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Improvements in Nighttime Sleep Quality and Daytime Sleepiness Are Associated With Better Quality of Life in Narcolepsy: Findings From LYRICAL

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Objective

- To explore associations between daytime and nighttime symptoms and quality of life (QoL) among LYRICAL participants with narcolepsy taking low-sodium oxybate (LXB)

Conclusions

- Improvements in nighttime sleep quality, and separately, daytime sleepiness, were linked to improvements across multiple 24-hour symptom burden, function, and QoL outcomes over the study period in participants with narcolepsy taking LXB
- Limitations include the lack of a comparator group, potential selection and recall bias (participants had been taking LXB for ≥12 weeks at enrollment), and small sample sizes for some analyses
- Survey and qualitative insights from the LYRICAL study highlight how addressing nighttime sleep and daytime sleepiness with LXB may translate into measurable real-world gains across a spectrum of function and QoL outcomes in narcolepsy

References: 1. Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. **2.** Cohen J. *Statistical power analysis for the behavioral sciences.* Hillsdale, NJ: Lawrence Erlbaum; 1988. **3.** Dauvilliers Y, et al. *Neurology.* 2017;88(14):1358-1365. **4.** Chasens ER, et al. *Sleep.* 2009;32(7):915-919. **5.** PROMIS Cognitive Function Scoring Manual. 2022. Available at: https://www.healthmeasures.net/images/PROMIS/manuals/Scoring_Manual_Only/PROMIS_Cognitive_Function_Scoring_Manual_03June2022.pdf. **6.** Reilly MC, et al. *PharmacoEconomics.* 1993;4(5):353-365. **7.** Bharmal M, et al. *Health Qual Life Outcomes.* 2009;7:36. **8.** Johns MW. *Sleep.* 1991;14(6):540-545.

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Introduction

- Low-sodium oxybate (LXB; Xywav®) is approved by the US Food and Drug Administration for the treatment of excessive daytime sleepiness or cataplexy in patients 7 years of age or older with narcolepsy and for the treatment of idiopathic hypersomnia in adults[1]
- The LYRICAL (**L**ongitudinal mixed methods stud**Y** of **R**eal-world patterns of use, effectiveness, and treatment satisfaction in adults with **I**diopathic hypersomnia and nar**C**olepsy t**A**king **L**ow-sodium oxybate) study was conducted to better understand the real-world experience of adults with narcolepsy or idiopathic hypersomnia taking LXB treatment
  - This poster reports associations between nighttime and daytime symptoms and quality-of-life (QoL) outcomes for participants with narcolepsy; results for the idiopathic hypersomnia cohort are presented in **Poster 535**
  - **Posters 359** and **360** describe participant-reported effectiveness and treatment satisfaction in narcolepsy and idiopathic hypersomnia, respectively; individualized dosing with LXB for participants with narcolepsy and idiopathic hypersomnia are explored in **Posters 362** and **361**, respectively

Methods

- This longitudinal, mixed-methods study gathered quantitative (survey) and qualitative (interview) data from participants currently taking LXB at enrollment and over the 24-week study period

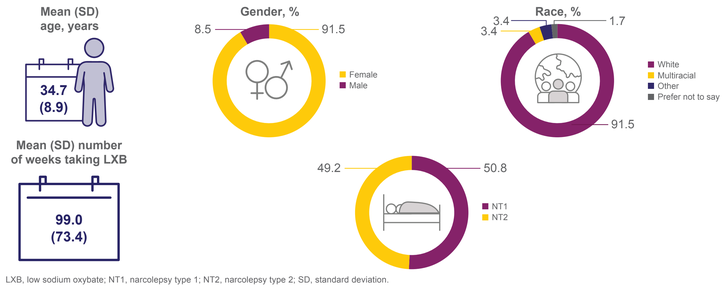
Figure 1. LYRICAL Study Design

[a]Participants were eligible if they were ≥18 years of age at the time the screening form was completed; a US resident; diagnosed with narcolepsy or idiopathic hypersomnia; prescribed and currently taking LXB for narcolepsy or idiopathic hypersomnia; and had been taking LXB for ≥12 weeks prior to completing the screening form. All participants provided written or electronic informed consent.
PRO, patient-reported outcome.

