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Real-World Patient Insights on Low-Sodium Oxybate for Idiopathic Hypersomnia: 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 taking 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 idiopathic hypersomnia

Methods

- An ongoing online survey consisting of standardized patient-reported outcome (PRO) 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 idiopathic hypersomnia; data were collected from 01/29/2024 to 08/28/2024
  - Results from participants with narcolepsy are reported separately in **Poster 420**
- Descriptive analyses were performed on the Epworth Sleepiness Scale (ESS [scale range 0–24]), Idiopathic Hypersomnia Severity Scale (IHSS [scale range 0–50]), Patient Global Impression of Change (PGI-C) symptom-specific and quality-of-life 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

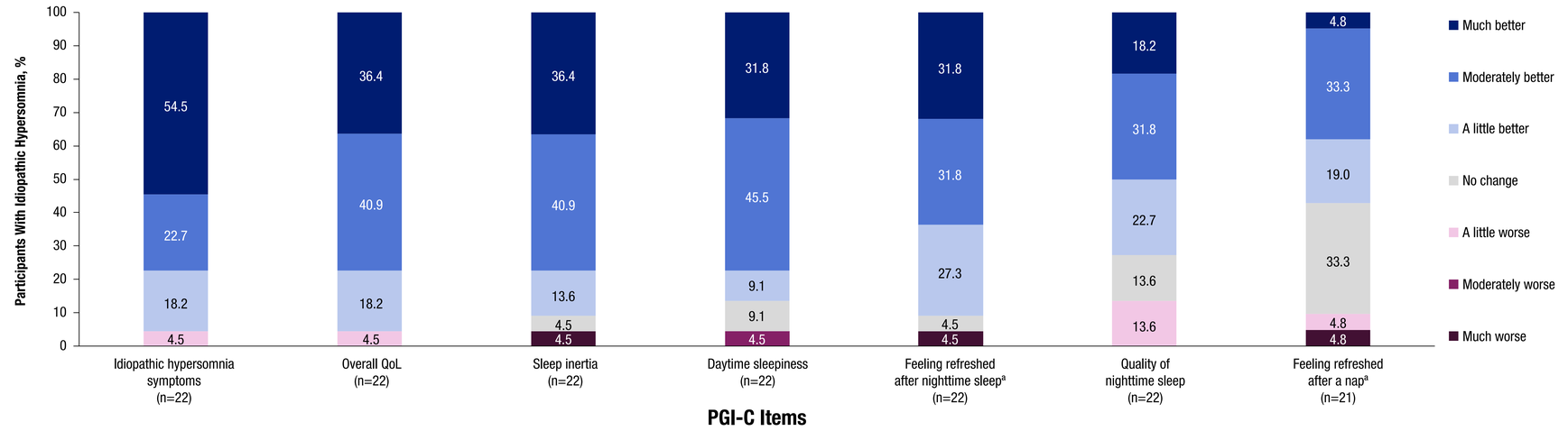
Table 1. Participant Characteristics

Characteristic	Participants With Idiopathic Hypersomnia (N=22)
Age (years)	
Mean (SD)	30.2 (6.9)
Median (min, max)	28.0 (21.0, 53.0)
Gender, n (%)	
Female	15 (68.2)
Male	7 (31.8)
Race, n (%)	
White	10 (45.5)
Black or African American	8 (36.4)
Other	2 (9.1)
Prefer not to say	2 (9.1)
Ethnicity, n (%)	
Hispanic or Latino/a	0
Not Hispanic or Latino/a	21 (95.5)
Prefer not to answer	1 (4.5)
Education, n (%)	
High school graduate	1 (4.5)
Some college	2 (9.1)
Associate's degree	1 (4.5)
Bachelor's degree	10 (45.5)
Master's degree	6 (27.3)
Doctorate	1 (4.5)
Other	1 (4.5)
Employment, n (%)[a]	
Working full-time	12 (54.5)
Working part-time	5 (22.7)
Student	5 (22.7)
Unable to work	3 (13.6)
Seeking work opportunities	2 (9.1)
Homemaker	1 (4.5)
Number of LXB doses per night, n (%)	
1	6 (27.3)
2	16 (72.7)
