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Real-World Experience and Satisfaction With Low-Sodium Oxybate in Narcolepsy: Interim Results From LYRICAL

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Introduction

- Low-sodium oxybate (LXB; Xywav®) is approved by the United States (US) Food and Drug Administration to treat excessive daytime sleepiness (EDS) or cataplexy in patients ≥7 years of age with narcolepsy and idiopathic hypersomnia in adults[1]
- Since the approval of LXB, limited information triangulating longitudinal survey and qualitative insights has been published regarding its patterns of use, treatment satisfaction, and overall effectiveness within real-world settings
- 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) is an ongoing study to better understand the real-world experience of adults with narcolepsy or idiopathic hypersomnia receiving LXB treatment

Objective

- To characterize the real-world treatment experience with LXB, including patterns of use, effectiveness, and treatment satisfaction based on patient-reported surveys and qualitative interviews among US adults with narcolepsy

Methods

- An ongoing online survey consisting of standardized patient-reported outcome instruments and de novo questions is being administered at enrollment and weeks 12 and 24 post-enrollment; semi-structured 1:1 remote qualitative interviews are being conducted among a subset of participants
- Eligible participants are aged ≥18 years; reside in the US; are able to communicate, read, and write fluently in English; have been prescribed and are currently taking LXB to treat narcolepsy or idiopathic hypersomnia; have been taking LXB for ≥12 weeks; and have provided written/electronic informed consent to participate in the study
- This interim analysis focuses on enrollment data from participants with narcolepsy; data were collected from 01/29/2024 to 08/28/2024
  - Results from participants with idiopathic hypersomnia are reported separately in **Poster 418**
- Descriptive analyses were performed on the Epworth Sleepiness Scale (ESS [scale range 0–24]), Patient Global Impression of Change (PGI-C) symptom-specific and quality-of-life (QoL) items, and Treatment Satisfaction Questionnaire for Medication–9 Items (TSQM-9 [scale range 0–100]) at enrollment
- Anecdotal qualitative interview data provided supporting evidence of the patient experience
- No statistical testing was performed

