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Personalized Strategies to Optimally Manage Insomnia: Have You Been Sleeping on Best Practices

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Disclosures



- **Research/Grants:** MECTA Corporation; Merck & Co., Inc.; VistaGen Therapeutics, Inc.
- **Consultant:** Jazz Pharmaceuticals, Inc.; Sage Therapeutics, Inc.
- **Advisory Committee:** Jazz Pharmaceuticals, Inc; Sage Therapeutics, Inc.

Learning Objective 1

Query your patients about insomnia to facilitate diagnosis and treatment to reduce the personal, clinical, and societal burden it imposes.

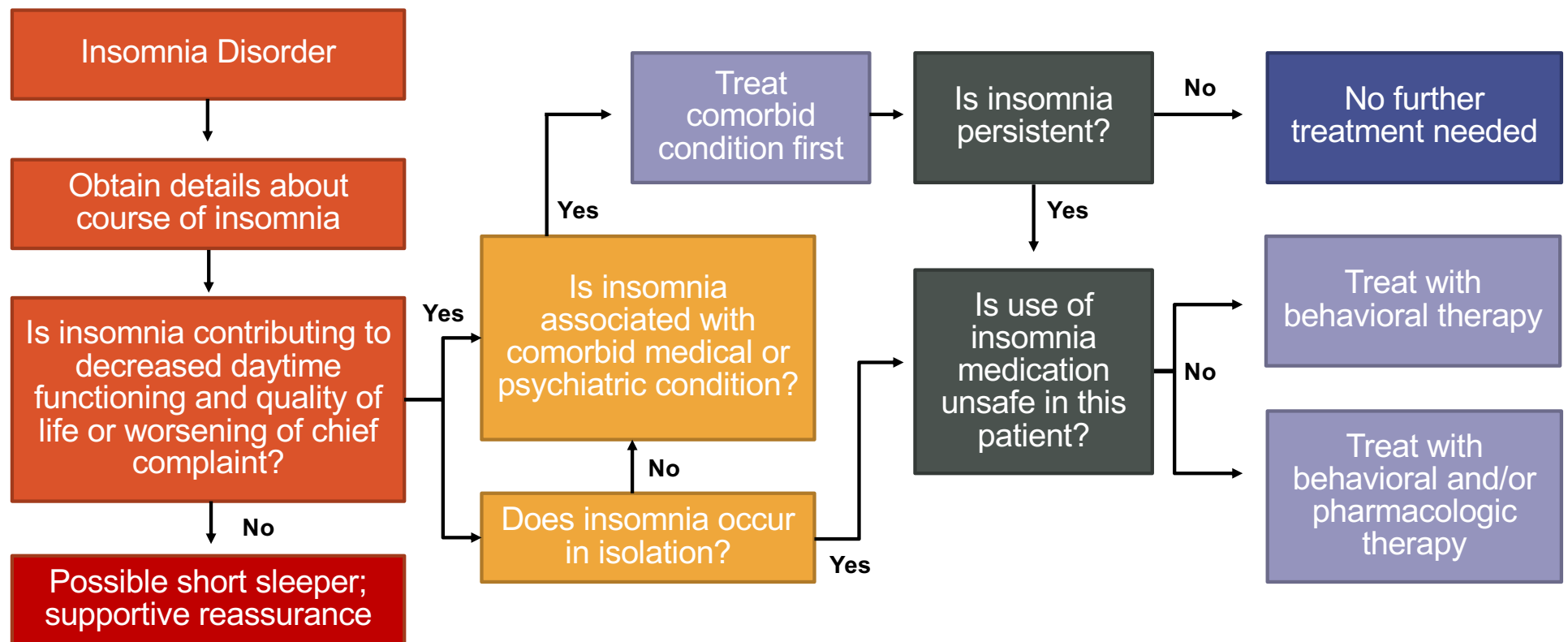


Learning Objective 2

Incorporate clinical trial updates on dual orexin reuptake inhibitors to identify effective strategies to safely manage insomnia, particularly in older adults with high medical burden and polypharmacy.



