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Real-world Use of Solriamfetol for Excessive Daytime Sleepiness in Patients Reporting Anxiety or Depression

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Key Question

- Is solriamfetol effective in treating excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea in patients with self-reported anxiety and/or depression?

Conclusions

- These real-world data describe treatment outcomes of solriamfetol in patients with narcolepsy or OSA, both with and without self-reported anxiety/depression
- Reductions in EDS were substantial and comparable in patients with and without self-reported anxiety/depression
- Most patients and physicians reported improvements in EDS
- These findings are consistent with clinical trial results and suggest that solriamfetol is effective in managing EDS in patients with psychiatric comorbidities

References

1. Fortuyn H, et al. *Gen Hosp Psychiatry*. 2010;32(1):49-56.
2. Sharafkhaneh A, et al. *Sleep*. 2005 28(11):1405-11
3. Kim JY, et al. *JAMA Otolaryngol Head Neck Surg*. 2019;145(11):1020-1026.
4. Garbarino S, et al. *Behav Sleep Med*. 2020; 18(1):35-57.
5. Alnefeesi Y, et al. *Neurosci Biobehav Rev*. 2021;131:192-210.
6. Gursahani H, et al W. *Sleep*. 2022;45(suppl 1):A329.
7. Sunosi® (solriamfetol) [Prescribing Information]. New York, NY. Axsome Therapeutics, Inc.
8. Sunosi™ (solriamfetol) tablets Summary of Product Characteristics. Waterford, Ireland: TMC Pharma (EU) Limited; 2022

Acknowledgments

This study was supported by Axsome Therapeutics, Inc. and Pharmanovia.

Disclosures

U. Kallweit is on the advisory board at, is consultant to, and has accepted research support from Jazz Pharmaceuticals.

H. Benes and **L. Burghaus** has nothing to disclose.

G.M.L. Eglit is an employee of Axsome Therapeutics, Inc.

S. Floam is an employee of Axsome Therapeutics, Inc and former employee of Jazz Pharmaceuticals.

G. Parks is a former employee of Axsome Therapeutics, Inc and Jazz Pharmaceuticals.

Y Winter has received honoraria for educational presentations and consultations from Arvelle Therapeutics, Angelini Pharma, Bayer AG, Bial, Bioprojet Pharma, Bristol Myers Squibb, Eisai, Ethypharm GmbH, GW Pharmaceuticals, Idorsia Pharmaceuticals, Jazz Pharmaceuticals, LivaNova, Neuraxpharm, Novartis, and UCB Pharma.

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27th Congress of the European Sleep Research Society September 24-27, 2024
Seville, Spain

Introduction

- Psychiatric comorbidities are prevalent in patients with excessive daytime sleepiness (EDS) from narcolepsy or obstructive sleep apnea (OSA)[1,2]
  - Depression and anxiety are particularly common in these patients, with prevalence rates of ≥ 30% each[3,4]
- Efficacy and safety data for wake-promoting agents in these populations are limited
- Solriamfetol (Sunosi®) is a dopamine-norepinephrine reuptake inhibitor with agonistic properties at the trace amine-associated receptor 1 and serotonin 1A receptor[5,6]; it is approved for use in adults in the United States, Canada and select countries in Europe for the treatment of EDS associated with narcolepsy or OSA[7,8]
- Clinical trials with solriamfetol have excluded patients with severe psychiatric comorbidities, and the prescribing information advises against its use in this population
  - As a result, there are limited data available on the efficacy and safety of solriamfetol in these patients

Methods & Study Design

- **SU**nosi **R**eal **W**orld **E**xperience Stud**Y** (SURWEY) was a retrospective chart review among physicians in Germany who have prescribed solriamfetol to patients with EDS associated with narcolepsy or OSA
- Eligible patients were ≥ 18 years of age, had a diagnosis of EDS and narcolepsy or OSA, had reached a stable maintenance dose of solriamfetol and completed ≥ 6 weeks of treatment; patients who received solriamfetol during a clinical trial or early access program were excluded
- The present analysis focused on data from 154 adult patients with narcolepsy or OSA, stratified by self-reported anxiety and/or depression
  - Patients were classified as anxious and/or depressed based on their answer at baseline to a single yes/no question
- Data related to comorbidities, Epworth Sleepiness Scale (ESS) scores, patient-and physician-reported improvement in EDS, and adverse events were summarized descriptively

