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Effects of Solriamfetol on Neuropsychological Outcomes in Patients With Obstructive Sleep Apnea in the Real-World SURWEY Study

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Key Objective

- To evaluate the effect of solriamfetol on cognition in participants with excessive daytime sleepiness associated with obstructive sleep apnea in a real-world setting

Introduction

- Excessive daytime sleepiness (EDS) is a common symptom of obstructive sleep apnea (OSA)[1]
- Although improvements in sleep quality and reductions of hypoxic events are observed with positive airway pressure (PAP), residual EDS persists in approximately 10%–28% of PAP-treated patients[2-5]
- Up to 68% of patients with EDS associated with OSA show deficits in cognitive domains, including alertness, attention, executive function, and decision-making[1,6,7]
  - Cognitive impairment can also persist despite PAP treatment[1]
- 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[8-10]
- Solriamfetol demonstrated improvements in cognitive performance in participants with EDS and OSA in the phase 4 randomized SHARP study[11]
- Here, we report a post hoc analysis of neuropsychological outcomes in participants treated with solriamfetol for EDS associated with OSA in the real-world SURWEY study, including subjective and objective measurements of cognition

Methods

- **SU**nosi **R**eal **W**orld **E**xperience Stud**Y** (SURWEY) was a retrospective, observational study using data from physicians who prescribed solriamfetol for EDS associated with OSA in Germany
- The present analysis is of a subgroup of 46 patients with OSA who underwent cognitive assessments (**Table 1**) at baseline and 3 months after initiating solriamfetol
- Results are pooled across dosages, and most patients received less than 150 mg/day, the maximum recommended dose
- Change from baseline on neuropsychological outcomes was analyzed with repeated-measures analysis of variance
- Linear regression was used to analyze the association between changes in EDS and changes in cognition

Table 1. Cognitive Assessments

Assessment	Task	Domain
BC-CCI	Rate level of impairment on 6 items, including memory, concentration, and expressing thoughts	Subjective cognitive impairment
TAP: Alertness, without warning	Push button in response to displayed signal	Sustained alertness
TAP: Alertness, with warning	Push button in response to displayed signal preceded by warning tone	Acute alertness
WAIS-IV: Coding subtest	Variation of the Digit Symbol Substitution Test; match symbols to numbers based on key	Processing speed
RWT: S-words	Write down as many words starting with "s" as possible in 1 minute	Verbal fluency
RWT: Animals	Write down as many animal names as possible within 1 minute	Verbal fluency
WMS: Visual Reproduction I	Reproduce displayed images from memory	Visual memory
WMS: Visual Reproduction II	Reproduce displayed images from memory after a delay	Visual memory

BC-CCI, British Columbia Cognitive Complaints Inventory; RWT, Regensburger Word Fluency Test; TAP, Test of Attentional Performance; WAIS-IV, Wechsler Adult Intelligence Scale-IV; WMS, Wechsler Memory Scale.

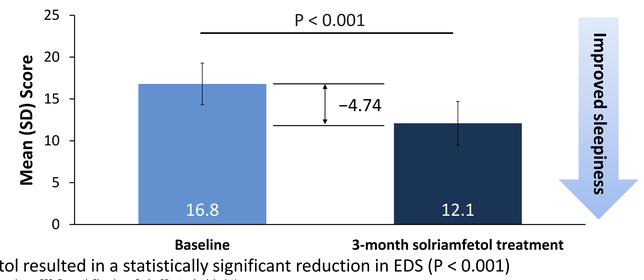
Results

Table 2. Baseline Demographic and Clinical Characteristics

Participants	46
Age, mean ± SD	45 ± 14
Sex	
Male, n (%)	30 (65.2)
Female, n (%)	16 (34.8)
ESS score, mean ± SD	16.8 ± 2.5

ESS, Epworth Sleepiness Scale.