- Online surveys were conducted via an IQVIA-hosted platform between March 2024 and August 2025 and comprised standardized patient-reported outcome (PRO) instruments and *de novo* items; surveys were administered at enrollment, week 12, and week 24
- Virtual 45-minute interviews were conducted using semi-structured discussion guides with a subset of participants at enrollment (n=15) and week 24 (n=7)
  - Interviews were audio-recorded, transcribed, and coded and analyzed using MAXQDA (VERBI Software, 2021) and Microsoft Excel
- Correlation coefficients (r) were used to quantify associations at enrollment between 4 Patient Global Impression of Change (PGI-C) items since starting LXB and PROs assessing excessive daytime sleepiness (EDS) and overall narcolepsy symptoms (Epworth Sleepiness Scale [ESS]; Narcolepsy Severity Scale [NSS]; Narcolepsy Severity Scale for Narcolepsy Type 2 [NSS2]), activity impairment (Work Productivity and Activity Impairment [WPAI]), cognitive function (PROMIS-Cognitive Function [CF]-Short Form [SF]-8a), sleep-related QoL (10-item Functional Outcomes of Sleep Questionnaire [FOSQ-10]), depression (9-item Patient Health Questionnaire [PHQ-9]), and treatment satisfaction (9-itemTreatment Satisfaction Questionnaire for Medication [TSQM-9])
- Correlations were calculated between categorical improvements in Patient Global Impression of Severity (PGI-S) items from enrollment to weeks 12 and 24 and changes in PRO scores over the same time period
- Measurable improvements in PRO scores at weeks 12 and 24 (defined as >0.5 SD improvement from enrollment score) were assessed alongside PGI-S category improvements at weeks 12 and 24
- Polyserial (continuous data) and polychoric (ordinal items) correlations were calculated; thresholds for correlation strength were based on Cohen's cutoffs[2]
  - Minimal: |r| < 0.2
  - Weak: 0.2 ≤ |r| < 0.3
  - Moderate: 0.3 ≤ |r| < 0.4
  - Strong: 0.4 ≤ |r| ≤ 0.6
  - Very strong: |r| > 0.6

Results

Figure 2. Characteristics of Participants With Narcolepsy



LXB, low sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SD, standard deviation.

- Among 59 participants with narcolepsy who completed the enrollment survey, the mean (SD) age was 34.7 (8.9) years
- The majority of participants were female (91.5%) and White (91.5%)
- Mean (SD) duration of LXB treatment at enrollment was 99.0 (73.4) weeks or approximately 23 months
- Additional participant characteristics are reported in the Supplement, accessed via the QR code

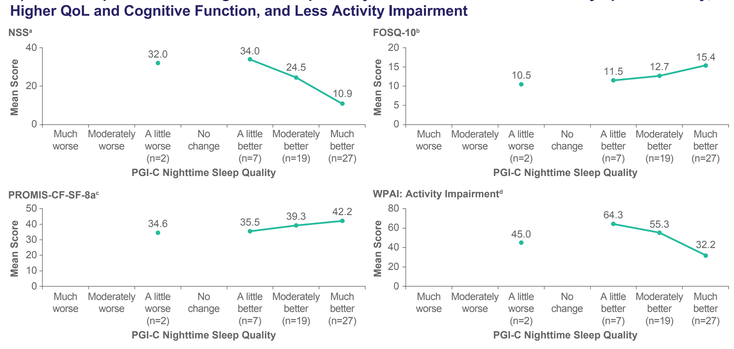
Figure 3. Associations Between PGI-C Improvements and Better PRO Scores at Enrollment

A) Improvements in Nighttime Sleep Quality and Daytime Sleepiness Were Consistently Associated With Better Scores on Multiple PROs