Key Findings

Patient Population

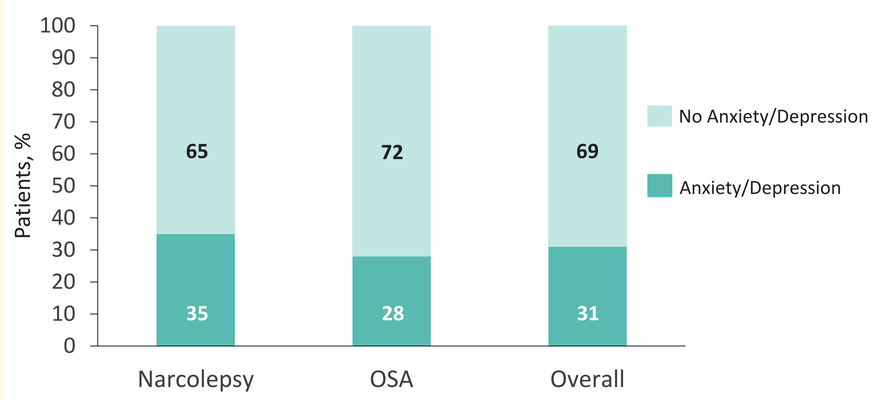
Table 1. Baseline Demographics and Clinical Characteristics

	Anxiety/ Depression n=48	No Anxiety/ Depression n=106	Overall N=154
Indication, n (%)			
Narcolepsy	25 (52)	46 (43)	71 (46)
OSA	23 (48)	60 (57)	83 (54)
ESS, mean (SD)	17.0 (3.3)	16.6 (3.2)	16.7 (3.2)
Age, mean (SD), years	43.9 (12.8)	42.8 (15.9)	43.1 (15.0)
Sex, n (%)			
Female	21 (44)	48 (45)	69 (45)
Male	27 (56)	58 (55)	85 (55)
BMI	29.2 (6.2)	29.9 (6.4)	29.7 (6.3)
ADHD, n (%)	1 (2.1)	1 (0.9)	2 (1.3)
Other psychiatric disorder, n (%)	0	4 (3.8)	4 (2.6)
Other neurological disorder, n (%)	4 (8.3)	2 (1.9)	6 (3.9)
Other sleep disorder, n (%)	5 (10)	18 (17)	23 (15)

ADHD, attention deficit hyperactivity disorder; BMI, body mass index; ESS, Epworth Sleepiness Scale; SD, standard deviation

- Baseline demographics were similar between patients with and without self-reported anxiety and/or depression (**Table 1**)

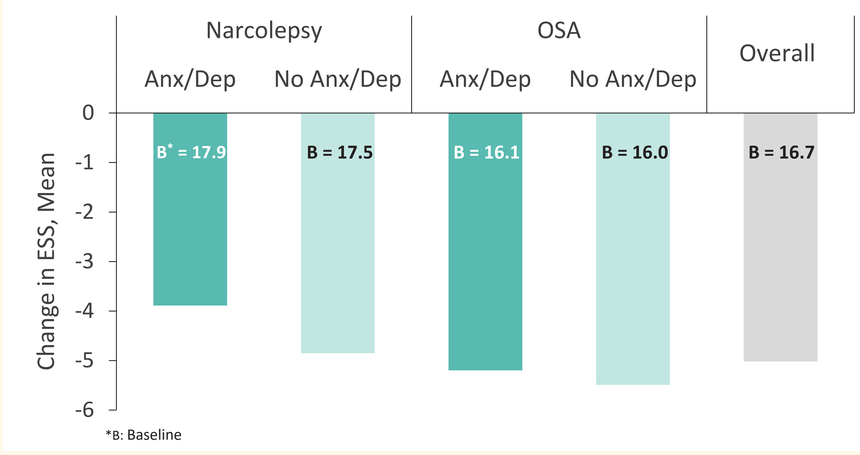
Figure 1. Incidence of Anxiety / Depression in Patients With Narcolepsy or OSA



- Rates of anxiety/depression were similar between patients with narcolepsy (35.2%) and OSA (27.7%) (**Figure 1**)

Efficacy

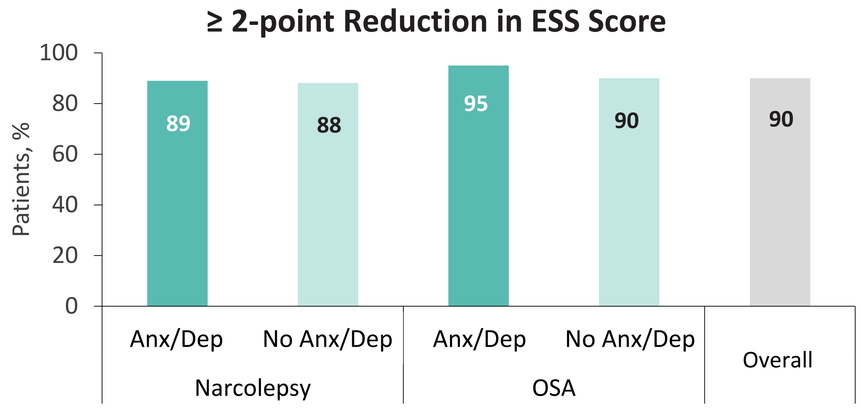
Figure 2. Reductions in ESS Scores for Patients With and Without Anxiety / Depression



