

# Navigating Narcolepsy in Family Practice

*Patient-Centered Strategies to Optimize  
the Experience and Outcomes of Treatment*



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program evaluation

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Program Evaluation: **[PeerView.com/Narcolepsy-Eval-UVZ](https://www.peerview.com/Narcolepsy-Eval-UVZ)**

Please feel free to ask questions at the end of the presentation.

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# Our Goals for Today

- Improve the ability to identify patients whose symptoms suggest narcolepsy
- Recognize the pervasive ripple effect that disrupted nighttime sleep has on patients' overall health and quality of life
- Understand how burdens of treatment, including dosing schedules, undermine optimal adherence
- Tailor narcolepsy treatment plans to the needs of each patient



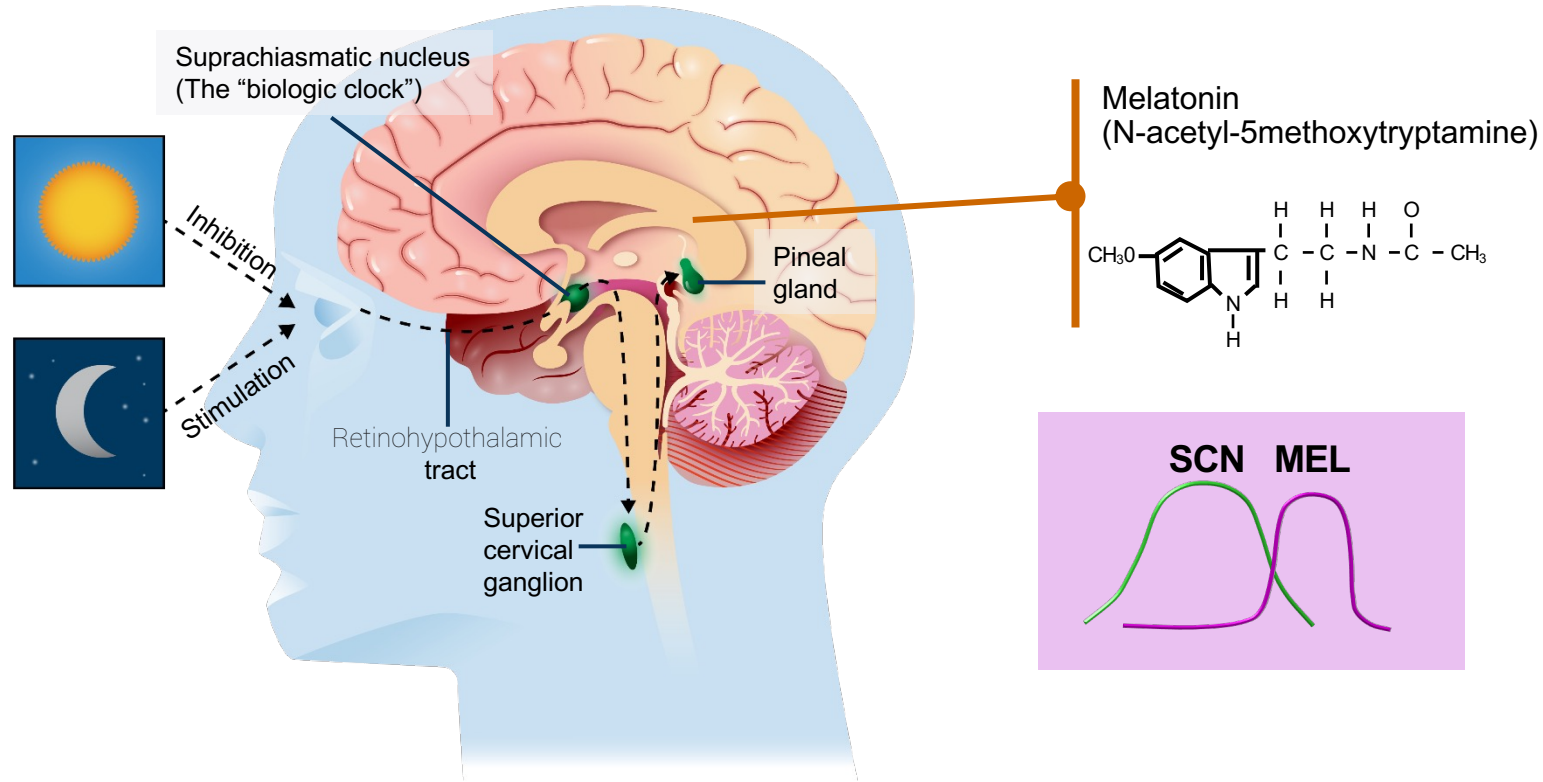
# Sleep Is a Fundamental Homeostasis Drive

## Consequences of Inadequate Sleep

- Decreased alertness
- Microsleeps
- Automatic activity
- Apathy
- Fatigue
- Memory loss

- Mood changes
- Accidents
- Productivity impairment
- Metabolic changes
- Autonomic tone changes
- Immune response