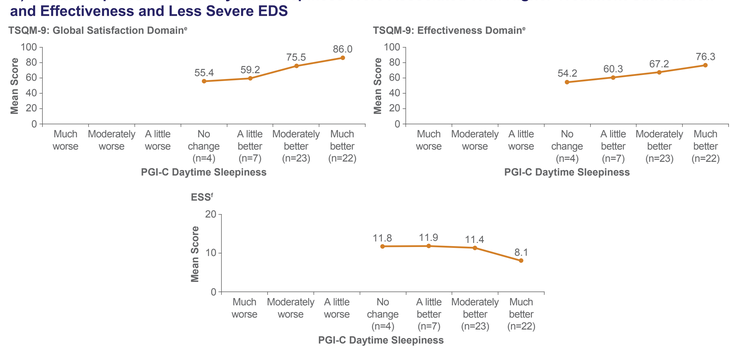
Very strong, Strong, Moderate, Weak, Minimal

		PGI-C at Enrollment: |r|			
		Narcolepsy Symptoms	Daytime Sleepiness	Nighttime Sleep Quality	Feeling Refreshed After Nighttime Sleep
Symptoms	ESS Total Score	0.342	0.456	0.374	0.197
	NSS Total Score	0.477	0.686	0.842	0.368
	NSS2 Total Score	0.276	0.165	0.365	0.108
QoL	Overall QoL PGI-C	0.817	0.919	0.785	0.660
	FOSQ-10 Total Score	0.419	0.393	0.567	0.360
	PHQ-9 Total Score	0.180	0.293	0.311	0.204
	FOSQ-10 Social Outcomes subscale	0.262	0.209	0.339	0.074
	FOSQ-10 Activity Level subscale	0.449	0.432	0.540	0.315
	FOSQ-10 Vigilance subscale	0.292	0.246	0.289	0.317
Cognition	PROMIS-CF-8a T-scores	0.132	0.246	0.337	0.214
	FOSQ-10 General Productivity subscale	0.338	0.313	0.461	0.258
	FOSQ-10 item: Concentrating	0.417	0.387	0.574	0.107
	FOSQ-10 item: Remembering Things	0.259	0.216	0.315	0.374
Work Impacts (WPAI)	Absenteeism	0.168	0.242	0.305	0.163
	Presenteeism	0.031	0.123	0.249	0.173
	Overall Work Productivity Loss	0.040	0.164	0.329	0.279
	Activity Impairment	0.161	0.210	0.383	0.263
Treatment Satisfaction (TSQM-9)	Global Satisfaction	0.499	0.531	0.467	0.462
	Effectiveness	0.502	0.477	0.378	0.468
	Convenience	0.105	0.142	0.258	0.404

B) Greater Improvements in Nighttime Sleep Quality Were Associated With Lower Symptom Severity, Higher QoL and Cognitive Function, and Less Activity Impairment



C) Greater Improvements in Daytime Sleepiness Were Associated With Higher Treatment Satisfaction and Effectiveness and Less Severe EDS



[a]NSS scores range from 0 to 57, with higher values indicating greater levels of narcolepsy symptom frequency or severity.[3] [b]FOSQ-10 total scores range from 5 to 20, with higher scores indicating less impact of daytime sleepiness on activities of daily living.[4] [c]PROMIS-CF-SF-8a T-scores range from 22.41 to 63.48, with higher scores indicating better cognitive function.[5] [d]WPAI outcomes are expressed as impairment percentages (range 0–100), with higher numbers indicating greater impairment and less productivity.[6] [e]TSQM-9 scores range from 0 to 100, with higher scores indicating greater treatment satisfaction.[7] [f]ESS scores range from 0 to 24, with higher values indicating higher levels of daytime sleepiness.[8]
EDS, excessive daytime sleepiness; ESS, Epworth Sleepiness Scale; FOSQ-10, 10-item Functional Outcomes of Sleep Questionnaire; NSS, Narcolepsy Severity Scale; NSS2, Narcolepsy Severity Scale for Narcolepsy Type 2; PGI-C, Patient Global Impression of Change; PHQ-9, 9-item Patient Health Questionnaire; PRO, patient-reported outcome; PROMIS-CF-8a, Patient Reported Outcome Measurement Information System–Cognitive Function–8a; QoL, quality of life; TSQM-9, 9-item Treatment Satisfaction Questionnaire for Medication; WPAI, Work Productivity and Activity Impairment.