Insomnia Evaluation and Treatment Algorithm



Adapted from Doghramji K, et al. *Clinical Management of Insomnia*. 2nd Ed. 2015.

Goals of Treatment



- **Primary Goals:**

- Improve sleep quality and quantity
- Improve insomnia related daytime impairments

- **Specific Outcomes Indicators:**

- Wake time after sleep onset (WASO)
- Sleep onset latency (SOL)
- Number of awakenings
- Sleep time or sleep efficiency
- Formation of a positive and clear association between the bed and sleeping
- Improvement of sleep related psychological distress

Monitoring



- Sleep diary prior to and during active treatment.
- Clinical reassessment every few weeks and/or monthly until insomnia appears stable or resolved; then every 6 months.
- Repeated administration of questionnaires/surveys may be useful to assess outcomes and guide future treatment.
- When a single treatment or combination of treatments has been ineffective, other behavioral therapies, pharmacological therapies, combined therapies, or reevaluation for comorbid disorders should be considered.

Individualizing Treatment Selection for Insomnia



Patient-Related Factors

Age
BMI
Comorbid conditions
Polypharmacy
Fall risks
Gender

Drug-Related Factors

Adverse effects
Mechanism of action
Pharmacokinetics
Pharmacodynamics

Disease-Related Factors

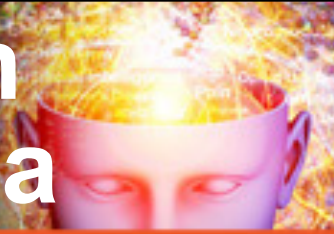
Duration of insomnia
Timing of insomnia

Approved Indications for Insomnia Medications

Medication	Unspecified insomnia	Sleep onset	Sleep maintenance	Early awakening
Estazolam		✓	✓	✓
Flurazepam		✓	✓	✓
Quazepam		✓	✓	✓
Temazepam	✓			
Triazolam	✓			
Eszopiclone		✓	✓	
Zaleplon		✓		
Zolpidem		✓		
Zolpidem ER		✓	✓	
Zolpidem spray		✓		
Zolpidem sublingual		✓		
Zolpidem sublingual— middle of the night			✓	
Ramelteon		✓		
Low-dose doxepin			✓	
Suvorexant		✓	✓	
Lemborexant		✓	✓	

FDA approved package inserts

Safety and Efficacy of Dual Orexin Receptor Antagonists for Insomnia



● Lemborexant

- Efficacy
 - SUNRISE 1 (one-month) and SUNRISE 2 (six months) trials demonstrated statistically significant superiorities on sleep onset and sleep maintenance compared to placebo.
 - Significantly improved both latency to persistent sleep and sleep maintenance (wake-after-sleep onset and sleep efficiency) compared to zolpidem extended release in patients \geq 55-years-old.¹
 - No significant residual effects of single and repeated bedtime dosing of lemborexant compared to zopiclone on driving when taken 9 hours prior in elderly and non-elderly patients.²
- Safety
 - Common adverse events are headache and somnolence.

● Suvorexant

- Efficacy
 - Shown effective relative to placebo over 3 months on patient self-reported and PSG sleep maintenance and onset endpoints in non-elderly and elderly patients.³
 - Preserved the ability to respond to nocturnal stimuli (10 and 20mg), whereas the 20mg dose also reduced wake-after-sleep onset and increased total sleep time.⁴
- Safety
 - Common side effects include headache, somnolence, and next day drowsiness.

1. Rosenberg R, et al. *JAMA Netw Open*. 2019;2(12):e1918254. 2. Vermeeren A, et al. *Sleep*. 2019;42(4). pii: zsy260.
3. Herring WJ, et al. *J Clin Sleep Med*. 2016;12(9): 1215–1225. 4. Drake CL, et al. *J Clin Sleep Med*. 2019;15(9):1285–1291.

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely



- Develop personalized, evidence-based treatment strategies for insomnia that include the use of dual orexin reuptake inhibitors to optimize clinical outcomes.

Questions & Answers

Don't forget to fill out your evaluations to collect your credit.