# Circadian Rhythms and the Suprachiasmatic Nucleus<sup>1</sup>



# Circadian Rhythms

Ubiquitous among  
living organisms

Suprachiasmatic  
nucleus (SCN) is the  
“master clock”<sup>1</sup>

**In humans, circadian timing  
modulates daily cycles in<sup>1,2</sup>:**

Core body temperature

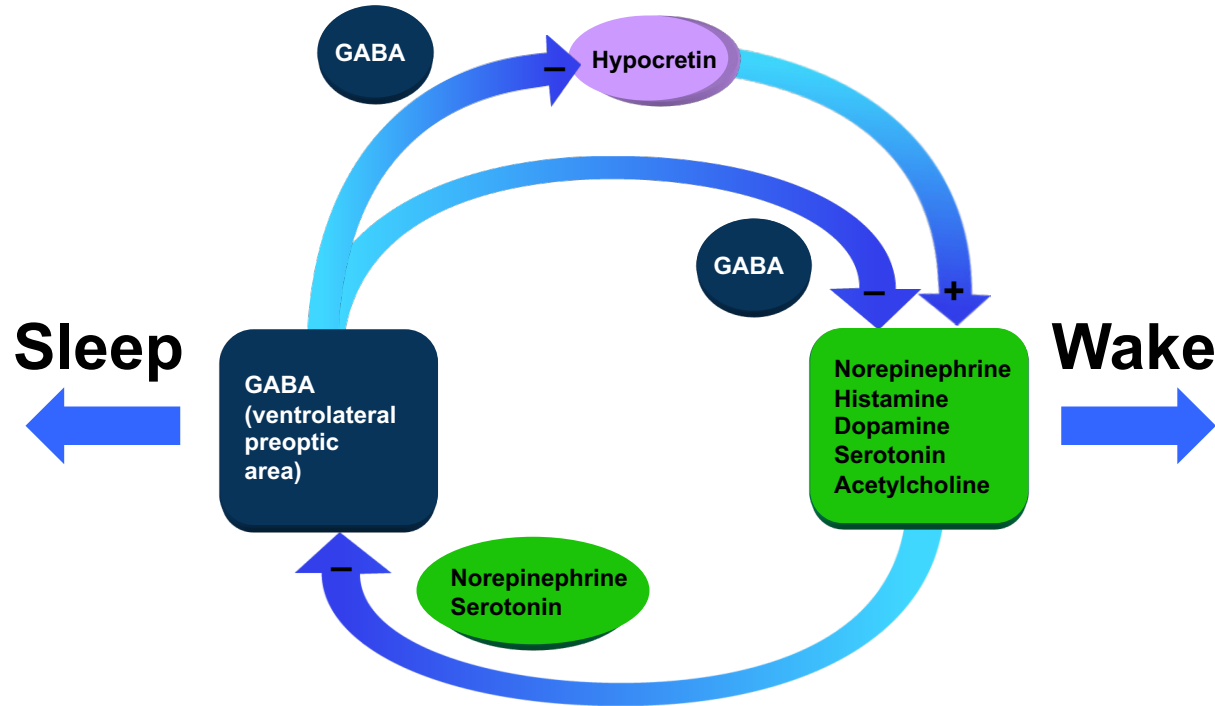
Blood pressure

Hormone secretion

Immune response

Sleep-wake cycle

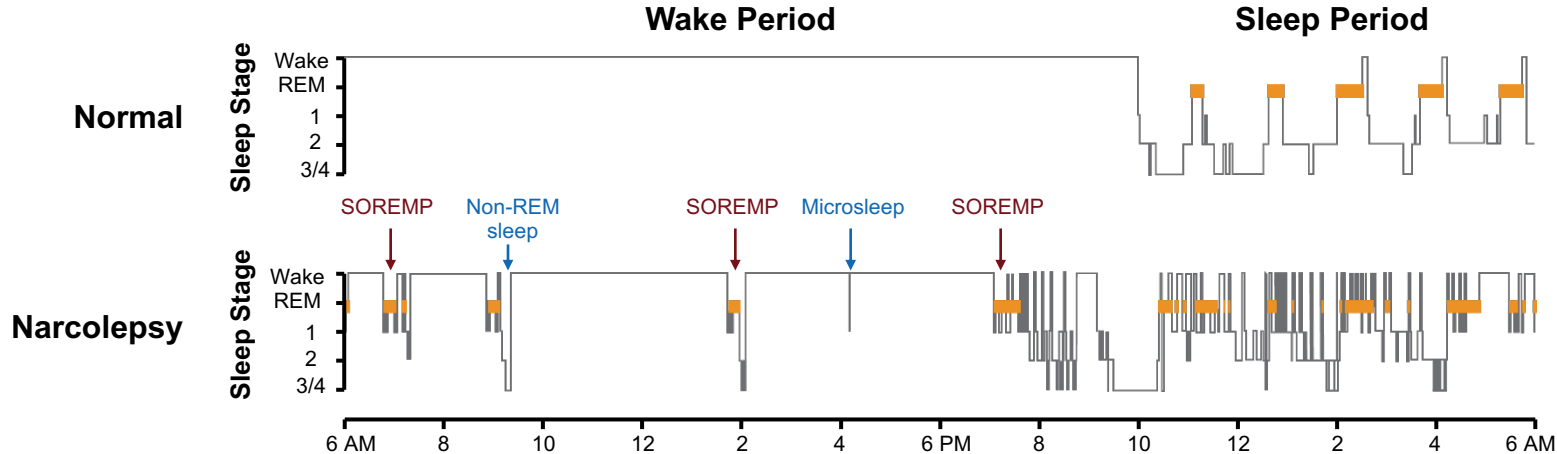
# Hypocretin Stabilizes the Sleep/Wake Switch<sup>1</sup>



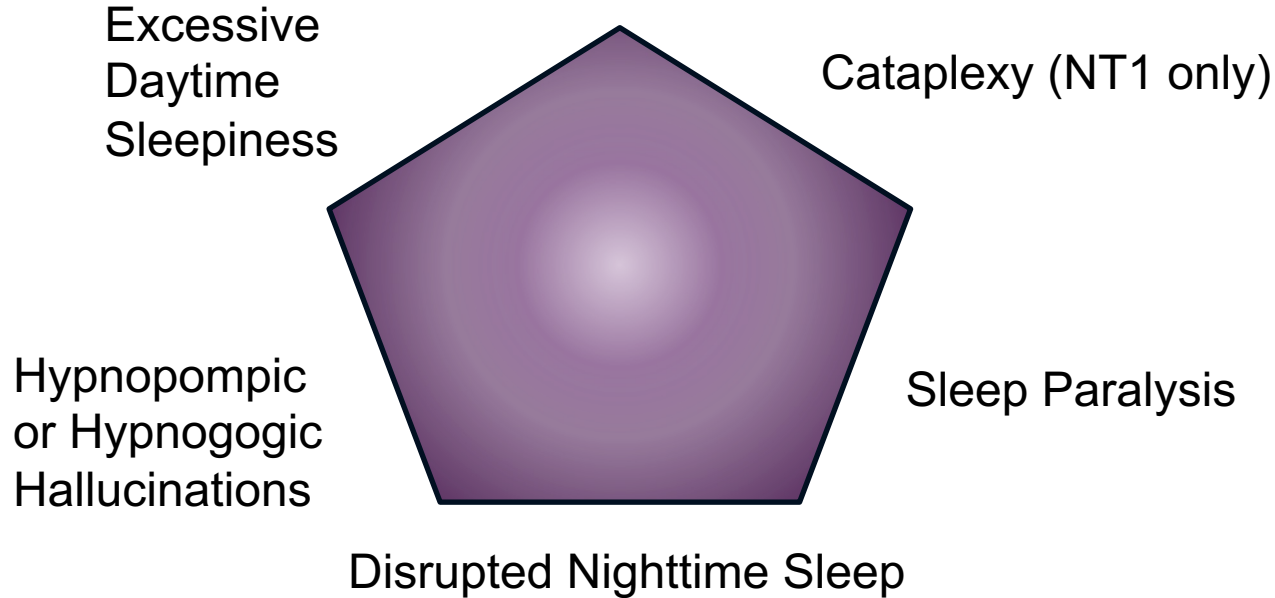
# Narcolepsy Is a Chronic Neurologic Disorder Characterized by Sleep-Wake State Instability<sup>1-4</sup>



Patients with narcolepsy have frequent, unpredictable transitions between sleep-wake states



# Narcolepsy Pentad<sup>1</sup>



**Full pentad is seen in only 10%-15% of cases**



# ICSD-3 Diagnostic Criteria: Narcolepsy<sup>1,2</sup>

**Chronic excessive daytime sleepiness (EDS)  $\geq 3$  months**

**Mean sleep latency  $\leq 8$  minutes +  $\geq 2$  SOREMPs on MSLT  
Or a SOREMP within 15 minutes of sleep onset on nocturnal polysomnogram**

## **Narcolepsy Type 1**

- Cataplexy  
and/or
- CSF  $\downarrow$  levels of orexin A  
(hypocretin 1)

## **Narcolepsy Type 2**

- Absence of cataplexy
- Normal or unmeasured orexin A
- No better alternate explanation  
(eg, effects of medication or  
withdrawal of medication)

1. American Academy of Sleep Medicine (AASM). *International Classification of Sleep Disorders*. 3rd Ed. Darien, IL: American Academy of Sleep Medicine. 2014.

2. AASM. *International Classification of Sleep Disorders*. 3rd Ed, Text Revision. ICSD-3-TR. 2023.

# Patient Case: Kaylie

**Name:** Kaylie

**Age:** 27

**Diagnosis:** ADHD

- Struggled to focus in school and was diagnosed with ADHD, inattentive type
- With coaching and methylphenidate, symptoms improved and she completed undergraduate and master's degrees
- Loves her job as high school guidance counselor but constantly feels tired; her low energy and tendency to “space out” at work hamper her performance
- ESS 16
- Kaylie asks if she needs a change in her ADHD medication or possibly an antidepressant



# The Road to a Narcolepsy Diagnosis Can Be Long and Full of Detours<sup>1-4</sup>

- Diagnostic delays can persist >10 years<sup>1,2</sup>
  - 29% of individuals saw ≥5 physicians before getting a correct diagnosis<sup>3</sup>
- Common initial diagnoses include depression, sleep apnea, ADHD<sup>1,2</sup>
- Patient complaints of EDS are unspecific, subjective, attributable to causes such as sleep deprivation, sedating effects of medication, poor sleep hygiene
- Diagnosis in adolescents and children can be particularly challenging due to different presentation than what is found in adults<sup>3,4</sup>
  - EDS can be misinterpreted as attentional issues, mood swings
  - Atypical cataplexy presentation (eg, facial hypotonia, ptosis, tongue protrusion)

1. Ortiz L et al. *Sleep*. 2023;46(suppl 1):A262. 2. Morse M et al. *Sleep*. 2024;47(suppl1):A281. 3. Ohayon MM et al. *Sleep Med*. 2021;84:405-414.

4. Maski K et al. *J Clin Sleep Med*. 2017;13:419-425.

# Diagnostic Process

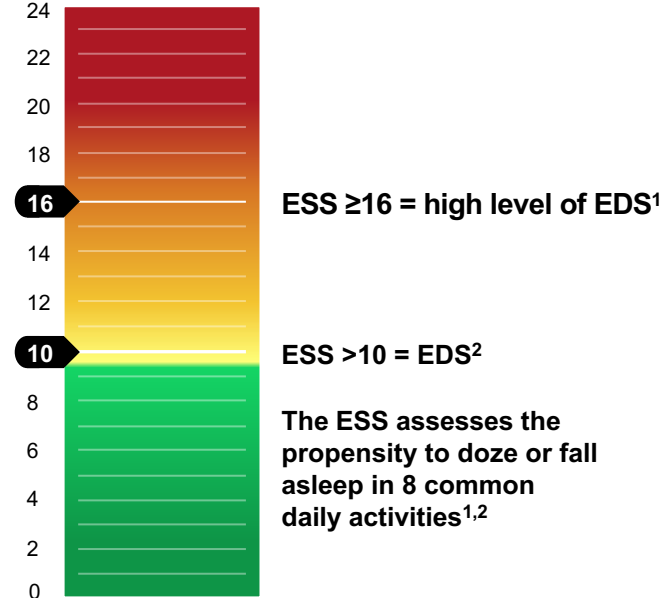
- Detailed sleep history
- Medical, psychiatric, social, family history
- Physical examination
- Sleep questionnaires
  - Epworth Sleepiness Scale (ESS)
  - Functional Outcomes of Sleep Questionnaire
  - Fatigue Severity Scale
  - Idiopathic Hypersomnia Severity Scale
- Laboratory testing as appropriate
- Sleep study/polysomnography
- Multiple Sleep Latency Test
- Maintenance of Wakefulness Test
- Performance Testing
  - Psychomotor Vigilance Test
  - Oxford Sleepiness Resistance Test

# Measuring the Severity of EDS With the ESS

0 = would never doze  
2 = moderate chance of dozing

1 = slight chance of dozing  
3 = high chance of dozing

Situation	Chance of Dozing
Sitting and reading	
Watching television	
Sitting inactive in a public place (eg, a theater or meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	
<b>Total score<sup>a</sup>:</b>	



Mean ESS scores lower in OSA ( $9 \pm 5$ ) than narcolepsy ( $17 \pm 4$ )<sup>3,4</sup>

<sup>a</sup> Total score ranges from 0-24.