- PGI-C improvement in nighttime sleep quality was very strongly correlated with less severe narcolepsy symptoms, strongly correlated with fewer sleep-related QoL impacts, and moderately correlated with less severe narcolepsy type 2 symptoms, less activity impairment, and better cognitive function
- PGI-C improvement in daytime sleepiness was very strongly correlated with improved QoL, and strongly correlated with less severe EDS and higher treatment satisfaction

Figure 4. Category Improvements in PGI-S Narcolepsy Symptoms and Daytime Sleepiness at Weeks 12 and 24 Were Associated With Score Improvements Across Multiple PROs

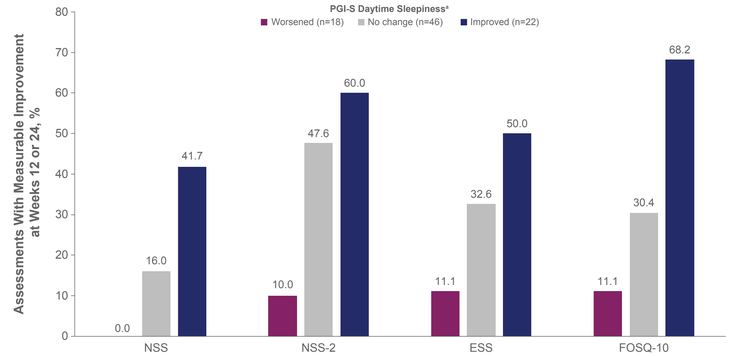
Very strong, Strong, Moderate, Weak, Minimal

		PGI-S at Weeks 12 and 24: |r|			
		Narcolepsy Symptoms	Daytime Sleepiness	Nighttime Sleep Quality	Feeling Refreshed After Nighttime Sleep
Symptoms	ESS Total Score	0.355	0.396	0.145	0.264
	NSS Total Score	0.745	0.817	0.346	0.145
	NSS2 Total Score	0.513	0.445	0.304	0.286
QoL	Overall QoL PGI-S	0.224	0.507	0.233	0.357
	FOSQ-10 Total Score	0.512	0.580	0.176	0.203
	PHQ-9 Total Score	0.425	0.315	0.193	0.408
	FOSQ-10 Social Outcomes subscale	0.434	0.449	0.062	0.095
	FOSQ-10 Activity Level subscale	0.572	0.366	0.205	0.379
	FOSQ-10 Vigilance subscale	0.438	0.411	0.284	0.246
Cognition	PROMIS-CF-8a T-scores	0.214	0.298	0.000	0.019
	FOSQ-10 General Productivity subscale	0.200	0.328	0.062	0.071
	FOSQ-10 item: Concentrating	0.215	0.331	0.079	0.087
	FOSQ-10 item: Remembering Things	0.165	0.287	0.047	0.035
Work Impacts (WPAI)	Absenteeism	0.442	0.437	0.286	0.182
	Presenteeism	0.447	0.341	0.264	0.230
	Overall Work Productivity Loss	0.425	0.475	0.333	0.078
	Activity Impairment	0.567	0.495	0.304	0.137
Treatment Satisfaction (TSQM-9)	Global Satisfaction	0.079	0.196	0.211	0.496
	Effectiveness	0.070	0.017	0.004	0.343
	Convenience	0.309	0.158	0.213	0.283

ESS, Epworth Sleepiness Scale; FOSQ-10, 10-item Functional Outcomes of Sleep Questionnaire; NSS, Narcolepsy Severity Scale; NSS2, Narcolepsy Severity Scale for Narcolepsy Type 2; PGI-S, Patient Global Impression of Severity; PHQ-9, 9-item Patient Health Questionnaire; PRO, patient-reported outcome; PROMIS-CF-SF-8a, Patient Reported Outcome Measurement Information System–Cognitive Function–Short Form–8a; QoL, quality of life; TSQM-9, 9-item Treatment Satisfaction Questionnaire for Medication; WPAI, Work Productivity and Activity Impairment.