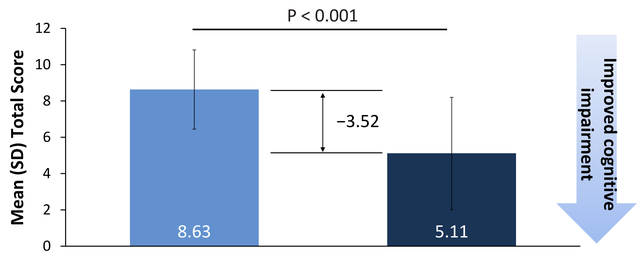
Figure 1. ESS Scores at Baseline and After 3 Months of Solriamfetol Treatment



- Solriamfetol resulted in a statistically significant reduction in EDS (P < 0.001)

EDS, excessive daytime sleepiness; ESS, Epworth Sleepiness Scale; SD, standard deviation.

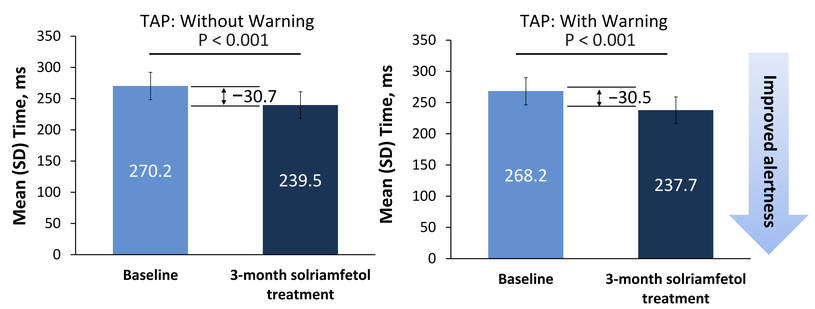
Figure 2. Scores on the BC-CCI at Baseline and After 3 Months of Solriamfetol Treatment



- Mean baseline score on the British Columbia Cognitive Complaints Inventory (BC-CCI) indicated moderate cognitive impairment
- Solriamfetol substantially and statistically significantly improved subjective cognitive function as measured by the BC-CCI (40.8% improvement from baseline to 3-month follow-up: P < 0.001)

BC-CCI, British Columbia Cognitive Complaints Inventory; SD, standard deviation.

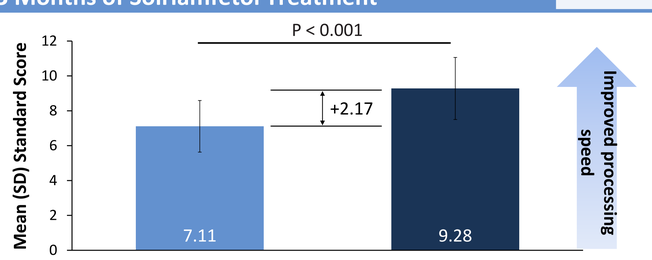
Figure 3. Scores on TAP: Alertness at Baseline and With Solriamfetol



- Baseline scores indicated impaired alertness on both Test of Attentional Performance (TAP) assessments
- Solriamfetol statistically significantly improved alertness on both TAP measures (both 11.4%, P < 0.001)

SD, standard deviation; TAP, Test of Attentional Performance.

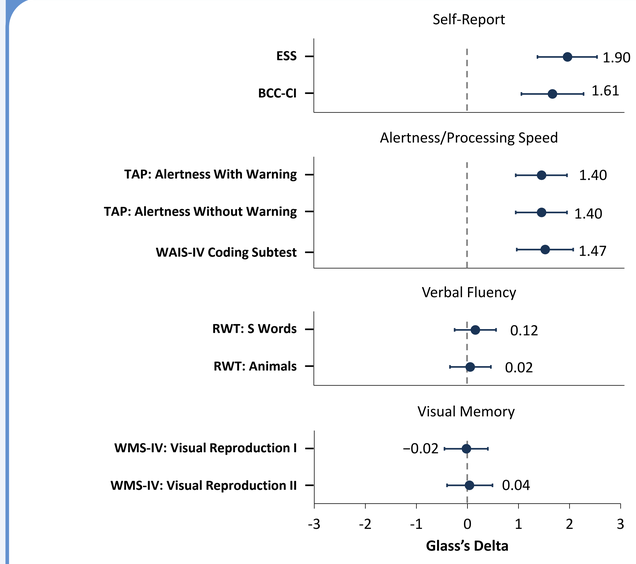
Figure 4. Scores on the WAIS-IV Coding Subtest at Baseline and After 3 Months of Solriamfetol Treatment



