the association of an underlying medical condition with insomnia disorder can be challenging. It is imperative that the workup of other medical conditions that may coincide with insomnia disorder remain focused only on those conditions suggested by the patient's history and physical exam. For example, laboratory evaluation may include complete blood count with iron studies if anemia is suspected. Likewise, patients who demonstrate signs and symptoms of hypothyroidism should be evaluated with a thyroid-stimulating hormone test and additional thyroid studies if indicated.¹ Other laboratory studies are generally not useful for the diagnosis of insomnia disorder.

Polysomnography (sleep study) is not required for the diagnosis of insomnia disorder but may be considered for patients who may have a sleep-related breathing or movement disorder.¹ Patients whose history and physical exam suggest obstructive sleep apnea (presence of hypertension, increased neck circumference, and snoring); narcolepsy; or sleep disturbances that are potentially self-injurious (parasomnias) should be referred for formal sleep studies.³ Reserving polysomnography for only those patients with a high probability of a concomitant sleep disorder reduces unnecessary testing and added expense. Imaging is not of clinical value for the diagnosis of insomnia disorder.

# Nonpharmacologic treatment

Many pharmacologic options have serious side effect profiles with little long-term proven benefit.<sup>5</sup> As a result, cognitive behavioral therapy for insomnia (CBT-I) is the recommended treatment approach. CBT-I includes stimulus control; sleep restriction; relaxation training; setting up an environment that promotes sleep (eg, temperature, lighting); education about sleep hygiene and daytime habits that may impair sleep (eg, napping, caffeine/ nicotine use, screen time, diet, exercise, stress); and reframing cognitive distortions about sleep (see Table 2).<sup>4,5,9</sup> In general, treatment involves customized sessions over the course of 6 to 8 weeks.

When compared with pharmacologic therapy, CBT-I is safe and highly effective. Trauer *et al* presented a systematic review and meta-analysis in the *Annals of Internal Medicine* in 2015

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that demonstrated clinically meaningful improvement in sleep onset latency, wake after sleep onset and sleep efficiency post-treatment with *P* values of 0.040, 0.026, and 0.017 respectively.<sup>10</sup> These results were maintained at early and late follow-up in study participants, which translates into a 6- to 18-month benefit for the patient after comprehensive CBT-I.<sup>5,11,12</sup> This is in comparison to Food and Drug Administration–approved medications, which are typically recommended for short-term use only, with a maximum advised time period of 4–5 weeks. For these reasons, many institutions recommend CBT-I as first-line for insomnia treatment; providers should emphasize to patients that this is the safest and most effective long-term treatment.<sup>4,5,6,9,11,13,14,15</sup>

TABLE 2:
Typical Components of CBT-I

Cognitive Therapy	Techniques aimed at identifying and altering dysfunctional beliefs and attitudes toward sleep and insomnia		
Stimulus Control	Strengthening the association of bed and sleep and avoiding nonsleep activities in the bedroom		
Sleep Restriction	Limiting time in bed to match perceived sleep duration, with a goal of >85% of time in bed to be asleep		
Sleep Hygiene	Sleep schedule, environmental avoidances such as caffeine and nicotine, no screen time, no access to clock, normal sleep-wake cycles, dark environments at night, exposing pupils to daylight in the morning		
Relaxation Techniques (RT)	Meditation, mindfulness, yoga, guided imagery, etc, with the goal to reduce muscular tension and facilitate sleep		

As with any other behavioral intervention, this approach takes active patient participation and can be timely and expensive in nature; thus, it may be prohibitive for many patients. Perceived hardship of therapy and low patient effort commonly result in premature termination of treatment. Additionally, there are a limited number of qualified sleep medicine practitioners to address the widespread need for CBT-I.<sup>6,12</sup> Ideally, sleep therapists would be available in medical clinics, perhaps as a virtual medicine service, essentially offering an in-house ancillary option for patients. This has not yet been accepted or widely adopted.<sup>6</sup> It has also been noted that patients must utilize many components of CBT-I, not just one isolated component of therapy, for treatment to be optimized.<sup>12,15</sup> This brings the difficulty in therapy back to patient compliance, making readily available and easily accessible CBT-I providers a costly and somewhat nonproductive model.

Along with CBT-I, evidence supporting complementary and alternative medicine for treatment of insomnia is gaining traction. A few key complementary practices are available, including mind/body practice, stress management, yoga, multicomponent therapy, paradoxical intention,<sup>2,12,16</sup> and traditional Chinese medicine—which encompasses herbal therapy, acupuncture, auriculotherapy, psychotherapy, aromatherapy, music therapy, moxibustion, scraping and exercise therapy such as tai chi.<sup>12,17,18,19</sup> Further research is needed to fully understand the clinical utility of these complementary and alternative approaches to care.

## Pharmacologic treatment

As with any disease process, underlying medical and behavioral causes of insomnia should be ruled out before considering pharmacologic intervention. Patients should be closely examined to determine if medical intervention is necessary, and in many cases it is advised that pharmacologic therapy be used as an adjunct only to CBT-I and other behavioral interventions. 13 As previously mentioned, 2 of the most common concomitant diagnoses to consider are obstructive sleep apnea and restless leg syndrome (RLS)/periodic limb movement disorder (PLMD), both of which can be discovered by polysomnography. Once it is established by the provider that pharmacotherapy may be beneficial, the following categories of medications may be considered: nonbenzodiazepines or "Z-drugs," orexin receptor antagonists, melatonin agonists, antidepressants, benzodiazepines (gammaaminobutyric acid agonists), antipsychotics, antiepileptics and over-the-counter medications such as antihistamines. 4,5,9,13,20,21 The overarching concern in the literature points to unfavorable side effect profiles, especially of Z-drugs and benzodiazepines. This has brought into question the long-term effectiveness of these medications in comparison to their risk profile. There has been additional controversy regarding the use of these pharmacologic classes and increased mortality.<sup>5,9</sup> Notably, both categories have a high abuse potential.4

Outlined in Table 3 are the most common medication classes with specific medication names, mechanism of action, common side effect profile and relative benefit/specific population use.