Number of weeks taking LXB	
Mean (SD)	61.4 (37.5)
Total nightly dosage (g), n (%)	
≤5	6 (27.3)
5 to <7	2 (9.1)
7 to <9	9 (40.9)
9	5 (22.7)
ESS score	
Mean (SD)	10.8 (4.7)
IHSS score	
Mean (SD)	28.0 (7.2)
Other current comorbid diagnoses, n (%)[a]	
Attention deficit disorder/attention deficit hyperactivity disorder	4 (18.2)
Anxiety	13 (59.1)
Cancer	1 (4.5)
Depression	5 (22.7)
Diabetes	1 (4.5)
Hypertension or high blood pressure	1 (4.5)
Obesity	2 (9.1)
Obstructive sleep apnea	3 (13.6)
Periodic limb movement disorder	1 (4.5)
Restless leg syndrome	1 (4.5)
Other mental health condition	1 (4.5)
Other current diagnosis	5 (22.7)
None of the above	5 (22.7)
Current concomitant treatments, n (%)[a]	
Amphetamine	6 (27.3)
Armodafinil	1 (4.5)
Fluoxetine	3 (13.6)
Methylphenidate	2 (9.1)
Modafinil	1 (4.5)
Pitolisant	1 (4.5)
Solriamfetol	3 (13.6)
Other current treatment	3 (13.6)
None of the above	9 (40.9)

[a]Response options are not mutually exclusive.
ESS, Epworth Sleepiness Scale; IHSS, Idiopathic Hypersomnia Severity Scale; LXB, low-sodium oxybate; max, maximum; min, minimum; SD, standard deviation.

- Among the 22 participants with idiopathic hypersomnia who completed the enrollment survey, most were White (45.5%) or Black or African American (36.4%) and identified as female (68.2%); the mean (standard deviation [SD]) age was 30.2 (6.9) years
- The mean (SD) time taking LXB was 61.4 (37.5) weeks (or approximately 15 months), with most participants taking twice-nightly LXB (72.7%)
  - The most common total nightly dosage category was 7 to <9 g (40.9%)
  - 50.0% of participants were taking a concomitant alerting agent (wake-promoting agent or stimulant)

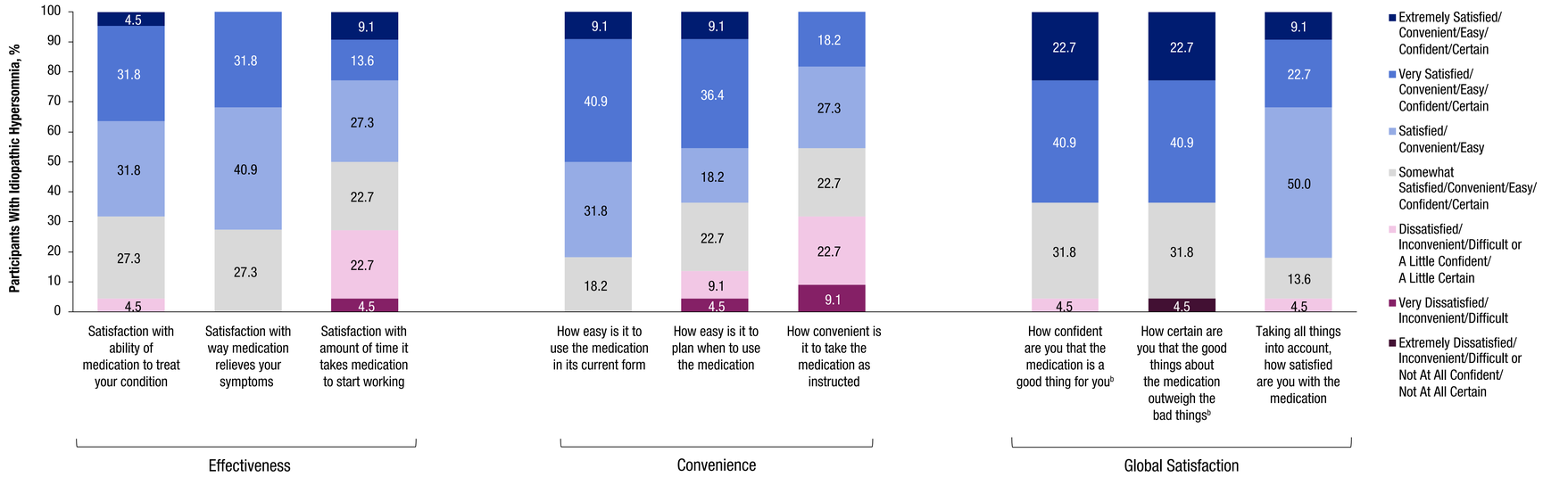
Figure 1. Idiopathic Hypersomnia Symptom and QoL PGI-C Items