- PGI-S improvements in narcolepsy symptoms from enrollment to weeks 12 and 24 were very strongly correlated with improvements in narcolepsy symptom severity, and strongly correlated with improvements in depression, narcolepsy type 2 symptom severity, sleep-related QoL, and activity impairment ; weaker correlations for nighttime sleep quality and feeling refreshed after nighttime sleep may reflect limited variability over time among participants already taking LXB for a prolonged period

Figure 5. Category Improvements in PGI-S Daytime Sleepiness at Weeks 12 and 24 Were Associated With Measurable Improvements in Symptoms and QoL



[a]Sample sizes are reported for the number of follow-up PGI-S assessments, not the number of participants.
ESS, Epworth Sleepiness Scale; FOSQ-10, 10-item Functional Outcomes of Sleep Questionnaire; NSS, Narcolepsy Severity Scale; NSS2, Narcolepsy Severity Scale for Narcolepsy Type 2; PGI-S, Patient Global Impression of Severity.

- Assessments reporting PGI-S category improvements in daytime sleepiness from enrollment to weeks 12 and 24 were more likely to show measurable improvements in outcomes including EDS, narcolepsy symptom severity, and sleep-related QoL

Figure 6. Interview Participants Described More Restorative Sleep, Easier Morning Function, and Increased Motivation for Daily Activities

LXB, low-sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

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Supplemental Results

Supplemental Table S1. Additional Participant Characteristics

Characteristic	Participants With Narcolepsy (N=59)
Age (years)	
Mean (SD)	34.7 (8.9)
Median (range)	34.0 (21.0–55.0)
Narcolepsy subtype, n (%)	
NT1	30 (50.8)
NT2	29 (49.2)
Gender, n (%)	
Female	54 (91.5)
Male	5 (8.5)
Race, n (%)	
White	54 (91.5)
Multiracial	2 (3.4)
Other	2 (3.4)
Prefer not to answer	1 (1.7)
Employment, n (%)[a]	
Working full-time	43 (72.9)
Student	7 (11.9)
Seeking work opportunities	5 (8.5)
Working part-time	6 (10.2)
Other	6 (10.2)
Homemaker	3 (5.1)
Retired	1 (1.7)
Unable to work	1 (1.7)
Number of LXB doses per night, n (%)	
1	1 (1.7)
2	57 (96.6)
3	1 (1.7)
Number of weeks taking LXB	
Mean (SD)	99.0 (73.4)
ESS score	
Mean (SD)	10.5 (4.3)
Other current comorbid diagnoses, n (%)[a]	
Attention deficit disorder/attention deficit hyperactivity disorder	9 (15.3)
Anxiety	21 (35.6)
Depression	13 (22.0)
Hyperlipidemia/high cholesterol	2 (3.4)
Hypertension	5 (8.5)
Obesity	7 (11.9)
Obstructive sleep apnea	10 (16.9)
Periodic limb movement disorder	1 (1.7)
Restless leg syndrome	3 (5.1)
Current concomitant treatments, n (%)[a]	
Amphetamine	19 (32.2)
Armodafinil	4 (6.8)
Fluoxetine	6 (10.2)
Methylphenidate	3 (5.1)
Modafinil	6 (10.2)
Pitolisant	6 (10.2)
Sertraline	7 (11.9)
Solriamfetol	8 (13.6)
Venlafaxine	5 (8.5)
Other current treatment	5 (8.5)
None of the above[b]	14 (23.7)

[a]Response options are not mutually exclusive. [b]"None of the above" indicates that participants were not taking any of the medications listed in this table; however, they may have been taking other concomitant medications.
ESS, Epworth Sleepiness Scale; LXB, low-sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SD, standard deviation.