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SURWEY: Treatment of Excessive Daytime Sleepiness With Solriamfetol: Initiation, Titration, and Outcomes

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Objective

- This real-world study characterizes dosing and titration strategies among European physicians initiating solriamfetol, as well as treatment outcomes following initiation in patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA)

Conclusions

- This pooled analysis of SURWEY results shows that the majority of patients with narcolepsy and OSA were new to therapy; switching to solriamfetol was also common
- Clinically meaningful improvements in Epworth Sleepiness Scale (ESS) scores were observed with solriamfetol regardless of initiation strategy and across etiologies
  - Overall, mean improvements were substantially greater than the minimum clinically important difference of 2–3 points[13]
- Overall, patients and physicians perceived improvements in EDS after switching to solriamfetol or adding solriamfetol to ongoing medication
- Common adverse events were consistent with those previously reported for solriamfetol[14-16]

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Introduction

- Excessive daytime sleepiness (EDS) is a core symptom of narcolepsy types 1 and 2[1,2]; EDS is also a common symptom of obstructive sleep apnea (OSA) that can persist in patients despite positive airway pressure therapy[3,4]
- Solriamfetol (Sunosi®) is a dopamine-norepinephrine reuptake inhibitor with agonistic properties at the trace amine–associated receptor 1 (TAAR1) and serotonin 1A (5-hydroxytryptamine 1A [5-HT1A]) receptors[5]; 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 (75–150 mg/day) or OSA (37.5–150 mg/day)[6-8]
- Real-world evidence is limited on how physicians prescribe and initiate treatment with solriamfetol in patients with EDS associated with narcolepsy or OSA[9]; such data may help clinicians optimize patient care

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 OSA or narcolepsy, had reached a stable maintenance dose of solriamfetol, and had completed ≥6 weeks of treatment; patients who received solriamfetol during a clinical trial or early access program were excluded
- Solriamfetol initiation and titration strategies included: **changeover** (switched/switching from existing EDS medication[s]), **add-on** (added/adding to current EDS medication[s]), and **new-to-therapy** (no current/previous EDS medication)
- The present pooled analysis includes data from a total of 154 patients with OSA or narcolepsy from Germany
  - Initiation and titration strategies and Epworth Sleepiness Scale (ESS) scores are reported for each diagnosis and the pooled population to examine EDS as a symptom independent of etiology
  - Data related to solriamfetol dosing/titration, comorbidities, changes in ESS, patient- and physician-reported effectiveness of solriamfetol, and adverse events were summarized descriptively