[a]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; 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 idiopathic hypersomnia symptoms (95.5%), overall QoL (95.5%), feeling rested after nighttime sleep (90.9%), sleep inertia (90.9%), daytime sleepiness (86.4%), and quality of nighttime sleep (72.7%), compared with before starting LXB

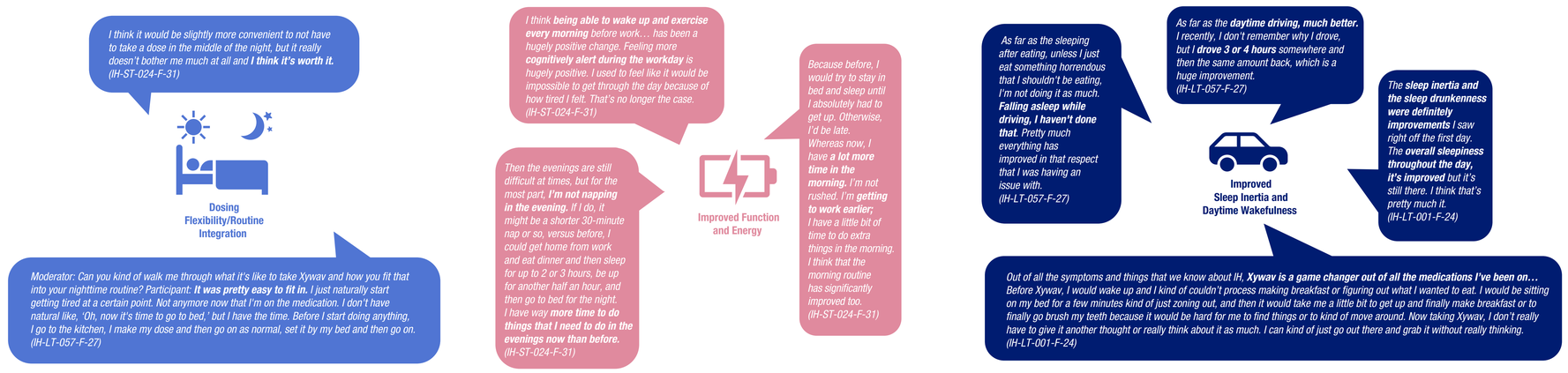
Figure 2. Treatment Satisfaction Questionnaire for Medication–9 Items[a]



[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 the 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 69.8 (16.1), with 81.8% 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 64.7 (16.1), with 81.8% 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 64.4 (13.5), with 72.7% of participants reporting that they were "satisfied" to "very satisfied" with symptom relief provided by LXB

Figure 3. Participant Perspectives on LXB Treatment Experience and Changes Since Starting LXB (n=4)



IH, idiopathic hypersomnia; LXB, low-sodium oxybate.

Conclusions

- Interim results of patient-reported survey and interview data from the ongoing LYRICAL study suggest improvements in multiple idiopathic hypersomnia symptoms, including EDS and sleep inertia, and in QoL, compared with before starting LXB
- Many participants reported high treatment satisfaction, citing improvements in symptom relief and LXB ease of use and integration into daily routines
- 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 idiopathic hypersomnia symptoms, QoL, and treatment satisfaction, including durability of effectiveness

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

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