1. Johns MW. *Sleep*. 1991;14:540. 2. Johns MW. *Sleep*. 1991;20:844-848. 3. Lipford MC. *J Clin Sleep Med*. 2019;15:33-38.

4. Luca G. *J Sleep Res*. 2013;22:482-495.

# Differential Diagnosis<sup>1-4</sup>

## EDS

- Insufficient sleep
- OSA
- Poor sleep hygiene
- Circadian rhythm abnormality
- Idiopathic hypersomnia
- Kleine-Levin syndrome
- Periodic limb movement disorder
- Behavioral symptoms of EDS (irritability, poor attentiveness, aggression, hallucinations) can be misinterpreted as:
  - Conduct or oppositional defiant disorder
  - Depression, ADHD
  - Substance abuse

## CATAPLEXY

- Seizure
- Myasthenia gravis
- Prader-Willi syndrome
- Syncope
- Postural orthostatic hypotension
- Syndrome of autosomal dominant cerebellar ataxia, deafness, and narcolepsy

## HALLUCINATIONS

- Schizophrenia
- Night terrors
- Panic attacks

# Adverse Effects of Sleep Disturbances<sup>1-4</sup>

- Impaired daytime function
  - Includes impaired cognitive function, judgement, and reaction time, resulting in suboptimal productivity; work and traffic accidents
- Elevated risk for cardiovascular and cardiometabolic comorbidities (eg, hypertension, obesity, type 2 diabetes, dyslipidemia)
  - In people with NT1, normal nighttime decreases in blood pressure are often reduced or absent
- Elevated CRP, IL-6, and other markers of inflammation
- Increased risk of infection and higher antibiotic use
- Increased all-cause mortality

# Multiple Narcolepsy Comorbidities<sup>1-4</sup>

- Affecting multiple domains—emotional, metabolic, sleep, and immune health, including
  - Endocrine (diabetes, obesity)
  - Other sleep disorders (OSA, RLS)
  - Musculoskeletal diseases (pain, arthritis)
  - Psychiatric symptoms or disorders
    - Anxiety, mood disorders, ADHD, autism/disrupted social interactions, eating disorders, suicidality
- Higher levels of health-care utilization in patients with narcolepsy

# Patient Case: Gabe

**Name:** Gabe

**Age:** 49

**Diagnosis:** NT2

- Diagnosed with NT2 four years ago and is treated with modafinil
- He reports feeling more alert during the day, but has a great deal of trouble getting up in the morning (he's often late for work) and never feels fully rested
- HbA1c and BMI have been steadily increasing and are currently 6.2% and 31 kg/m<sup>2</sup>, respectively
  - Both were under control when he jogged regularly, but he complains that he no longer has the energy to go for a run or even a stroll

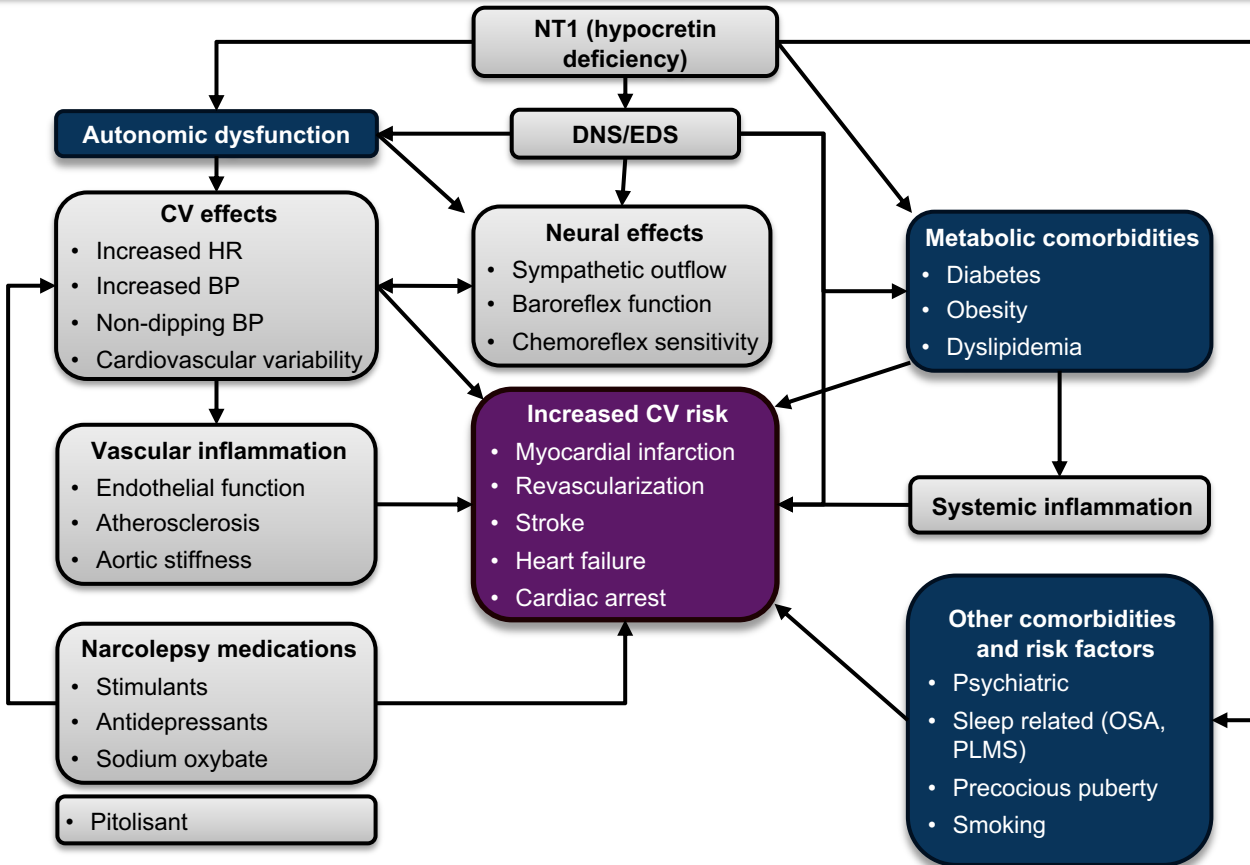
# DNS: Most Common Narcolepsy Symptom After EDS and Cataplexy<sup>1,2</sup>

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- Sleep instability is intrinsic to narcolepsy
- DNS is estimated to affect 30% to 95% of patients with narcolepsy, but gets less clinical attention than EDS and cataplexy
  - Only 1 question of the 15-item validated Narcolepsy Severity Scale (NSS) asks about DNS
- PSG findings: DNS in NT1 can be defined as sleep instability, with frequent brief awakenings and sleep stage transitions, frequent arousals, increased wake time after sleep onset, more stage 1 (N1), and more shifts to N1/wake from deeper stages



# Elevated CV Risk in People With Narcolepsy Is Multifactorial But Includes DNS<sup>1</sup>



## Narcolepsy associated with:

- 2.5 times higher risk of stroke
- 2.6 higher rate of heart failure
- 1.5 higher rate of all-cause mortality
- Unclear whether CV risk differs between NT1 and NT2

# Narcolepsy: Goals of Treatment



**Reduce daytime sleepiness**



**Control REM-associated features**

*Cataplexy; nightmares and frequent unpleasant dreams; hallucinations; sleep paralysis; disrupted nocturnal sleep*