Key Findings

Patients

Table 1. Baseline Demographics and Clinical Characteristics

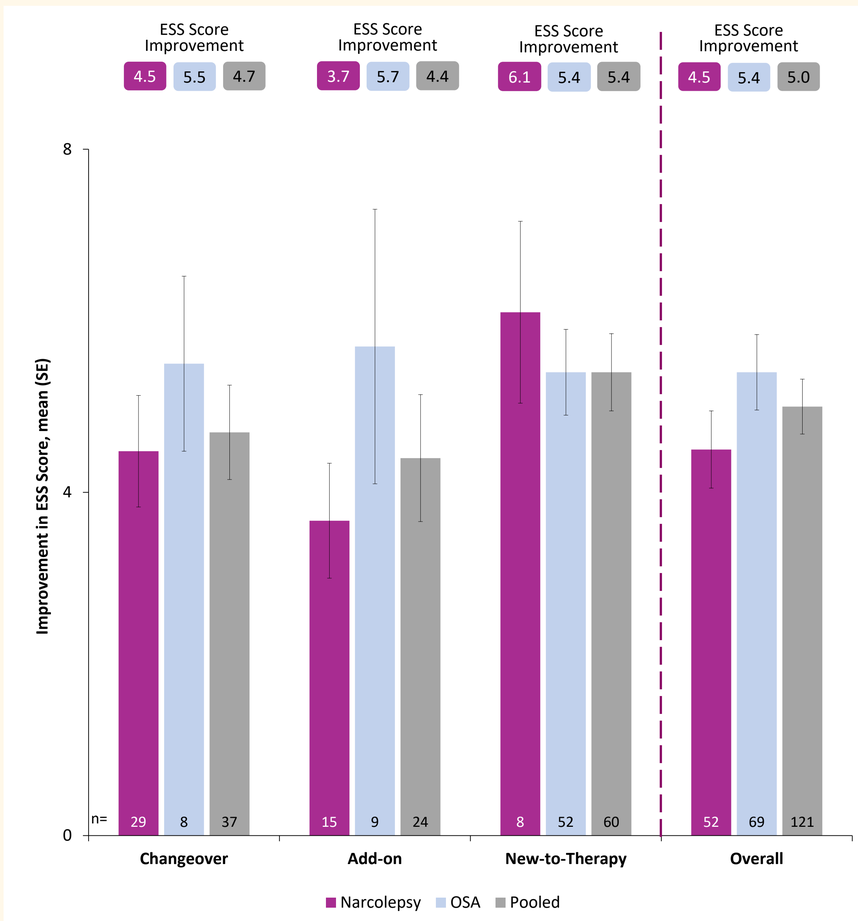
	Changeover (N=53)	Add-on (N=31)	New-to-Therapy (N=70)	Overall (N=154)
Age, mean (SD), years	39 (15)	38 (12)	49 (15)	43 (15)
Sex (female), n (%)	28 (53)	16 (52)	25 (36)	69 (45)
BMI, mean (SD), kg/m^2	27.6 (5.8)	28.9 (5.7)	31.5 (6.4)	29.7 (6.3)
ESS score, mean (SD)	17.1 (3.3)	17.6 (3.1)	16.1 (3.1)	16.7 (3.2)
Comorbidities,[a] n (%)				
Obesity	14 (26)	13 (42)	31 (44)	58 (38)
Hypertension	10 (19)	9 (29)	30 (43)	49 (32)
Anxiety/depression	20 (38)	11 (35)	17 (24)	48 (31)
Diabetes type 2	7 (13)	7 (23)	15 (21)	29 (19)
Other sleep disorder	4 (8)	4 (13)	15 (21)	23 (15)

The present pooled analysis includes 71 patients with narcolepsy; previously published SURWEY analysis included 70 patients with narcolepsy.[9]
BMI, body mass index; ESS, Epworth Sleepiness Scale; OSA, obstructive sleep apnea.
[a]Comorbidities reported in ≥15% of the overall pooled population (N=154).

- Pooled analysis included 71 (46%) patients who were prescribed solriamfetol for narcolepsy and 83 patients (54%) with OSA; baseline data for these 2 patient groups have been presented previously (**Table 1**)[9,10]
- The most common initiation strategy was changeover in patients with narcolepsy (n=44/71; 62%) and new-to-therapy in patients with OSA (n=62/83; 75%)
  - Solriamfetol was initiated as add-on therapy in 27% (19/71) of patients with narcolepsy, 14% (12/83) of patients with OSA, and 20% (31/154) overall
  - Patients most commonly switched to or added on solriamfetol when taking modafinil and/or pitolisant
- Most of the pooled group reported switching due to lack of efficacy (91%); most (89%) switched abruptly from prior medication
- Among patients with available data, the final solriamfetol dose was ≥150 mg/day in 46% (31/68) of patients with narcolepsy, 20% (16/82) of patients with OSA, and 31% (47/150) overall