Results

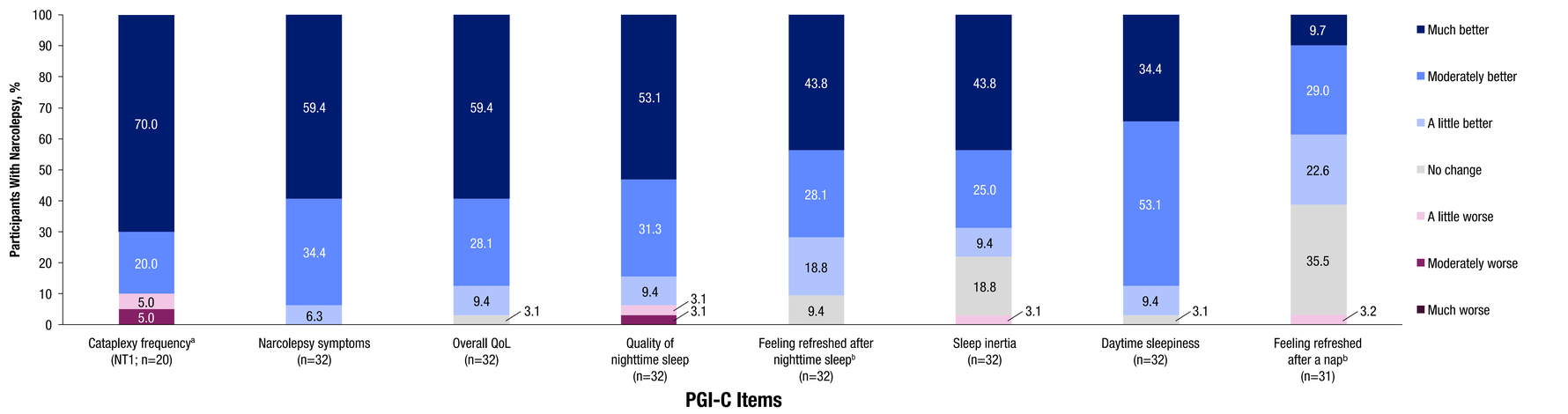
Table 1. Participant characteristics

Characteristic	Participants With Narcolepsy (N=33)
Age (years)	
Mean (SD)	32.7 (7.7)
Median (mix, max)	32.0 (22.0, 54.0)
Narcolepsy subtype, n (%)	
Narcolepsy type 1	21 (63.6)
Narcolepsy type 2	12 (36.4)
Gender, n (%)	
Female	31 (93.9)
Male	2 (6.1)
Race, n (%)	
White	31 (93.9)
Multi-racial	1 (3.0)
Prefer not to answer	1 (3.0)
Ethnicity, n (%)	
Hispanic or Latino/a	2 (6.1)
Not Hispanic or Latino/a	31 (93.9)
Education, n (%)	
High school graduate	1 (3.0)
Some college	3 (9.1)
Associate degree	3 (9.1)
Bachelor's degree	14 (42.4)
Master's degree	10 (30.3)
Doctorate	1 (3.0)
Other	1 (3.0)
Employment, n (%)[a]	
Working full-time	24 (72.7)
Student	6 (18.2)
Seeking work opportunities	4 (12.1)
Working part-time	4 (12.1)
Other	3 (9.1)
Homemaker	2 (6.1)
Retired	1 (3.0)
Unable to work	1 (3.0)
Number of LXB doses per night, n (%)	
2	32 (97.0)
3	1 (3.0)
Number of weeks taking LXB	
Mean (SD)	98.2 (64.8)
Total nightly dosage, g, n (%)	
≤5	0
5 to <7	11 (33.3)
7 to <9	10 (30.3)
9	12 (36.4)
ESS score	
Mean (SD)	11.2 (4.2)
Other current comorbid diagnoses, n (%)[a]	
Attention deficit disorder/attention deficit hyperactivity disorder	6 (18.2)
Anxiety	10 (30.3)
Depression	4 (12.1)
Hyperlipidemia/high cholesterol	1 (3.0)
Hypertension (high blood pressure)	3 (9.1)
Obesity	5 (15.2)
Obstructive sleep apnea	7 (21.2)
Periodic limb movement disorder	1 (3.0)
Restless leg syndrome	1 (3.0)
Current concomitant treatments, n (%)[a]	
Amphetamine	12 (36.4)
Armodafinil	3 (9.1)
Fluoxetine	4 (12.1)
Methylphenidate	2 (6.1)
Modafinil	5 (15.2)
Pitolisant	4 (12.1)
Sertraline	5 (15.2)
Solriamfetol	5 (15.2)
Venlafaxine	5 (15.2)
Other current treatment	3 (9.1)
None of the above[b]	3 (9.1)

[a]Response options are not mutually exclusive. [b]"None of the above" indicates 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; max, maximum; min, minimum; SD, standard deviation.

- Among the 33 participants who completed the enrollment survey, most were White (93.9%) and identified as female (93.9%); mean (standard deviation [SD]) age was 32.7 (7.7) years
  - 63.6% of participants had narcolepsy type 1
- The mean (SD) time taking LXB was 98.2 (64.8) weeks (or approximately 24 months)
  - The most common total nightly dosage was 9 g (36.4%)
  - 84.8% of participants were taking a concomitant alerting agent (wake-promoting agent or stimulant)

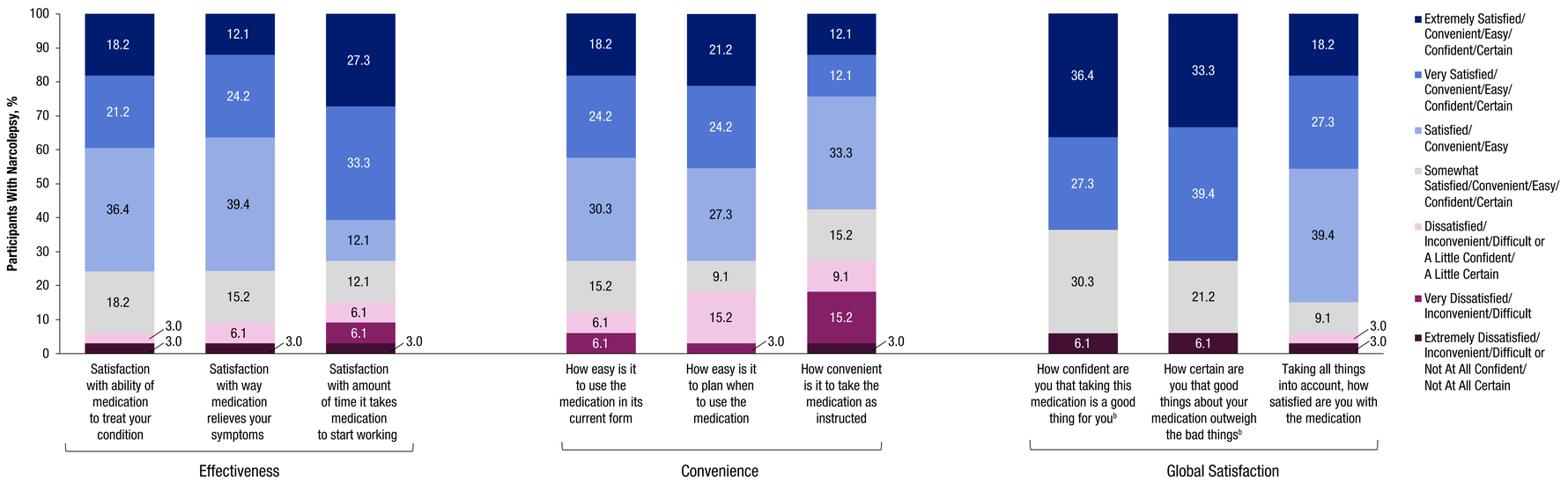
Figure 1. Narcolepsy Symptom and QoL PGI-C Items



[a]Response options were "Much less often," "Moderately less often," "A little less often," "No change," "A little more often," "Moderately more often," and "Much more often." [b]Response options were "Much more refreshed," "Moderately more refreshed," "A little more refreshed," "No change," "A little less refreshed," "Moderately less refreshed," and "Much less refreshed."
LXB, low-sodium oxybate; NT1, narcolepsy type 1; PGI-C, Patient Global Impression of Change; QoL, quality of life.