**Improve cognition, psychosocial function, and workplace performance**



**Improve safety of patient and public**



**Acceptable risk/benefit ratio and adverse effects of medication**

# 2021 AASM Clinical Practice Guidelines: Treatment of Adults With Narcolepsy<sup>1</sup>

## **Recommends**

*Strong; for almost all patients*

Modafinil

Pitolisant

Sodium oxybate

Solriamfetol

## **Suggests**

*Conditional; for most patients, but  
different choices may be appropriate*

Armodafinil

Dextroamphetamine

Methylphenidate

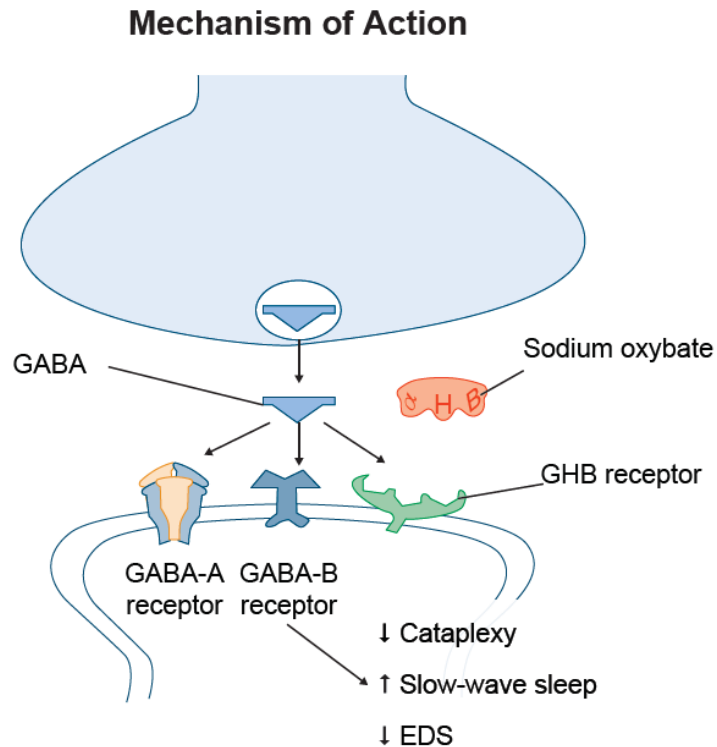
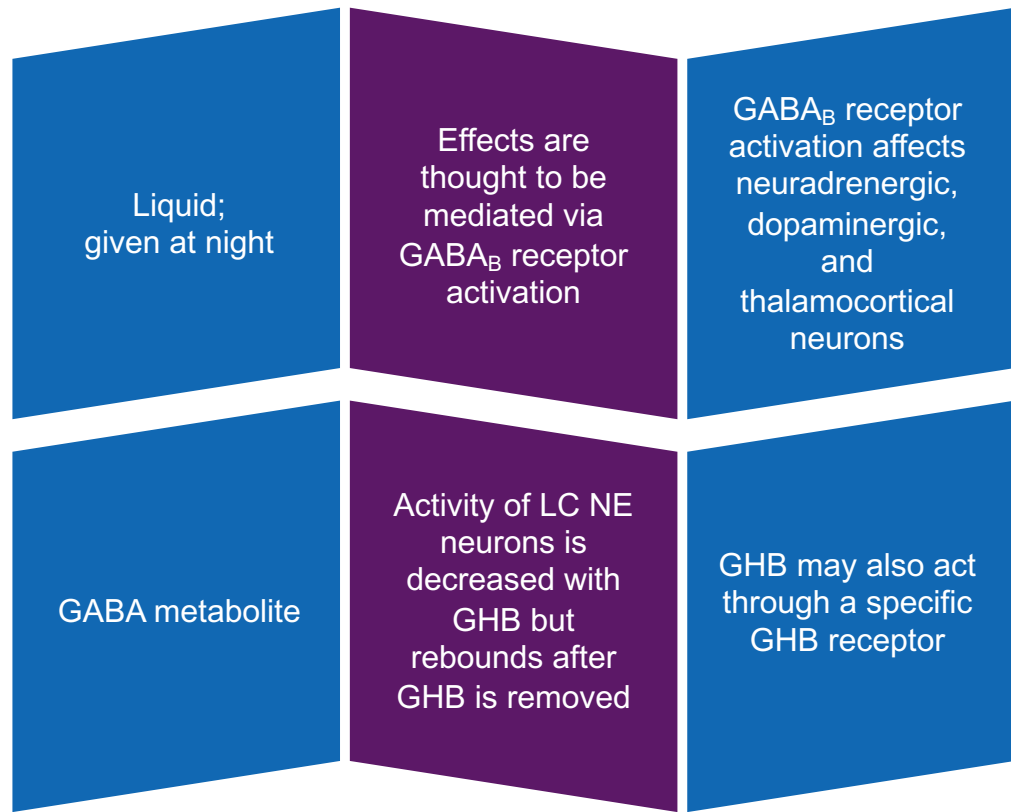


# Sodium Oxybate:

## First-Line Drug for Treatment of Narcolepsy<sup>1-3</sup>

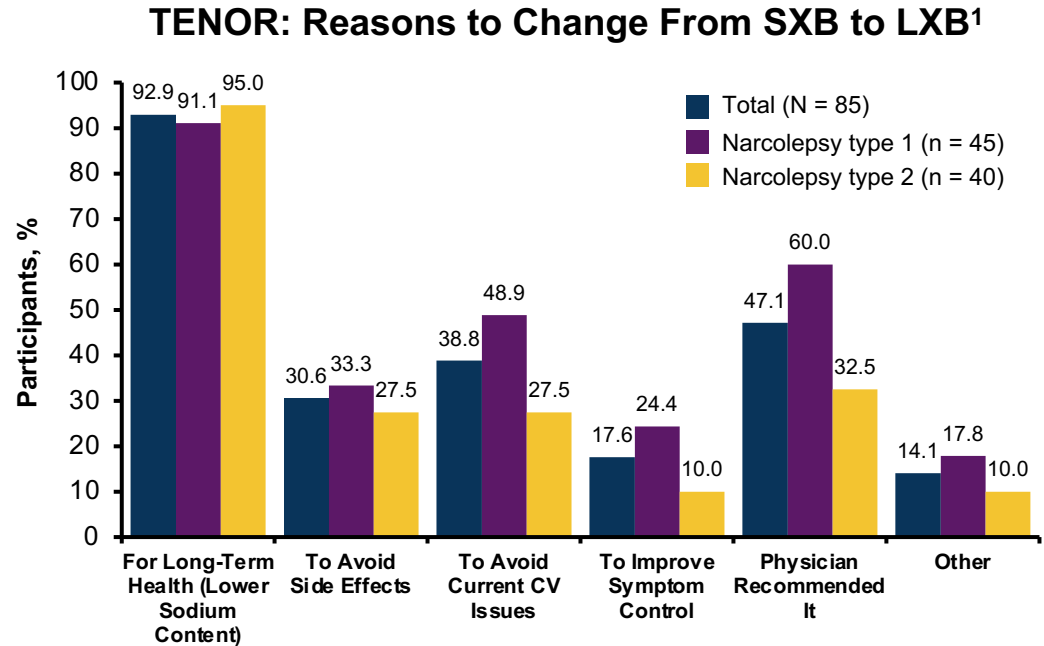
- SXB is the sodium salt of gamma-hydroxybutyrate
  - Indicated to treat cataplexy and EDS in narcolepsy
  - Some evidence indicates that it also improves sleep architecture and DNS in people with narcolepsy
- Because SXB substantially increases daily sodium intake in a population already at elevated risk for HTN and other CV comorbidities, a formulation with 92% less sodium was approved by the FDA in 2020
  - LXB contains the same active moiety as conventional SXB, with comparable safety and efficacy
- SXB is administered at night
  - Short half-life has required split dosing—at bedtime and 2.5 to 4 hours later—an additional sleep disruption for people with a sleep-disrupting condition
  - An extended-release, once-nightly formula was approved by the FDA in 2023

# Oxybate Formulations: A Unique Mechanism of Action<sup>1</sup>



# Patient Reasons and Experiences With Transitioning to LXB

- **TENOR:**<sup>1</sup> 21-week prospective observational study (N = 85)
- Most patients transitioned gram-to-gram
- 84% of the participants categorized the transition as easy
- **SEGUE:**<sup>2</sup> 6-week, phase 4, open-label, single-arm study (N = 60)
- Patients on stable SXB regimens transitioned gram-per-gram to LXB with opportunity for titration if needed
- 93% of participants categorized the transition as easy
- PGIC scores reflected no change (48%) or improvement (45%) in narcolepsy symptoms