*B: Baseline

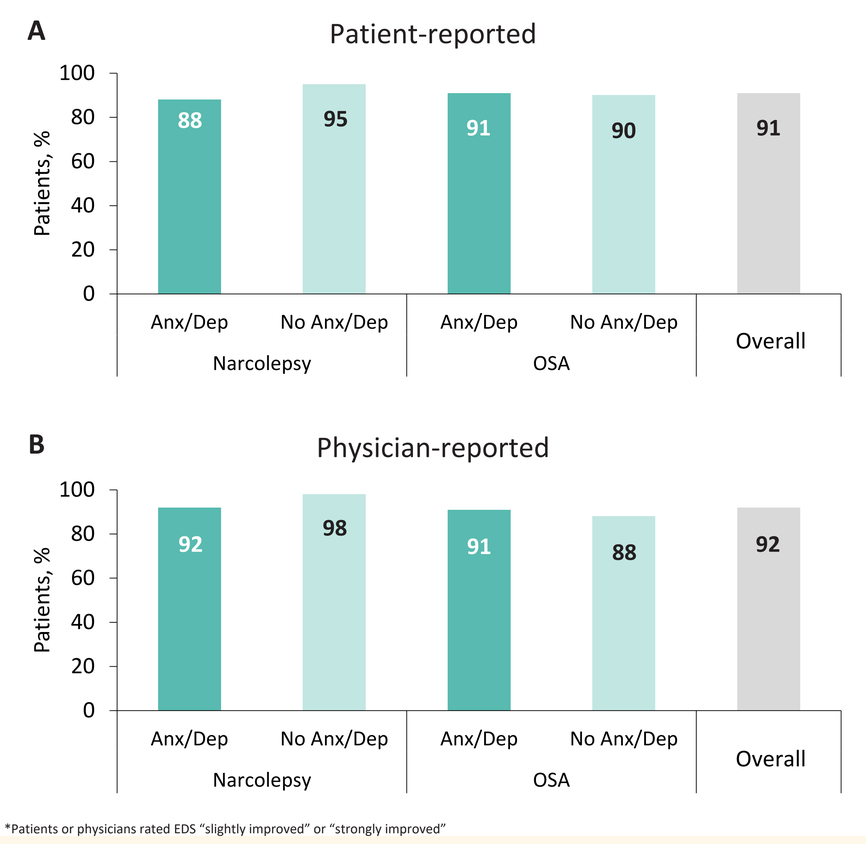
- All efficacy results were pooled across dosages, and most patients took less than the maximum recommended dose of 150 mg/day
- In patients with narcolepsy or OSA, those with anxiety/depression experienced comparable reductions in ESS to those without (**Figure 2**)

Figure 3. Proportion of Patients Achieving a ≥ 2-point Reduction in ESS Score



- In patients with narcolepsy or OSA, ≥ 88% experienced clinically meaningful improvement in EDS, achieving a reduction of ≥ 2 points in ESS score, regardless of anxiety/ depression status (**Figure 3**)

Figure 4. Proportion of Patients and Physicians Reporting Improvement in EDS*



*Patients or physicians rated EDS "slightly improved" or "strongly improved"

- In patients with narcolepsy or OSA, ≥ 88% reported experiencing improvement in EDS, regardless of anxiety/depression status, consistent with physician reports (**Figure 4**)

Safety

Table 2. Adverse Events (≥3% Overall)

Adverse event, n (%)	Narcolepsy		OSA		Overall
	Anxiety/ depression n=25	No anxiety/ depression n=46	Anxiety/ depression n=23	No anxiety/ depression n=60	N=154
Headache	2 (8.3)	4 (8.9)	3 (13.0)	4 (6.8)	13 (8.6)
Decreased appetite	1 (4.2)	3 (6.7)	3 (13.0)	3 (5.1)	10 (6.6)
Insomnia	2 (8.3)	2 (4.4)	2 (8.7)	3 (5.1)	9 (6.0)
Irritability	3 (12.5)	0	2 (8.7)	2 (3.4)	7 (4.6)
Other	3 (12.5)	0	0	3 (5.1)	6 (4.0)
Dizziness	1 (4.2)	1 (2.2)	1 (4.3)	2 (3.4)	5 (3.3)
Feeling jittery	1 (4.2)	0	1 (4.3)	3 (5.1)	5 (3.3)

OSA, obstructive sleep apnea.

- The most common adverse events overall were headache, decreased appetite, and insomnia (**Table 2**)
- Adverse events were generally more common in patients reporting anxiety/depression (**Table 2**)