- Solriamfetol substantially and statistically significantly improved processing speed as evaluated using the Wechsler Adult Intelligence Scale-IV (WAIS-IV) coding subtest (30.5%: P < 0.001)

SD, standard deviation; WAIS-IV, Wechsler Adult Intelligence Scale-IV.

Figure 5. Standardized Effects of Solriamfetol on Cognition and EDS

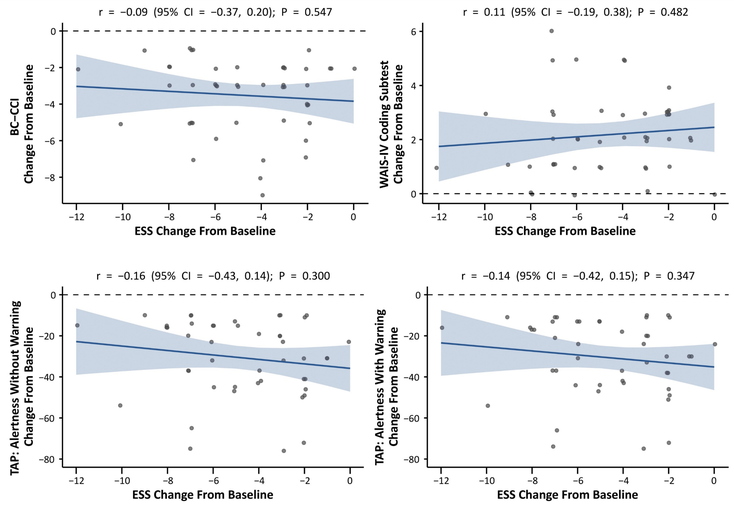


Effect sizes are presented where positive values indicate improvement.

- Substantial effect sizes were observed for the improvements in EDS (1.90), self-reported cognitive function (1.61, BC-CCI), alertness (1.40, TAP: Alertness with or without warning), and processing speed (1.47, WAIS-IV coding subtest)
- No meaningful effects on verbal fluency or visual memory were observed
  - Neither verbal fluency nor visual memory were impaired at baseline or after solriamfetol initiation

BC-CCI, British Columbia Cognitive Complaints Inventory; EDS, excessive daytime sleepiness; RWT, Regensburger Word Fluency Test; TAP, Test of Attentional Performance; WAIS-IV, Wechsler Adult Intelligence Scale-IV; WMS, Wechsler Memory Scale.

Figure 6. Regression Analysis of Association Between Improvements in Cognition and Sleepiness



- ESS change was not predictive of improvements in self-reported cognitive function, alertness, or processing speed

BC-CCI, British Columbia Cognitive Complaints Inventory; ESS, Epworth Sleepiness Scale; TAP, Test of Attentional Performance; WAIS-IV, Wechsler Adult Intelligence Scale-IV.

Conclusions

- At baseline, participants reported moderate subjective cognitive impairment; objective assessments revealed impairment in alertness and processing speed
  - Substantial improvements in these domains were observed following treatment with solriamfetol
- A regression analysis found this improvement in cognitive impairment was not associated with changes in EDS, suggesting that the cognitive benefits observed with solriamfetol treatment are independent of its effects on EDS
- These real-world results show that solriamfetol not only reduces EDS in participants with OSA but also has the potential to improve OSA-associated cognitive impairment

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Disclosures

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.
G. Eglit is an employee of Axsome Therapeutics, Inc.
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U. Kallweit is on the advisory board at, is consultant to, and has accepted research support from Jazz Pharmaceuticals.