# Patient Case: Arianna

**Name:** Arianna

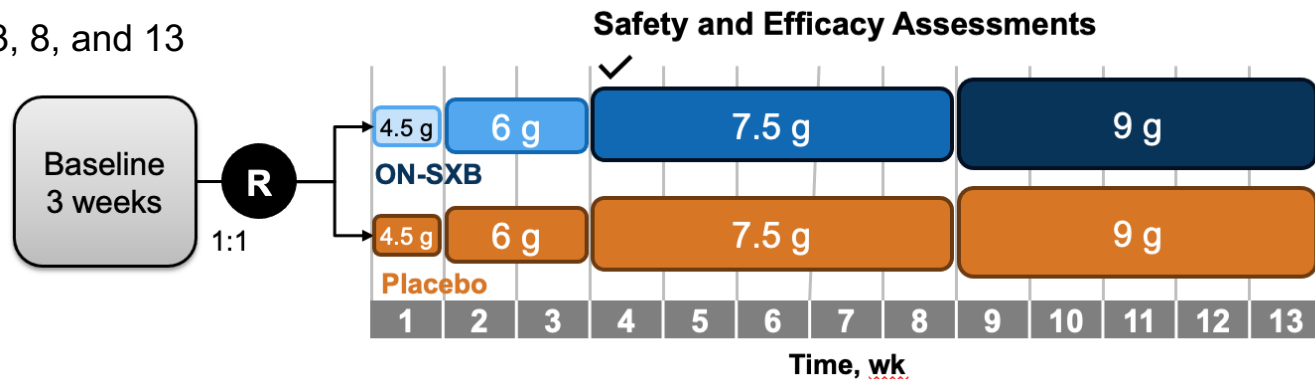
**Age:** 34

**Diagnosis:** NT1

- Arianna is a stay-at-home mother of three with a 13-year history of NT1
- Her long-time regimen of sodium oxybate plus solriamfetol has generally been working well for her
- On occasion, she has taken her second dose late, leaving her sluggish in the morning
- Her husband is an accountant who works long hours during tax season and she worries about waking him up when she takes her second dose, so sometimes she skips it “accidentally on purpose”

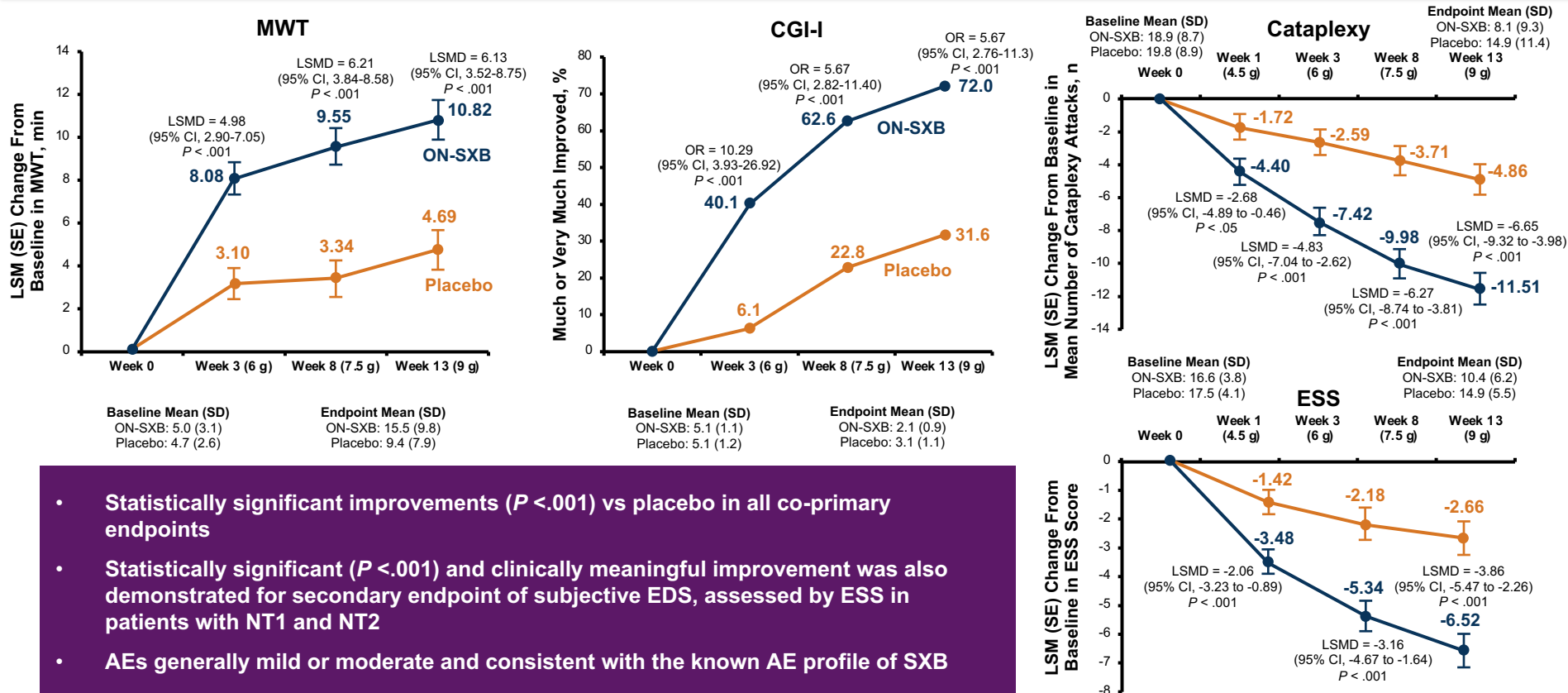
# REST-ON, Phase 3 Trial of Once-Nightly Sodium Oxybate<sup>1</sup>

- 13-week double-blind RCT to evaluate safety and efficacy of ON-SXB for the treatment of EDS and cataplexy in narcolepsy
- Patients (N = 222) randomized 1:1 to placebo or to ON-SXB, titrated from 4.5 g at week 1 to 9 g in weeks 9-13
- Primary endpoints: change from baseline in mean sleep latency on MWT; in “much” or “very much improved” on CGI-I; mean number of cataplexy attacks/week
- MWT, ESS, PSG scores and number of cataplexy attacks assessed at baseline and weeks 3, 8, and 13 of treatment
- CGI-I recorded at weeks 3, 8, and 13