**TABLE 3:**Commonly Prescribed Medications

MEDICATION CLASS	MEDICATION NAME	MECHANISM OF ACTION	UNIQUE SIDE EFFECT PROFILE	RELATIVE BENEFIT/SPECIFIC INDICATIONS
Nonbenzodiazepines or "Z-drugs," Hypnotics	Zolpidem (Ambien) Zaleplon (Sonata) Eszopiclone (Lunesta)	Selectively binds to GABA receptors targeting the sedative effect rather than the anxiolytic effect	Memory loss Hallucinations Sleep walking, eating, driving Accidental injury Suicidal ideation Abuse potential	Decreases sleep latency Improves total sleep time Improves sleep quality
Orexin Receptor Antagonists	Suvorexant (Belsomra)	Suppresses wakefulness through orexin receptor antagonism	Cataplexy Sleep paralysis Hallucinations Retrograde amnesia Suicidal ideation Abuse potential	Decreases sleep latency Improves total sleep time
Melatonin Agonists	Melatonin Ramelteon (Rozerem)	Binds to melatonin receptors and works as agonist to them, inducing sleep	Dizziness Nausea Sleep behavioral disorder (rare)	Stabilizes sleep wake cycle  Decreases sundowning  Pediatrics and geriatrics
Antidepressants	Doxepin (Silenor)	Varies/Unknown	Sexual dysfunction Suicidal ideation	Limited evidence to prove benefit
Benzodiazepines	Estazolam Flurazepam Quazepam (Doral) Temazepam (Restoril) Triazolam	GABA receptor agonists	Distorts sleep architecture Accidental injury Retrograde amnesia Dependence and high abuse potential	Improves sleep bruxism, but otherwise generally discouraged

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Researchers have evaluated these medications to compare and contrast the effectiveness with other methods, such as sleep hygiene and CBT-I. Current recommendations from the Best Practices in Sleep Medicine: Choosing Wisely® campaign are noted in Table 4.

# TABLE 4:

Best Practices in Sleep Medicine: Recommendations from the Choosing Wisely® Campaign, adapted from AAFP.org, December  $2015^2$ 

## **RECOMMENDATION**

Avoid use of hypnotics as primary therapy for chronic insomnia in adults; instead offer cognitive behavioral therapy and reserve medication for adjunct treatment when necessary. (American Academy of Sleep Medicine)

Do not use benzodiazepines or other sedative hypnotics in older adults as first choice for insomnia, agitation or delirium. (American Academy of Sleep Medicine)

Do not prescribe medication to treat childhood insomnia that usually arises from parent-child interactions and responds to behavioral intervention.

(American Geriatrics Society)

Interestingly, the Agency for Healthcare Research and Quality recommends re-evaluating insomnia only 10 days after starting pharmacologic therapy. If at that point there is no improvement, it is advised to reconsider the therapy being provided. This is particularly interesting considering that the number of prescriptions for insomnia is over 20.8 million annually, per 2010 data.<sup>4</sup>

## Osteopathic approach

Osteopathic family physicians share a core belief that each person is a unit composed of body, mind, and spirit. As such, the osteopathic physician should take a careful history in each of these areas to uncover all possible factors contributing to insomnia. In keeping with the recommendation that nonpharmacologic therapy is the best first-line approach for patients with insomnia, the osteopathic physician should encourage patients to optimize their own personal health in a way that promotes restorative sleep.

A thorough evaluation of the literature American Academy of Sleep Medicine presented no clinically validated studies regarding the use of OMT to treat insomnia disorder specifically. However, the authors propose that OMT directed toward normalizing parasympathetic and sympathetic tone would be of benefit for patients who struggle with insomnia disorder. Additionally, techniques targeted at underlying chronic medical disorders as well as any areas of chronic pain and somatic dysfunction may be of benefit. Cutler *et al* developed a small pilot study in 2005 that suggested cranial manipulation—specifically, the CV4 technique—can alter sleep latency, as can muscle sympathetic nerve activity.<sup>22</sup> Further research is needed to bolster these initial findings.

Though additional research is needed regarding the efficacy of OMT as an adjunct treatment for insomnia, basic osteopathic principles can be easily applied to promote comprehensive care of the patient who struggles with insomnia.

## **CONCLUSION**

Insomnia is a common medical disorder that all osteopathic family medicine physicians will encounter on a regular basis; thus, an understanding of proper diagnosis and management is imperative. The osteopathic physician has the unique ability to treat the whole patient and incorporate OMT in the office, refer to behavioral health specialists for cognitive behavioral therapy, and utilize pharmacologic therapies when needed. Research has clearly shown that pharmacologic intervention should be initiated after cognitive behavioral therapy in light of well-known medication side effects from the vast majority of medications utilized to treat insomnia. Effective management of insomnia has the potential to improve patient quality of life, increase productivity in the workplace and at home, and save the health care system billions of dollars.

## **AUTHOR DISCLOSURE(S)**

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