Insomnia in Patients with Comorbid Psychiatric Disorders: Shared Neurobiology and Clinical Solutions

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Sleep Clinic Case: History

- 59-year-old woman requests help for her persistent insomnia
- Difficulty falling asleep and especially remaining asleep
- Mood OK now, but past treatment for recurrent major depression and suicide attempts (numerous antidepressant trials and ECT)
- Medical history: Chronic congestive heart failure, deep vein thrombosis with pulmonary emboli, hypertension, stroke, hypothyroidism, hyperlipidemia, gastroesophageal reflux

ECT = electroconvulsive therapy.

Sleep Clinic Case: Medications

- Aripiprazole 10 mg in AM
- Bupropion XL 450 mg in AM
- Duloxetine 90 mg in AM
- Mirtazapine 30 mg in PM
- Quetiapine 25 mg BID PRN
- Morphine 15 mg twice daily
- Oxycodone 15 mg q6hr PRN
- Alendronate
- Apixaban
- Bacidifen
- Bumetanide
- Celecoxib
- Celecoxib
- Docosate
- Furosemide
- Gabapentin
- Levothyroxine
- Loratadine
- Oxycodone
- Pantoprazole
- Polyethylene glycol
- Potassium chloride
- Prochlorperazine
- Simethicone
- Spironolactone
- Torsemide
- Alendronate
- Apixaban
- Bacidifen
- Bumetanide
- Celecoxib
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- Docosate
- Furosemide
- Gabapentin
- Levothyroxine
- Loratadine
- Oxycodone
- Pantoprazole
- Polyethylene glycol
- Potassium chloride

Homeostatic and Circadian Sleep Regulation

Circadian Entrainment

- Retina photosensitive systems
- Retinohypothalamic tract
- Suprachiasmatic nucleus
- Pineal gland (melatonin)
Human Pineal Gland

Images are generated by Life Science Databases (LSDB).
https://upload.wikimedia.org/wikipedia/commons/6/6d/Pineal_gland.gif.

Sleep and Neurotransmitters

- Wake-promoting
  - Acetylcholine
  - Dopamine
  - Norepinephrine
  - Serotonin
  - Histamine
  - Glutamate
  - Orexin/hypocretin

- Sleep-promoting
  - GABA
  - Galanin
  - Adenosine
  - (Melatonin)

GABA = γ-aminobutyric acid.

Sleep and Mental Health: Interactions

- Psychiatric disorders may disturb sleep
- Psychiatric disorders may alter sleep stages
- Sleep disorders may worsen psychiatric conditions
- Sleep manipulations may worsen psychiatric symptoms
- Sleep manipulations may improve psychiatric symptoms

Sleep and Mental Health

Sleep Health ⇒ Mental Health

DSM-5 Disorder | Diagnostic Criteria Include
---|---
Manic/Hypomanic Episodes | Decreased need for sleep
Major Depressive Episode | Insomnia or hypersomnia
Premenstrual Dysphoric Disorder | Hypersomnia or insomnia
Melancholic Features | Early-morning awakening
Generalized Anxiety Disorder | Sleep disturbance
Posttraumatic Stress Disorder | Recurrent distressing dreams; sleep disturbance
Acute Stress Disorder | Sleep disturbance
Alcohol Withdrawal | Insomnia
Caffeine Intoxication | Insomnia
Cannabis Withdrawal | Sleep difficulty – insomnia, disturbing dreams
Opioid Withdrawal | Insomnia
Sedative, Hypnotic, Anxiolytic Withdrawal | Insomnia
Stimulant Withdrawal | Insomnia or hypersomnia
Tobacco Withdrawal | Insomnia
### DSM-5 Disorders Commonly Associated with Disturbed Sleep

- Mood disorders
- Anxiety disorders
- Trauma- and stressor-related disorders
- Schizophrenia spectrum and other psychotic disorders
- Substance-related and addictive disorders
- Neurocognitive disorders

### DSM-5 Insomnia Disorder: Key Criteria

- Dissatisfaction with sleep quality or quantity in relation to difficulty initiating or maintaining sleep or early morning awakening
- There must be clinically significant distress or impairment
- The sleep difficulty must be at least 3 nights per week persisting for at least 3 months
- The sleep problem must be in the context of adequate opportunity for sleep
- The sleep problem is not better explained or attributed to another sleep disorder, mental disorder or medical condition, or the effects of a substance
  - However, coexistence with another sleep disorder, mental disorder or medical condition, or mental disorder may be specified

### DSM-5 Insomnia Disorder: Daytime Impairment

- Fatigue
- Cognitive performance
  - Attention
  - Concentration
  - Memory
- Mood disturbance
  - Irritability
  - Lability
- Daytime sleepiness?