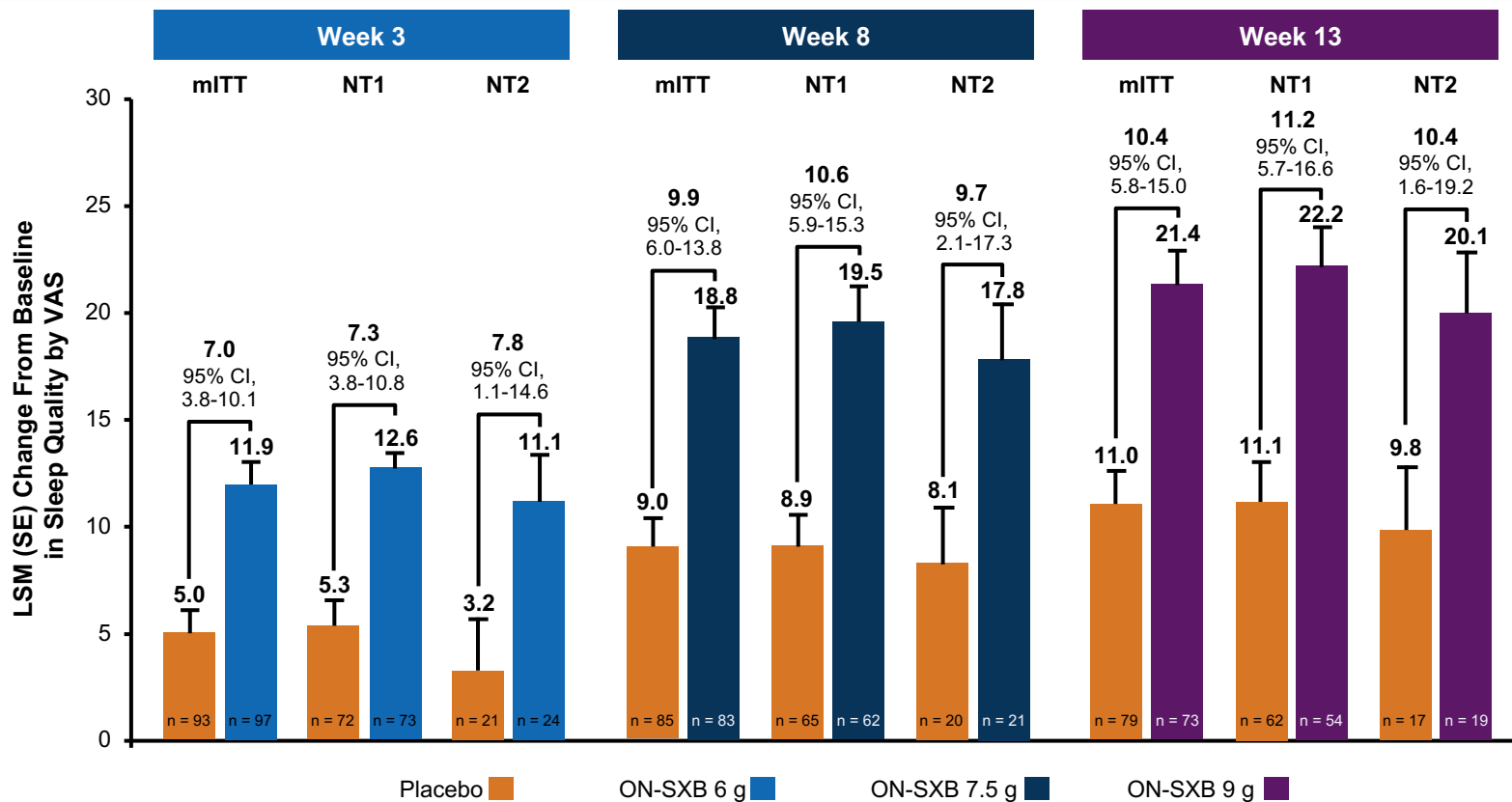




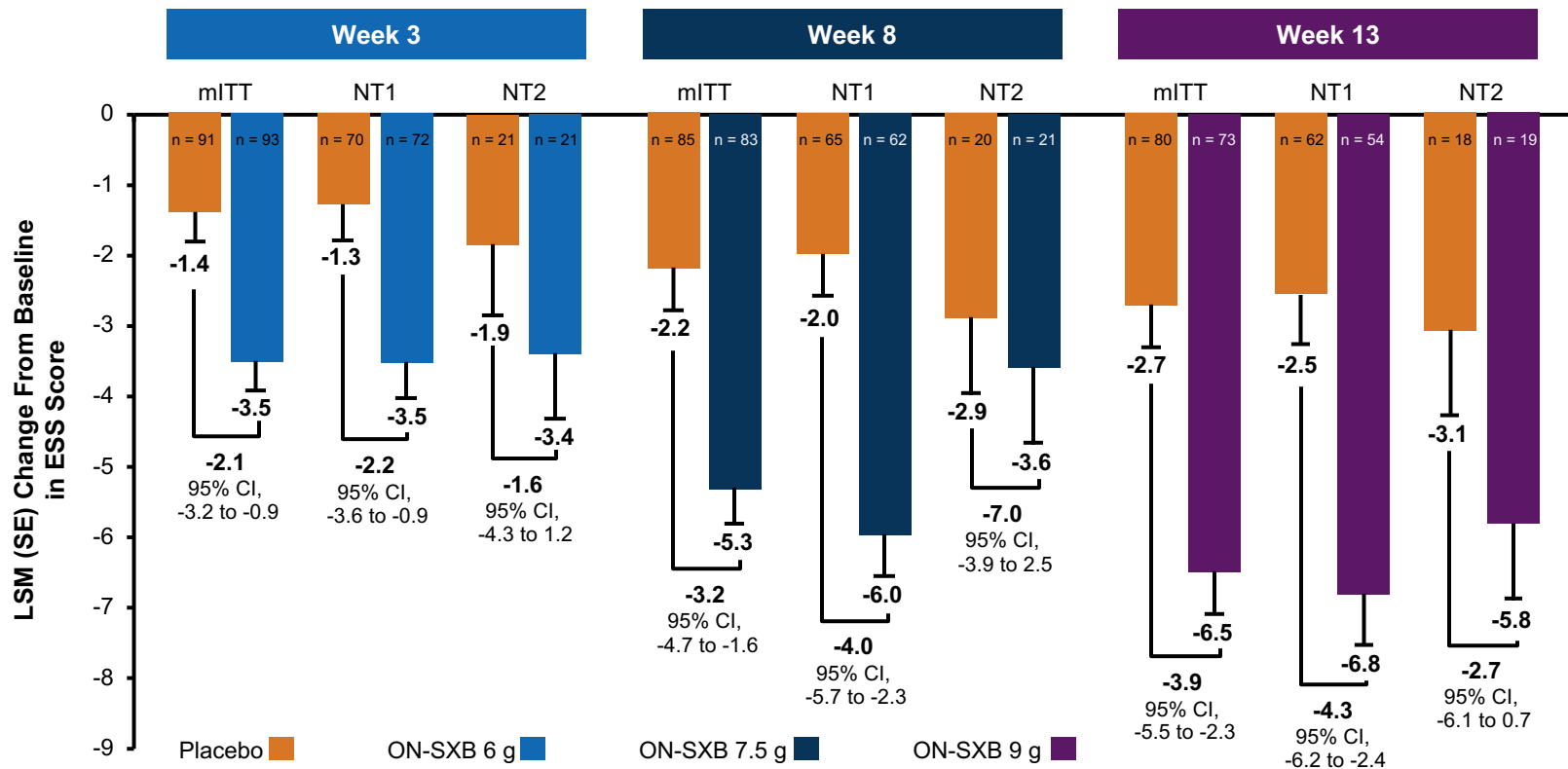
# REST-ON Results<sup>1</sup>



# REST-ON Post-Hoc Analysis: Change From Baseline in Sleep Quality (VAS)<sup>1</sup>



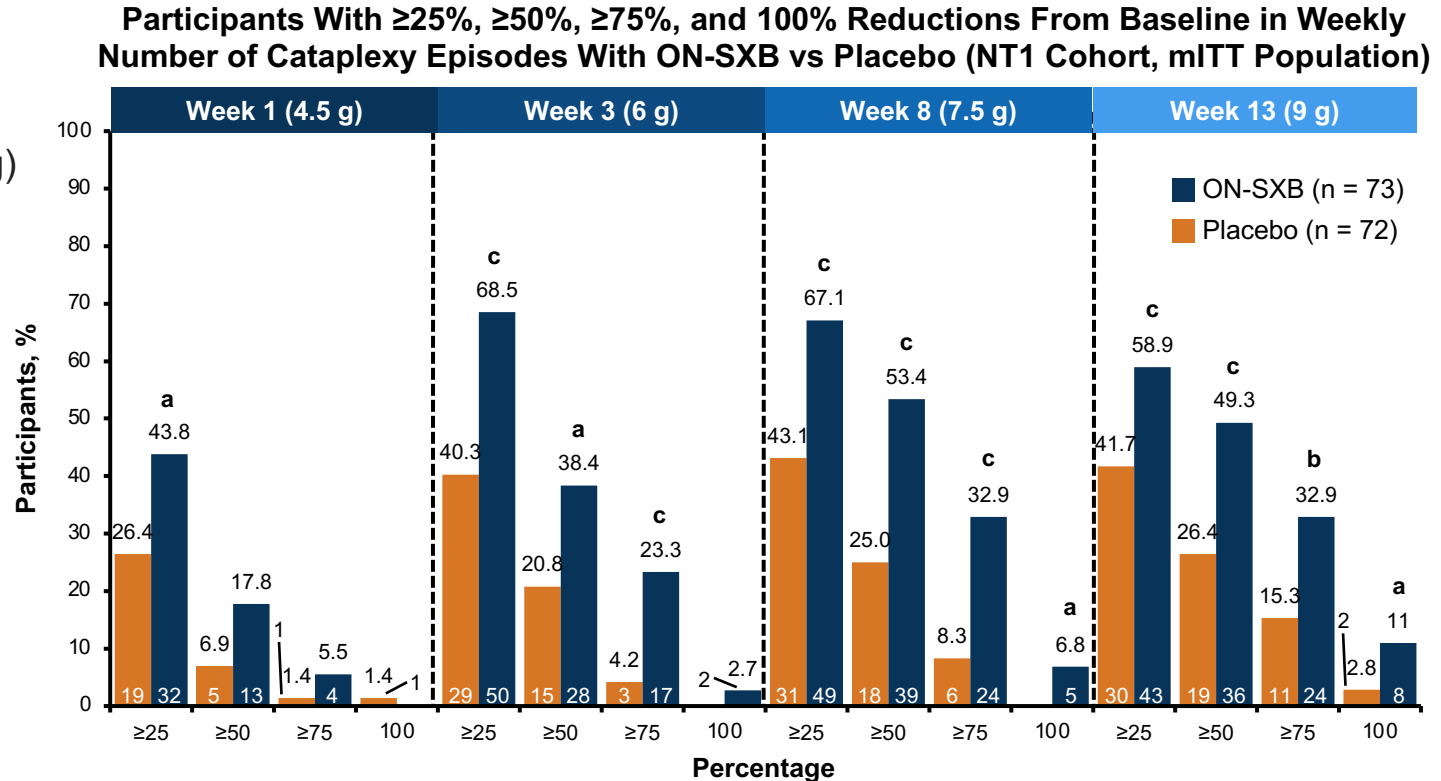
# REST-ON Post-Hoc Analysis: Change From Baseline in ESS<sup>1</sup>



# REST-ON Post-Hoc Responder Analysis: Change in Number of Cataplexy Episodes<sup>1</sup>

Among patients at the highest doses of ON-SXB (7.5 g and 9 g)

- ~Half had a 50% reduction
- 1/3 had a 75% reduction
- 1/10 had a 100% reduction in cataplexy episodes vs placebo



<sup>a</sup>  $P < 0.05$ . <sup>b</sup>  $P < 0.01$ . <sup>c</sup>  $P \leq 0.001$  (Fisher exact test).