- Most participants reported PGI-C improvements ("much better," "moderately better," or "a little better") in overall QoL (96.9%), daytime sleepiness (96.9%), quality of nighttime sleep (93.8%), feeling refreshed after nighttime sleep (90.6%), cataplexy frequency (90.0%), and sleep inertia (78.1%), compared with before starting LXB
- More than 50% of participants endorsed the largest possible PGI-C improvement level (ie, "much better") for cataplexy frequency, narcolepsy symptoms, overall QoL, and quality of nighttime sleep

Figure 2. Treatment Satisfaction Questionnaire for Medication–9 Items[a]



[a]The TSQM-9 yields 3 domain scores: Effectiveness, Convenience, and Global Satisfaction. Most items are rated on a 7-point Likert-type scale ranging from "Extremely Dissatisfied/Inconvenient/Difficult" to "Extremely Satisfied/Convenient/Easy," which are transformed into domain scores ranging from 0 to 100. Higher scores indicate greater satisfaction. [b]Item rated on a 5-point scale, with response options: "Extremely," "Very," "Somewhat," "A little," and "Not at all."
LXB, low-sodium oxybate; TSQM-9, Treatment Satisfaction Questionnaire for Medication–9 Items.

- Mean (SD) score for the TSQM-9 Global Satisfaction domain was 72.7 (23.0), with 84.8% of participants reporting that, taking all things into account, they were "satisfied," "very satisfied," or "extremely satisfied" with LXB
- Mean (SD) score for the TSQM-9 Convenience domain was 65.5 (21.5), with 72.7% of participants reporting that LXB was "easy," "very easy," or "extremely easy" to use in its current form
- Mean (SD) score for the TSQM-9 Effectiveness domain was 70.2 (19.3), with 75.8% of participants reporting that they were "satisfied" to "very satisfied" with symptom relief provided by LXB

Figure 3. Interview Participants (n=6) Described Improvements in Symptoms, Day-to-Day Life, and Functioning

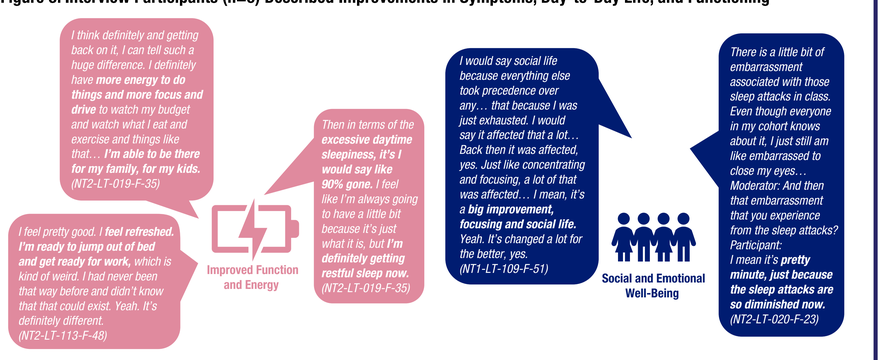
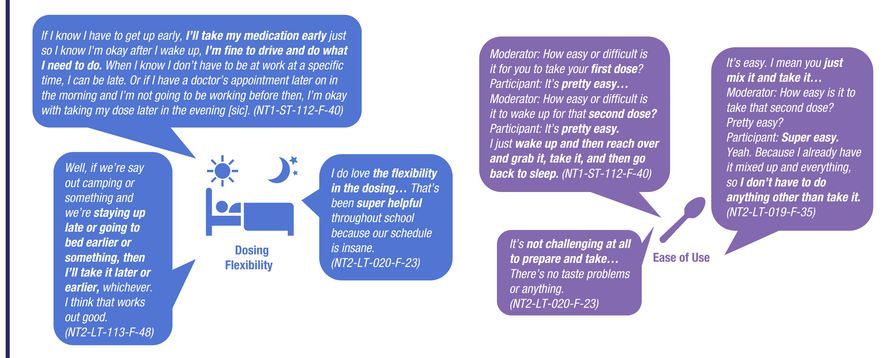


Figure 4. Interview Participants (n=6) Described Dosing Flexibility and Ease of Taking LXB



LXB, low-sodium oxybate.

Conclusions

- Interim results of patient-reported survey and interview data from the ongoing LYRICAL study suggest improvements in narcolepsy symptoms, including cataplexy frequency, quality of nighttime sleep, and QoL, compared with before starting LXB
- Many participants reported high treatment satisfaction with LXB, including with the ease of taking LXB
- Limitations include the lack of a comparator group, potential selection and recall bias, and small sample size
- Forthcoming longitudinal survey and interview data from LYRICAL will assess longer-term impacts of LXB on narcolepsy symptoms, QoL, and treatment satisfaction, including durability of effectiveness

Reference: 1. Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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