### DSM-5 Insomnia Disorder: Functional Consequences

- Increased future risk
  - Major depressive disorder
  - Hypertension
  - Myocardial infarction
- Decreased productivity and higher absenteeism
- Greater economic burden
- Decreased quality of life

### Major Depression and Sleep

- Subjective complaints
  - Insomnia – 80% to 85% experiencing acute episodes
    - Frequent or prolonged awakenings
    - Early morning awakenings
    - Difficulty falling asleep
  - Hypersomnia – 15% to 20%
    - Prolonged nighttime sleep episodes
    - Daytime fatigue and sleepiness
    - No objective hypersomnolence by MSLT
  - Insomnia often precedes a depressive episode
  - Insomnia is a common residual symptom following the resolution of a depressive episode

MSLT = Multiple Sleep Latency Test.
Sleep in *DSM-5* Major Depression

- Insomnia  
  - “…it typically takes the form of middle insomnia or terminal insomnia”  
  - “Initial insomnia may also occur”  
- Hypersomnia  
  - ‘Individuals who present with oversleeping (hypersomnia) may experience prolonged sleep episodes at night or increased daytime sleep’

Clinical Implications

“Hypersomnia” is a common complaint among depressed individuals, but typically there is not the profound objective sleepiness encountered with other sleep disorders (eg. OSA, narcolepsy, or hypersomnia disorder).

“Hypersomnia” with Mood Disorders

“Taken together, there is no objective evidence supporting the view that patients with mood disorder have either abnormal mean sleep latency on the MSLT or objective extended nocturnal sleep. However, these patients spent a substantial amount of time in bed, acknowledged as ‘resting’ more than sleeping….”

Manic Episodes and Sleep

- Subjective complaints  
  - Decreased need for sleep  
  - May feel refreshed after little or no sleep  
  - Insomnia may be severe – sleepless for days  
  - Less need for sleep may be the first evidence of an impending manic episode  
  - Insomnia or sleep loss may trigger a manic episode in bipolar patients

Clinical Implications

Advise your patients with bipolar disorder to avoid situations that may lead to acute or chronic sleep loss. Sedating medications may help prevent a hypomanic episode from progressing to full-blown mania.

Sleep and Anxiety Disorders

- There is a high prevalence of insomnia among anxiety and trauma/stress-related disorder patients  
  - GAD  
  - Panic disorder  
  - PTSD  
- Insomnia tends to begin with anxiety symptoms  
- Abrupt awakenings with panic disorder and PTSD  
- Persistent insomnia increases the future risk of anxiety disorders

GAD = generalized anxiety disorder; PTSD = posttraumatic stress disorder.
PTSD and Sleep Symptoms

- Nightmares – trauma related
- Insomnia – sleep onset and maintenance
- Vivid dreams/nightmares unrelated to trauma
- Nocturnal panic attacks
- Sleep terror
- Abnormal movements and vocalizations
- Sleep-disordered breathing

Schizophrenia and Sleep

- Subjective
  - Difficulty initiating and maintaining sleep
  - Sleep poorly restorative
  - Severity correlates with illness exacerbations
  - Insomnia may represent prodromal symptom
- Evaluating sleep disturbance in schizophrenia
  - Consider possible circadian phase delay
  - Difficulty falling asleep
  - “Day-night reversal”
  - Consider medication effects – daytime sleepiness?
  - Consider risk factors for obstructive sleep apnea

Insomnia Treatment Approaches

- Education about sleep and mental health
- Promote healthy sleep habits
  - Recommend regularity in sleep-wake timing
  - Discuss an environment conducive for sleep
  - Advise caution with caffeine, alcohol, and other drugs
- Optimize management of comorbid conditions
- Cognitive-behavioral therapy for insomnia (CBT-I)
- Pharmacotherapy
  - Directly targeting sleep
  - Indirectly facilitating sleep

Insomnia, CBT-I, and Mental Illness

- Behavioral treatment of insomnia in bipolar disorder
  - Authors noted potential problem of sleep deprivation precipitating mania
  - Sleep generally improved with regularizing bedtimes and wake up times
  - Of 15 stimulus control therapy patients, 2 reported mild hypomanic symptoms
  - Of 5 sleep restriction therapy, 2 reported mild hypomanic symptoms
- Conclusions
  - Behavioral insomnia treatments safe and effective with bipolar patients
  - Regularize bedtimes and wake up times
  - Carefully monitor mood symptoms and daytime sleepiness
**Insomnia, CBT-I, and Mental Illness (continued)**