1. Thorpy MJ et al. *Sleep Med X*. 2024;7:100109.

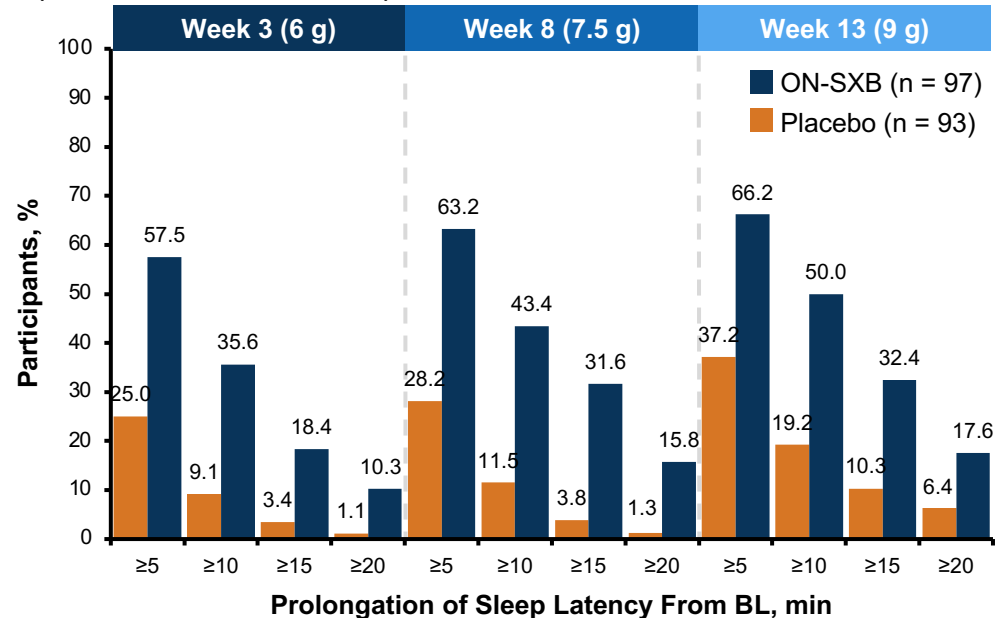
# REST-ON Post-Hoc Responder Analysis: Improvements in Sleep Latency and EDS

ON-SXB was associated with

- Improved mean sleep latency vs placebo on the MWT, with results significant ( $P < .05$ ) at weeks 3 (6-g dose) and 8 (7.5-g dose)
- Improvements in EDS on patient-reported ESS ( $P < .001$  at all doses)

**Responder Analysis: Maintenance of Wakefulness Test (Modified ITT Population)<sup>a</sup>**

Mean Sleep Latency	Week 3		Week 8		Week 13	
	Placebo (n = 88)	ON-SXB 6g (n = 87)	Placebo (n = 78)	ON-SXB 7.5g (n = 76)	Placebo (n = 78)	ON-SXB 9g (n = 68)
30 min, n (%)	0	5 (5.7)	1 (1.3)	8 (10.5)	4 (5.1)	9 (13.2)
P	<.05		<.05		.143	



<sup>a</sup> n = number of participants in the trial at the end of the treatment period.  
1. Thorpy MJ et al. *Sleep Med X*. 2024;7:100109.

# Considerations in Prescribing for Narcolepsy<sup>1-4</sup>

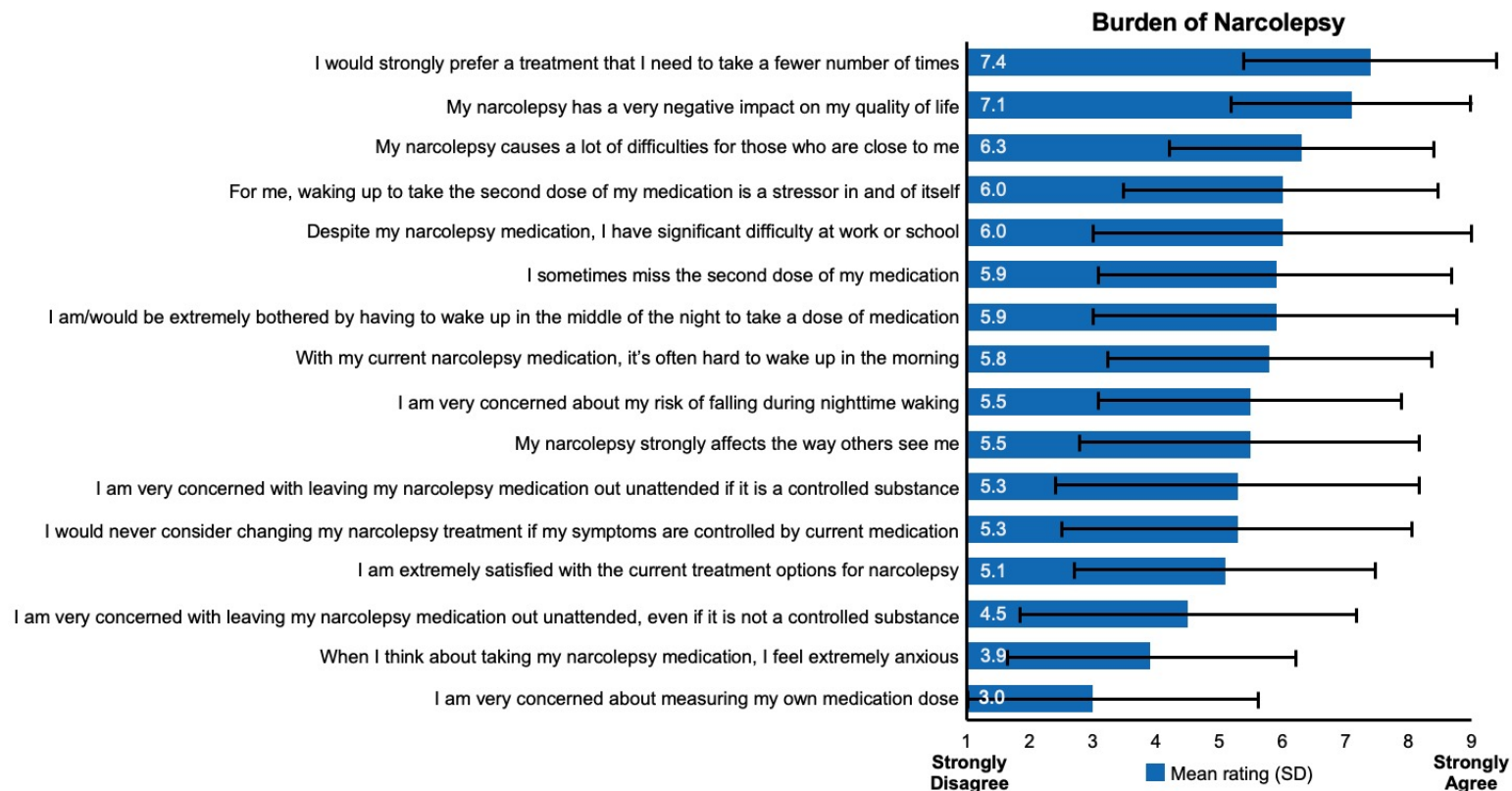
- Patients with narcolepsy often require multiple medications, using different mechanisms of action, to manage their symptoms (eg, SXB at night plus a stimulant during the day)
- Narcolepsy has many common comorbidities that also require medication, raising polypharmacy concerns
- Documented misalignments between clinician and patient priorities and perceptions of treatment success underscore the need for better communication surrounding narcolepsy care
- An open, collaborative environment supports shared decision-making and helps identify a treatment plan that meets individual needs

