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Real-world Use of Solriamfetol for Excessive Daytime Sleepiness in Patients with Obstructive Sleep Apnea in the US

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Key Objective

- To examine the real-world use of solriamfetol and related clinical outcomes (before and after initiation) using administrative claims data in patients with obstructive sleep apnea and excessive daytime sleepiness prescribed positive airway pressure therapy in the United States

Introduction

- Excessive daytime sleepiness (EDS) is a prominent and debilitating symptom in obstructive sleep apnea (OSA), estimated to persist in 12% to 65% of patients despite optimal treatment with primary airway therapy for OSA
- EDS has been linked to higher risk of comorbidities, reductions in function of daily activities, and poor quality of life. It is also a public health risk associated with driving and workplace accidents, and has a significant impact on healthcare utilization and work productivity[1,2]
- Solriamfetol (Sunosi®) is a dopamine-norepinephrine reuptake inhibitor with agonistic properties at the trace amine-associated receptor 1 and serotonin 1A receptor approved for treatment of EDS associated with narcolepsy or OSA[3]
- While solriamfetol demonstrated robust efficacy in clinical trials in patients with EDS and OSA,[4-6] there is a gap in its real-world utilization in the US, highlighting the need for further research to better understand its practical application

Methods

Study design

- This retrospective observational study included adult patients newly initiating solriamfetol in the Merative™ MarketScan® Commercial and Medicare Databases between July 2019-September 2022

Patient identification

Adult patients initiating solriamfetol 7/1/2019-9/30/2022 (1st claim = index date)
N=1,650

↓

Continuous enrollment with medical and pharmacy benefits for 6-month pre- and post-index periods
N=1,244

↓

≥1 claim with an OSA diagnosis (ICD-10-CM codes: G47.30, G47.33) and ≥1 claim for positive airway pressure between 7/1/2016 and the index date
N=1,135

↓

≥2 post-index claims (on different dates) for solriamfetol
N=909

↓

No pre-index evidence of narcolepsy, substance use disorder, or pregnancy, and no pre- or post-index evidence of central sleep apnea
N=665

Outcomes

- Patient demographic and clinical characteristics
- Twenty-two OSA-related comorbidities and 19 OSA-related symptoms (identified using ICD-10-CM diagnosis codes) during the 6-month pre- and post-index periods
- EDS-related medication use during the 6-month pre- and post-index periods: WPAs (solriamfetol, armodafinil, modafinil), and traditional stimulants (off-label use for the management of EDS due to OSA)
- Adherence to solriamfetol: proportion of days covered (PDC) >80% during the 6-month post-index period

Analyses

- Descriptive analysis was conducted with mean and standard deviation (SD) summarized for continuous variables and count and percentage of patients presented for categorical variables
- Statistical tests of significance for differences before and after the initiation of solriamfetol were conducted, using McNemar's tests for categorical variables and paired T-tests for continuous variables

Results

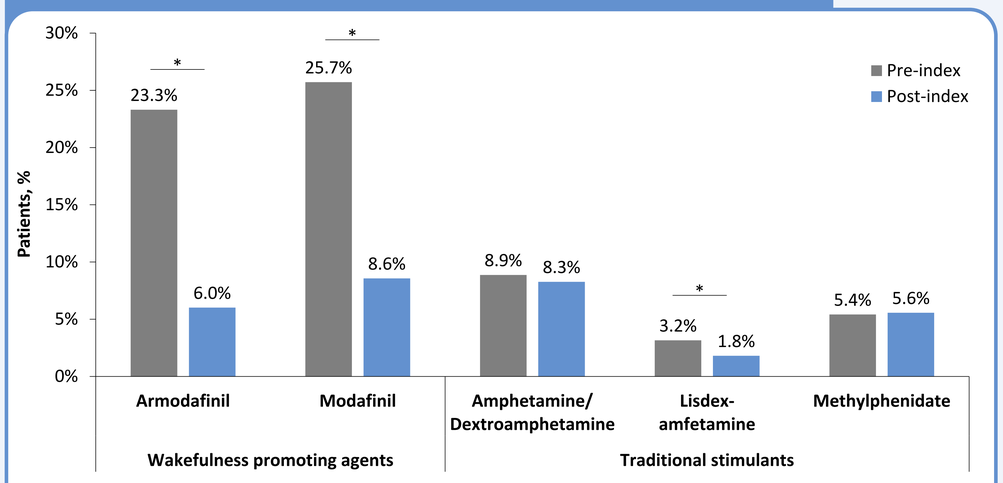
Table 1. Patient Characteristics

	Solriamfetol Patients (N=665)
Demographics: Measured on Index	
Age (Mean, SD)	50.7 (10.1)
Age groups (N, %)	
18-34	48 (7.2)
35-44	121 (18.2)
45-54	223 (33.5)
55-64	254 (38.2)
≥65 years old	19 (2.9)
Male (N, %)	361 (54.3)
Geographic region (N, %)	
Northeast	61 (9.2)
North Central	155 (23.3)
South	402 (60.5)
West	47 (7.1)
Payer (N, %)	
Commercial	644 (96.8)
Medicare	21 (3.2)
Clinical Characteristics: Measured During the 6-Month Pre-Index Period	
Charlson Comorbidity Index (Mean, SD)	0.7 (1.2)
Prior use of WPAs or stimulants (N,%)	365 (54.9)

- The mean age of patients taking solriamfetol (N=665) was 50.7 (SD 10.1) years, 54.3% were male
- 54.9% had prior EDS-related medications before initiating solriamfetol
  - 301 (45.3%) received other WPAs (armodafinil or modafinil), and 111 (16.7%) received traditional stimulants

WPA, wake-promoting agent.