- CBT for the management of insomnia comorbid with mental disorders
  - Discuss effective use of CBT for the treatment of insomnia in patients with mental disorders – especially depression, PTSD, and alcohol dependence


- CBT for insomnia comorbid with psychiatric and medical conditions: A meta-analysis
  - Identified 37 studies employing CBT-I with patients meeting criteria for insomnia disorder and a concomitant condition
  - Conclusions
    - Posttreatment insomnia remission
      - CBT-I group: 36.0%
      - Control group: 16.9%
    - “A small to medium positive effect was found across comorbid outcomes, with larger effects on psychiatric conditions compared with medical conditions.”

**Sleep and Neurotransmitters**

- **Wake-promoting**
  - Acetylcholine
  - Dopamine
  - Norepinephrine
  - Serotonin
  - Histamine
  - Glutamate
  - Orexin/hypocretin

- **Sleep-promoting**
  - GABA
  - Galanin
  - Adenosine
  - (Melatonin)


**FDA-Approved Insomnia Medications**

- Benzodiazepine receptor agonists
  - Benzodiazepines – 5 compounds
  - Non-benzodiazepines – 3 compounds, various formulations
- Selective melatonin receptor agonist – 1 compound
- Selective histamine receptor antagonist – 1 compound
- Orexin/hypocretin receptor antagonist – 1 compound

**What People Take for Insomnia**

- | Formal sleep indication? | No | Yes |
<table>
<thead>
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<tbody>
<tr>
<td>Dietary Supplements</td>
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<tr>
<td>Over-the-Counter Sleep Aids</td>
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<td>Assorted Sedating Medications “Off-label”</td>
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</table>

- Prescription required? | Yes | No |

- Generic name | Brand Name | Available Doses (mg) | Elimination Half-life (hr) |
- Benzodiazepine Immediate Release
  - Estazolam | ProSom | 1, 2 | 10 – 24 |
  - Flurazepam | Dalmane | 15, 30 | 2.3-4.8 – 160 active metabolite |
  - Quazepam | Doral | 7.5, 15 | 38/73 active metabolite |
  - Temazepam | Restoril | 7.5, 10, 22.5, 30 | 3.5 – 18.4 |
  - Triazolam | Halcion | 0.125, 0.25 | 1.8 – 5.5 |
- Non-benzodiazepine Immediate Release
  - Zolpidem | Ambien | 5, 10 | 2.8 in males |
  - Zolpidem | Zolpimist | 5, 10 | 2.7 – 3.0 |
- Non-benzodiazepine Alternate Delivery
  - Zolpidem | Ambien CR | 6.25, 12.5 | 1.6 – 4.5 |
  - Zolpidem | Intermezzo | 1.75, 3.5 | 2.6 |
  - Zolpidem | Edluar | 5, 10 | 2.7 – 3.0 |

Brand names are included in this table for participant clarification purposes only. No product promotion should be inferred.

### Benzodiazepine Receptor Agonists

#### Benzodiazepines

- **Pharmacodynamics**
  - Positive allosteric modulators of GABA responses at the \( \text{GABA}_A \) receptor complex
  - Multiple \( \text{GABA}_A \) receptor subunit subtypes
  - Targeted action in the hypothalamic sleep nuclei
  - Global CNS effects
- **Pharmacokinetics**
  - Relatively rapidly absorbed
  - Very wide range of elimination half-lives: hours to days
  - Expect prolonged half-life in older adults
  - Most efficacious for sleep onset and maintenance
  - Potential for residual daytime sedation

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### Melatonin Receptor Agonist

#### Ramelteon

- **Pharmacodynamics**
  - Melatonin MT1 and MT2 receptor agonist
  - Targeted action in the hypothalamic suprachiasmatic nucleus (SCN)
  - Reduces evening circadian driven arousal
  - Reinforces circadian periodicity
  - Enhances sleep onset
- **Pharmacokinetics**
  - Relatively rapidly absorbed
  - Relatively short elimination half-life: 1 to 2.6 hours
  - Indication for sleep onset
  - Limited potential for residual daytime sedation

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### Histamine Receptor Antagonist