Efficacy

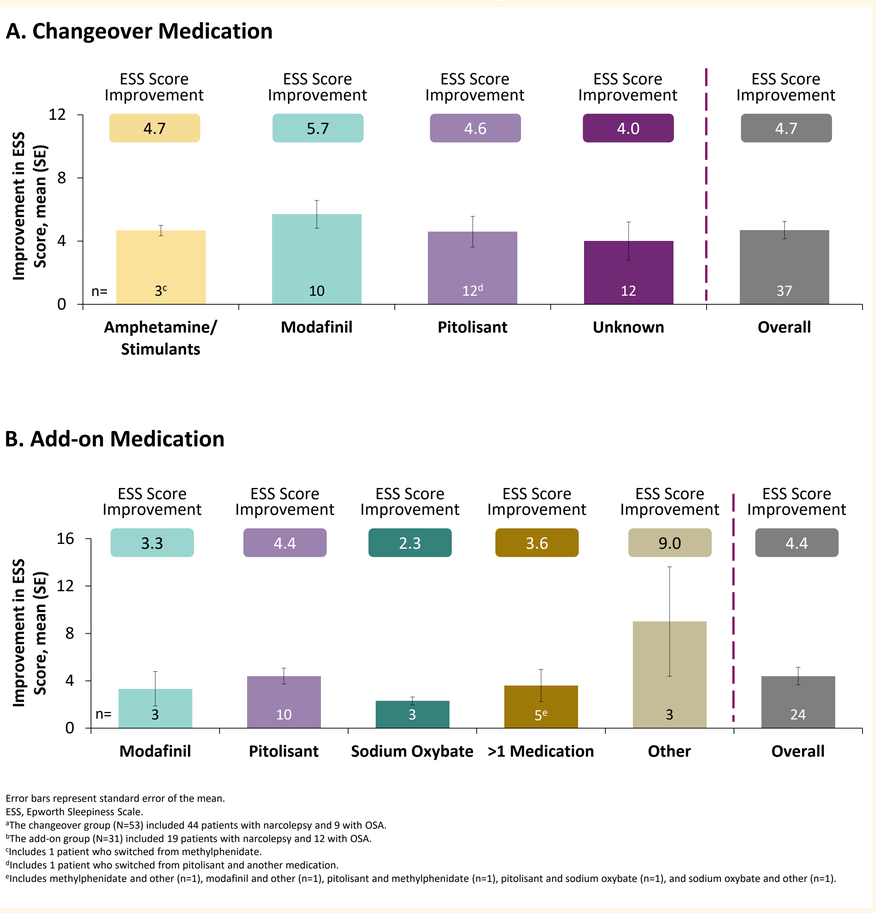
Figure 1. ESS Score[a] Mean Improvement From Baseline



Error bars represent standard error of the mean.
ESS, Epworth Sleepiness Scale; OSA, obstructive sleep apnea.
[a]Scale range: 0–24; ESS scores >10 indicate EDS.[11,12]

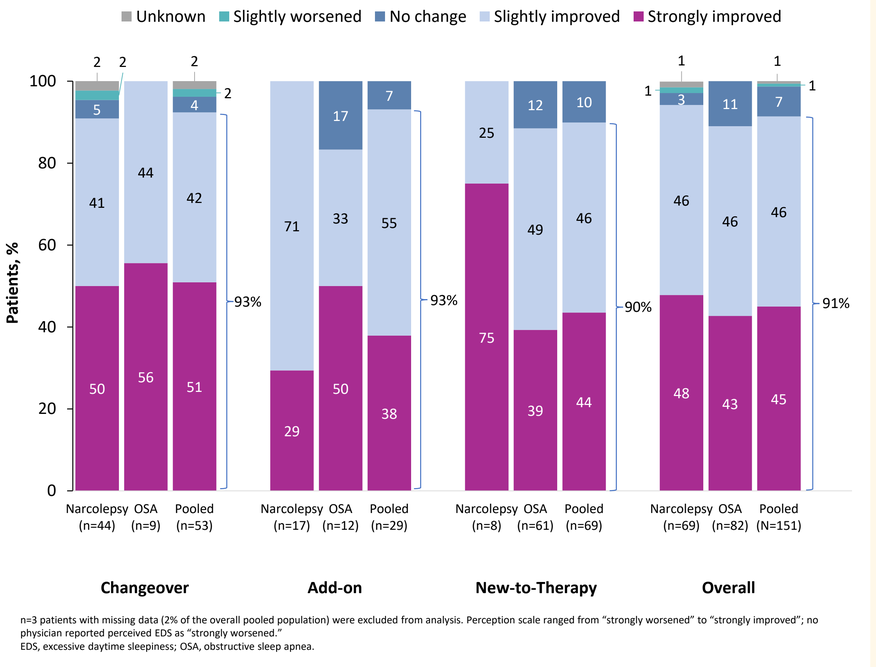
- ESS scores improved from baseline regardless of solriamfetol initiation strategy and across all etiologies (**Figure 1**)
- In the changeover group, ESS scores improved by 5.7, 4.7, 4.6, and 4.0 points in patients who switched to solriamfetol from modafinil (n=13), stimulants (n=3), pitolisant (n=16), or unknown medication (n=21), respectively (**Figure 2A**), while patients who added solriamfetol to pitolisant (n=13) or modafinil (n=3) improved by 4.4 and 3.3 points, respectively (**Figure 2B**)
- Across all etiologies and initiation strategies, mean improvements in ESS scores were substantially greater than the minimum clinically important difference of 2–3 points[13]