# Insight Into Patient Priorities: FDA's "Voice of the Patient" Report on Narcolepsy and Its Treatment<sup>1</sup>

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- There were >120 patients/patient representatives
- Nonpharmacologic management strategies (eg, scheduled naps) can help but are challenging to sustain
- Most patients use prescription medication to manage their narcolepsy
  - For many, medicine drastically improves symptoms
  - Symptoms sometimes worsen over time despite treatment
  - Many discontinue their medicine due to eventual physiologic tolerance, loss of effectiveness, or intolerable AEs

# Patient-Identified Burdens of SXB Treatment<sup>1</sup>





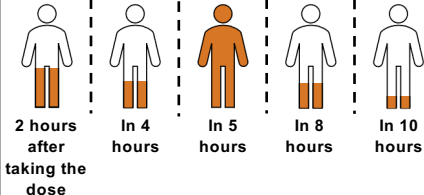
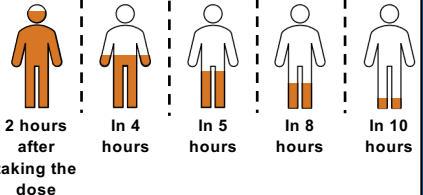
















# Patient Preferences for Attributes of SXB Tx: Results From a Web-Based Discrete Choice Experiment<sup>1</sup>

75 adults who were current (n = 50) or past (n = 25) users of SXB were presented with choice sets about hypothetical products and asked:

- Which do you prefer overall?
- Which are you most likely to take exactly as directed (eg, not skip a dose, delay a dose)?
- Which do you expect would involve less anxiety/stress when you think about taking the treatment?

Attribute Description	Attribute	Level 1	Level 2
Dosing frequency	How many doses are needed?	<b>Two</b> (once at bedtime and once 2.5-4 hours later in the night) You may need to set an alarm to wake up	<b>One</b> (at bedtime)
Medication form	What is the form of the medicine?	<b>Liquid solution</b> to be titrated (ie, mixed slowly) in water with a syringe 	<b>Sachet of granules</b> (ie, coarse powder) that is shaken in water 
Volume of water to be consumed	How much water do I need to drink each night with the medicine?	At least <b>half a cup</b> each night 	At least <b>one-third of a cup</b> each night 
How long the medication lasts in the body	How much medicine remains in my body when I wake up in the morning?	This is an immediate-release medicine, and <b>low levels</b> of medicine remain in your body in the morning <sup>a</sup> 	This is an extended-release medicine, and <b>very low levels</b> of medicine remain in your body in the morning <sup>a</sup> 
Adverse events	What are the common side effects with the medicine?	Nausea  <b>20%</b> Dizziness  <b>15%</b> Vomiting  <b>11%</b> Sleepiness  <b>8%</b> Bedwetting  <b>7%</b> Tremor  <b>5%</b>	Nausea  <b>1%</b> Dizziness  <b>5%</b> Vomiting  <b>5%</b> Sleepiness  <b>4%</b> Bedwetting  <b>9%</b> Tremor  <b>1%</b>

No restrictions

<sup>a</sup> Similar total amount of medicine in the body with both products.

1. Dubow J et al. *Patient Prefer Adherence*. 2022;16:937-947.

# Caregiver Preferences Echo Patient Preferences<sup>1</sup>

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- 75 adult caregivers of pediatric patients with narcolepsy completed a discrete web-based choice survey featuring profiles of twice-nightly and once-nightly SXB
  - 88% of patients were 10-15 years
  - 96% of patients used twice-nightly SXB
- Most important attributes driving product choice were dosing frequency and treatment efficacy at the highest dose
  - Similar results were found for adherence and reducing patient anxiety/stress when thinking about the medication

# RESTORE Results:

## Patient Preferences and SXB Dosing Schedules<sup>1</sup>

- RESTORE: Open-label, phase 3 study evaluating safety and tolerability of once-nightly SXB and patient preferences for once-nightly vs immediate release SXB—interim results presented at SLEEP 2023
- Participation criteria: NT1 or NT2 who completed phase 3 REST-ON study of ON-SXB **or** using twice-nightly SXB at a stable dose **or** SXB treatment-naïve
- ON-SXB was preferred by 94% of participants
- Participants reported problems with the immediate-release SXB
  - 65% of switch participants unintentionally missed the second dose in the previous 3 months
    - ~80% of those who missed the second dose reported feeling worse the next day
  - 39% took the second dose >4 hours after the first; of this group, 51% felt “somewhat,” “quite a bit,” or “extremely” groggy/unsteady the next morning
  - 91% rose from bed after taking the second dose; of this group, 9 reported having fallen (with 5 reporting injuries)

# RESTORE End-of-Study Results: Patient Feedback<sup>1</sup>

- RESTORE participants were asked to complete an end-of-study questionnaire on their experiences with ON-SXB
- 89 responses were received as of November 2023

After Initiating ON-SXB	Proportion of Patients Responding
Narcolepsy is better/much better	71% (63/89)
Very satisfied vs previously used treatments	75% (67/89)
Easier to get through the day without falling asleep	69% (61/89)
Better able to sleep through the night	91% (81/89)
Better able to get more done at work and school	64% (57/89)
Better able to socialize with friends and family	64% (57/89)
Better able to follow dosing instructions (among those who switched from twice-nightly OXB to ON-SXB)	91% (62/68)

# Clinician Perspectives on SXB Dosing<sup>1</sup>

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- Results of a web-based survey among 25 physicians treating  $\geq 2$  patients with SXB for  $\geq 6$  months showed that 68% of respondents occasionally modify dose amount or timing to accommodate changes in patients' routines
- Scenarios include alcohol consumption, travel, eating near bedtime, attending social or work-related events, caring for family members, or concomitant medication use
- 88% of respondents considered the ability to individualize dosing an important component of narcolepsy care

# Patient Case: Michael

**Name:** Michael

**Age:** 61

**Diagnosis:** NT1

- Diagnosed with NT1 after two incidents in which he lost control of his car while driving
- Treated with modafinil; he also uses CPAP for OSA
- Had been prescribed SXB, but he doesn't take it because he figured the CPAP was enough to improve his sleep at night

## Take-Home Points

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- ✓ Narcolepsy is rare but underrecognized, so consider it in your index of suspicion for patients with sleep issues
- ✓ Poor sleep quantity and quality, including the DNS that occurs in narcolepsy, has negative effects on multiple domains
- ✓ Although narcolepsy is not curable, a number of treatments improve symptoms and quality of life
  - However, narcolepsy medications have drawbacks that can discourage sustained use, highlighting the importance of shared decision-making to identify a treatment plan that aligns with a patient's needs and priorities

# Audience Q&A



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your Post-Test and Evaluation for CE credit.**

**[PeerView.com/Narcolepsy-Eval-UVZ](https://www.peerreview.com/Narcolepsy-Eval-UVZ)**

*Thank you, and have a good day.*

PeerView  
Live



**Scan to access the  
program evaluation**

# Abbreviations

AASM: American Academy of Sleep Medicine  
CDER: Center for Drug Evaluation and Research  
CGI-I: Clinical Global Impression-Improvement  
CPAP: continuous positive airway pressure  
CRP: C-reactive protein  
DNS: disrupted nighttime sleep, disrupted nocturnal sleep  
EDS: excessive daytime sleepiness  
ESS: Epworth Sleepiness Scale  
GABA: gamma-aminobutyric acid  
GHB: gamma-hydroxybutyrate  
HTN: hypertension  
ICSD-3: International Classification of Sleep Disorders 3  
IL-6: interleukin 6  
LC: locus coeruleus  
LSM: lease squares mean  
LSMD: lease squares mean difference  
LXB: low-sodium oxybate  
MEL: melatonin  
mITT: modified intent-to-treat  
MSLT: Multiple Sleep Latency Test

MWT: Maintenance of Wakefulness Test  
NE: norepinephrine  
NSS: Narcolepsy Severity Scale  
NT1: narcolepsy type 1  
NT2: narcolepsy type 2  
ON-SXB: once nightly sodium oxybate  
OSA: obstructive sleep apnea  
PLMS: periodic limb movements during sleep  
PSG: polysomnographic; polysomnography; or polysomnogram  
REM: rapid eye movement  
RLS: restless legs syndrome  
SCN: suprachiasmatic nucleus  
SLEEP 2023: 37th Annual Meeting of the Associated Professional Sleep Societies  
SOREMP: short onset REM period  
SXB: sodium oxybate  
T2DM: type 2 diabetes mellitus  
VAS: visual analog scale