#### Low-Dose Doxepin

- **Pharmacodynamics**
  - At very low doses primarily histamine receptor antagonist (avoiding receptor effects associated with higher doses)
  - Histamine is a potent wake-promoting neurotransmitter
  - Enhances sleep by reducing nighttime histamine arousal
- **Pharmacokinetics**
  - Relatively rapidly absorbed
  - Elimination half-life: About 1.5 hours
  - Indication for sleep maintenance
  - Limited potential for residual daytime sedation

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### H\(_1\) Antagonists for Insomnia

- **Review of the histamine system and the clinical effects of \( H_1 \) antagonists**
  - Basis for a new model for understanding the effects of insomnia medications

  In addition to the blood level, clinical effects reflect circadian variation in activity in the histamine system and other parallel wake promoting systems. We hypothesize that significant sleep enhancing effects are likely when the histamine system is relatively active and the activity of other parallel wake promoting systems is relatively minimal.

  Histamine levels in the hypothalamus were found to rise gradually throughout the sleep period, reaching a peak around the transition from sleep to wakefulness. Histamine release may be under circadian control and play a role in ‘waking from sleep’ at the end of the sleep period.
Orexin/Hypocretin Receptor Antagonist
Suvorexant

- Pharmacodynamics
  - Dual orexin receptor (OX1 and OX2) antagonist
  - Hypothalamic neurons with peptides orexin-A and orexin-B project to cortex and wake-promoting nuclei to reinforce and stabilize wakefulness
  - Suvorexant promotes sleep by decreasing orexin-associated CNS arousal

- Pharmacokinetics
  - Relatively rapidly absorbed
  - Elimination half-life: About 12 hours
  - Indication for sleep onset and maintenance
  - Dose-dependent potential for residual daytime sedation

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Pharmacokinetics

- Relatively rapidly absorbed
- Elimination half-life: About 12 hours
- Indication for sleep onset and maintenance
- Dose-dependent potential for residual daytime sedation

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<table>
<thead>
<tr>
<th>Medication</th>
<th>Unprescribed Insomnia</th>
<th>Sleep Onset</th>
<th>Sleep Maintenance</th>
<th>Early Awakening</th>
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<tbody>
<tr>
<td>Estazolam</td>
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<td>Flurazepam</td>
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<tr>
<td>Suvorexant</td>
<td>Yes</td>
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MOTN = middle of the night.

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What People Take for Insomnia

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<thead>
<tr>
<th>Prescription required?</th>
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<th>Dietary Supplements</th>
<th>Assorted Sedating Medications “Off-label”</th>
<th>Over-the-Counter Sleep Aids</th>
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“Off-Label” Prescriptions for Insomnia

- Antidepressants
- Antipsychotics
- Anxiolytics
- Antihistamines
- Anticonvulsants/mood stabilizers
- Antihypertensives
- Anesthetics

- Issues
  - Efficacy for insomnia
  - Safety in insomnia patients
  - Prescribing guidelines
  - Knowledge of sleep effects
  - Is there comorbidity with an indicated condition?
Trazodone

- Pharmacodynamics
  - 5-HT₂A partial agonist
  - 5-HT₂B/C antagonist
  - Serotonin reuptake inhibitor
  - α₂ receptor antagonist (strong)
  - H₁ receptor antagonist (mild)
- Pharmacokinetics
  - Peak plasma: 1 to 2 hours
  - Half-life: Biphasic
    - 3 to 6 hours
    - 5 to 9 hours
  - Metabolite: mCPP

- Side effects
  - Dizziness
  - Sedation
  - Hypotension
  - Arrhythmias
  - Priapism
  - Serotonin syndrome

What People Take for Insomnia

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Over-the-Counter Sleep Aids

- All are regulated by the FDA
- All are antihistamines
  - Diphenhydramine (most products)
    - Peak concentration: 2 to 3 hours
    - Elimination half-life: 8.5 ± 3.2 hours (short in children; longer in elderly)
  - Doxylamine
    - Peak concentration: 2 to 4 hours
    - Elimination half-life: 10 to 12 hours (longer in elderly)
  - Pharmacodynamics
    - Histamine H₁ receptor antagonist
    - Muscarinic acetylcholine receptor antagonist
    - Tolerance to sedating effects may develop with daily use
  - Adverse effects: Sedation, anticholinergic symptoms