Figure 1. EDS-Related Medications in 6-Month Pre- vs. Post-Index Periods



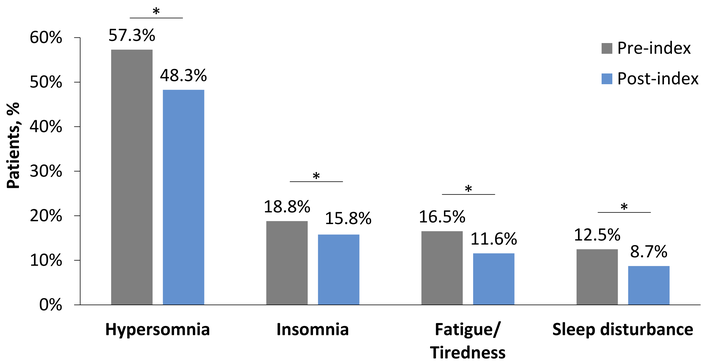
- Utilization of armodafinil and modafinil significantly reduced over the 6-month post-index period

*P-value <0.05.
Other traditional stimulants evaluated with low utilization (<1%) not included in figure were dexmethylphenidate, dextroamphetamine, and methamphetamine. No patients used amphetamine or dexmethylphenidate/ serdexmethylphenidate during the study period.

Solriamfetol Use in 6-Month Post-Index Period

- Solriamfetol was initiated as monotherapy (no pre-index use of EDS-related medications) in 300 (45.1%) patients and was used exclusively in 492 (74.0%) patients during the 6-month post-index period
- 79.2% of solriamfetol patients were adherent (PDC ≥80%) during the 6-month post-index period with a mean PDC of 0.9

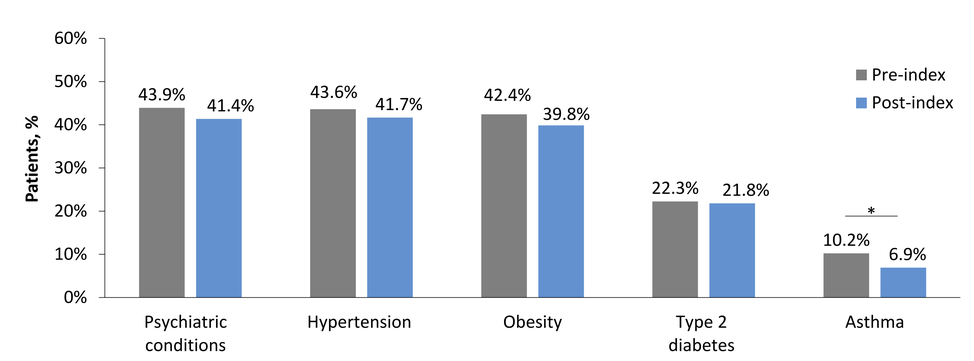
Figure 2. OSA-Related Sleep Symptoms in 6-Month Pre- vs. Post-Index Periods



- Significant reductions were observed in many OSA-related sleep symptoms in the 6-month post-index period

*P-value <0.05
Additional symptoms examined: Gastroesophageal reflux disease; somnolence, sleep-related movement disorders, sleep-related hypoventilation, confusional arousal, Alzheimer, dementia, mild cognitive impairment, irritability, headache, nocturia, and decreased libido.

Figure 3. OSA-Related Comorbidities in 6-Month Pre- vs. Post-Index Periods



- During the 6-month post-index period (versus the 6-month pre-index period) OSA-related comorbidities remained stable or had numerical reductions. Specifically, there was no evidence of an increase in hypertension

*P-value <0.05
Psychiatric conditions included ADHD, anxiety, depression, and binge eating disorder. Additional conditions evaluated (<10%) not shown in figure: hypercholesterolemia, cardiovascular diseases, chest pain, chronic obstructive pulmonary disease, pulmonary hypertension, decreased appetite, nausea, hyperhidrosis, and temporomandibular joint disease.

Limitations

- The study sample included individuals with commercial or Medicare coverage; thus, results may not be generalizable to other populations such as those covered by Medicaid
- Clinical characteristics were identified via diagnosis codes, which are subject to limitations in data coding and data entry error
- A short duration of 6 months was employed in the pre- and post-index periods

Conclusions

- Using a large claims database in the US, solriamfetol adherence was high during the 6-month period following initiation
- Significant reductions in OSA-related symptoms and other WPA medications were observed following solriamfetol initiation; OSA-related comorbidities remained stable
- These findings suggest that solriamfetol may improve clinical outcomes in the management of EDS in patients with OSA

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Disclosures

Y. Zhao and **S. Floam** are employees of Axsome Therapeutics Inc.
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