Figure 2. ESS Mean Improvement by (A) Changeover[a] and (B) Add-on[b] Medication in the Pooled Population



Error bars represent standard error of the mean.
ESS, Epworth Sleepiness Scale.
[a]The changeover group (N=53) included 44 patients with narcolepsy and 9 with OSA.
[b]The add-on group (N=31) included 19 patients with narcolepsy and 12 with OSA.
[c]Includes 1 patient who switched from methylphenidate.
[d]Includes 1 patient who switched from pitolisant and another medication.
[e]Includes methylphenidate and other (n=1), modafinil and other (n=1), pitolisant and methylphenidate (n=1), pitolisant and sodium oxybate (n=1), and sodium oxybate and other (n=1).

Figure 3. Physician Perceptions of EDS Improvement



n=3 patients with missing data (2% of the overall pooled population) were excluded from analysis. Perception scale ranged from "strongly worsened" to "strongly improved"; no physician reported perceived EDS as "strongly worsened."
EDS, excessive daytime sleepiness; OSA, obstructive sleep apnea.

- In the pooled population, 89% and 97% of patients in the changeover and add-on groups, respectively, reported improvement ("slightly improved" or "strongly improved") in EDS; physician perceptions on EDS are presented in **Figure 3**

Safety

Table 2. Treatment-Emergent Adverse Events[a]

	Changeover (N=53)	Add-on (N=31)	New-to-Therapy (N=70)	Overall (N=154)
Any TEAE, n (%)	19 (36)	11 (35)	18 (26)	48 (31)
Headache	5 (9)	3 (10)	5 (7)	13 (8)
Decreased appetite	5 (9)	1 (3)	4 (6)	10 (6)
Insomnia	3 (6)	1 (3)	5 (7)	9 (6)
Irritability	3 (6)	1 (3)	3 (4)	7 (5)
Other	2 (4)	2 (6)	2 (3)	6 (4)
Dizziness	1 (2)	3 (10)	1 (1)	5 (3)
Feeling jittery	1 (2)	2 (6)	2 (3)	5 (3)
Anxiety	3 (6)	0 (0)	0 (0)	3 (2)
Nausea	1 (2)	1 (3)	1 (1)	3 (2)
Abdominal pain	0 (0)	1 (3)	2 (3)	3 (2)

TEAE, treatment-emergent adverse event.
[a]Reported in ≥2% of the overall pooled population (N=154).

- **Table 2** summarizes the treatment-emergent adverse events
- Safety data for the narcolepsy and OSA populations have been presented previously[9,10]
- Adverse events were consistent with those previously reported in clinical trials of solriamfetol in participants with narcolepsy and OSA[14-16]