Dietary Supplements: Melatonin

- Hormone produced by the pineal gland with timing controlled by the circadian system
- Melatonin blood level:
  - Low throughout daytime
  - Gradually rises in the evening as bedtime approaches
  - Relatively high during the nighttime sleep period
  - Declines at the end of the normal sleep period in the morning
  - May free-run in totally blind individuals or in people not exposed to the photoperiod or 24-hour routines
- Minimal efficacy for insomnia when taken at typical bedtime
- Strong evidence for selected circadian rhythm disorders

Dietary Supplements: Everything Else

- Valerian
- Kava-Kava
- Passion flower
- Skullcap
- Lavender
- Hops
- Glycine
- Magnesium
- GABA
- Hyoscyamus
- Stramonium
- L-Theanine
- Griffonia
- Wild jujube seeds
- Lemon balm
- Chamomile
- L-Tryptophan
- L-Glutamine
- L-Wuling

There was no statistically significant difference between any herbal medicine and placebo, or any herbal medicine and active control, for any of the thirteen measures of clinical efficacy.
Dietary Supplements

- None are regulated by the FDA
- Safety issues
  - Purity
  - Concentration
  - Toxicity


Sleep Health ↔ Mental Health

Sleep and Neurotransmitters

- Wake-promoting
  - Acetylcholine
  - Dopamine
  - Norepinephrine
  - Serotonin
  - Histamine
  - Glutamate
  - Orexin/hypocretin

- Sleep-promoting
  - GABA
  - Galanin
  - Adenosine
  - (Melatonin)


Sleep and Mental Health: Psychotropic Medications May Cause

- Desirable nighttime sleep and daytime alertness
- Sleepiness at undesired times
- Wakefulness at undesired times
- Sleep architecture changes
- Nightmares
- REM sleep behavior disorder
- Restless legs syndrome and periodic limb movements

REM = rapid-eye movement.

Psychotropic Medications
Key Sleep Considerations

- Pharmacodynamics
  - Sedating effects
  - Arousing effects
  - Sleep architecture effects
  - Arousals
  - REM sleep
  - Slow wave sleep

- Pharmacokinetics
  - Onset of action
  - Duration of action

Psychotropic Medications
Key Sleep Considerations (continued)

- Drug-drug interactions
  - Cumulative and competing effects
  - CYP450 and related metabolic processes
    - Inhibitors
    - Inducers
    - Substrates
- Do not forget about non-psychotropic medications
- Opioids
  - Sedation
  - Respiratory depression
  - Central sleep apnea
  - Warnings: concurrent use with benzodiazepines
Somnolence with Second-Generation Antidepressants

- Increasing odds ratio of somnolence compared with placebo
  - Bupropion
  - Milnacipran
  - Agomelatine
  - Escitalopram
  - Fluoxetine
  - Citalopram
  - Sertraline
  - Venlafaxine
  - Duloxetine
  - Desvenlafaxine
  - Paroxetine
  - Reboxetine
  - Mirtazapine
  - Fluvoxamine


Insomnia with Second-Generation Antidepressants

- Increasing odds ratio of insomnia compared with placebo
  - Agomelatine
  - Mirtazapine
  - Milnacipran
  - Citalopram
  - Duloxetine
  - Venlafaxine
  - Paroxetine
  - Reboxetine
  - Fluoxetine
  - Fluvoxamine
  - Sertraline
  - Desvenlafaxine
  - Bupropion


Histamine

Antipsychotics, Histamine Receptor Antagonism, and Sedation

Antipsychotics, Histamine Receptor Antagonism, and Sedation (continued)

Prescribing Information: Sleep Disturbance Side Effect Risk

- Do patients with intake of drugs labeled as sleep disturbing really sleep worse? A population based assessment from the Heinz Nixdorf Recall Study
  - Population based study of 4221 adults (ages 45 to 75 years)
  - Analyzed
    - All prescription and nonprescription drugs currently taking for at least 4 weeks
    - Product summary cumulative sleep disturbance risk
    - Reported sleep complaints
      - Difficulty falling asleep
      - Difficulty staying asleep
      - Early morning awakening
  - Conclusions
    - No relationship between risk data and patient reports
    - 55% of drugs had risks for BOTH stimulation and sedation

Case Discussions

Take-Aways

• Think pharmacology
  – Pharmacodynamics (including potential adverse effects)
  – Pharmacokinetics
  – Interactions: psychotropic and somatic medications
• Promote non-pharmacologic therapies
• Optimize sleep duration, timing, and quality
• Advocate the identification and treatment of sleep disorders – especially
  – OSA
  – Circadian rhythm sleep-wake disorders
• Remember: Helping sleep can help the whole person