Real-World Impact of Olanzapine and Samidorphan on Rates of Relapse Among Young Adults With Schizophrenia or Bipolar I Disorder

Andrew J. Cutler, MD,^{1,2} Hemangi R. Panchmatia, MSc,³ Alejandro G. Hughes, MPH,⁴ Michael J. Doane, PhD,³ Hara E. Oyedeji, CRNP, MS,⁵ Rakesh Jain, MD⁶

¹Department of Psychiatry, SUNY Upstate Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX, USA; ¹Department of Psychiatry, Texas Tech University, Texas Texas Tech University, Texas Texa

BACKGROUND

- Olanzapine/samidorphan (OLZ/SAM) provides the antipsychotic efficacy of olanzapine while mitigating olanzapineassociated weight gain in patients with schizophrenia or bipolar I disorder^{1,2}
- OLZ/SAM has also maintained symptom control and had a long-term safety profile over 4 years with small changes in body weight and minimal changes in lipid and glycemic parameters over extended duration³
- In real-world studies,4-6 OLZ/SAM treatment significantly reduced disease-related acute care events, including inpatient (IP) admissions and emergency department (ED) visits, which serve as proxies for relapse⁷
- In a previous study comparing acute care events in the 12 months before and after initiating OLZ/SAM, proportions of patients who had disease-related IP admissions or ED visits decreased significantly after OLZ/SAM initiation in the schizophrenia and BD-I cohorts^{5,6}
- Absolute reductions from baseline in proportions of patients with IP admissions and ED visits were 8% and 6%, respectively, for the schizophrenia cohort, and 13% and 6%, respectively, for the BD-I cohort
- This analysis of data from the same study examined disease-related acute care events in a subgroup of young adults, a population vulnerable to relapse8

OBJECTIVE

 To compare disease-related IP admissions and ED visits, as proxies for relapse, in the 12 months before vs after initiating OLZ/SAM among young adult patients with schizophrenia or BD-I

METHODS

Patients and Study Design

• This retrospective analysis used IP, outpatient (OP), and pharmacy claims data from October 18, 2020, to December 31, 2023, from Komodo Healthcare Map

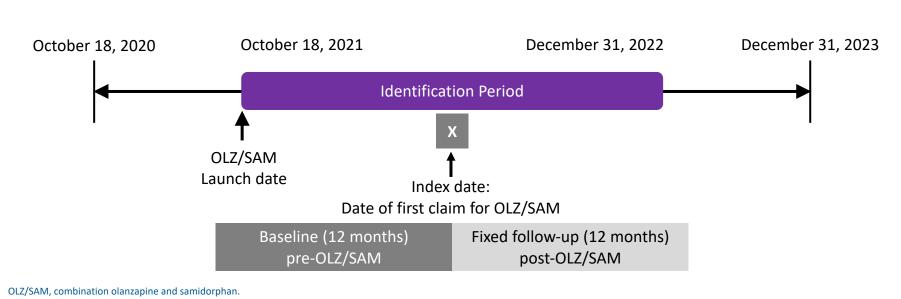
Main Study Criteria

- Inclusion:
- Age ≥18 years with ≥1 pharmacy or medical claim for OLZ/SAM
- -≥12 months of continuous enrollment with medical and pharmacy benefits before (baseline period) and after (fixed followup period) the index date (date of first medical or pharmacy claim for OLZ/SAM)
- –≥1 medical claim for schizophrenia or BD-I during the baseline or follow-up period; patients with medical claims for both schizophrenia and BD-I were assigned an indication of schizophrenia
- Exclusion: any pharmacy or medical claim for OLZ/SAM during the baseline period

Subgroup Analysis Criterion

Age 18–34 years as of the index date

Figure 1. Study Design



Outcomes

- Baseline patient demographics, clinical characteristics, and medication use
- Disease-related IP admissions and ED visits
- All-cause and mental health-related IP admissions and ED visits were assessed also

Statistics

 McNemar's tests were used for 12-month unadjusted pre-post pairwise comparisons of proportions of patients with ≥1 IP admission and proportions of patients with ≥1 ED visit in each acute care event category

RESULTS

BD-I, bipolar I disorder.

- The full analysis set included 1287 patients with schizophrenia and 1004 patients with BD-I
- This subgroup analysis included data from 564/1287 (43.8%) patients with schizophrenia and 418/1004 (41.6%) patients
- In the schizophrenia and BD-I cohorts, demographics, baseline characteristics, and baseline antipsychotic use were generally similar between the younger patient subgroups and the full study group
- A higher proportion of younger patients with schizophrenia was male (59.9%) compared with the full population (52.9%)
- Other medication usage was lower in the younger patient cohorts compared with the full study cohort

Table 1. Patient Demographics

Characteristics	Schizophrenia (N=564)	BD-I (N=418)	
Age, years, mean (SD)	27.0 (4.6) 27.2 (4.8)		
Sex, n (%)			
Female	219 (38.8)	280 (67.0)	
Male	338 (59.9)	137 (32.8)	
Unknown	7 (1.2) 1 (0.2)		
Insurance type, n (%)			
Commercial	122 (21.6)	157 (37.6)	
Medicaid	388 (68.8) 238 (56.9)		
Medicare Advantage	53 (9.4)	23 (5.5)	

Table 2. Baseline Clinical Characteristics and Medication Use

Characteristics	Schizophrenia (N=564)	BD-I (N=418)	
Select health characteristics reported by ≥10% of patients in either cohort during baseline, n (%)			
Anxiety disorder	322 (57.1)	312 (74.6)	
Any substance use disorder	237 (42.0)	181 (43.3)	
Major depressive disorder	232 (41.1)	204 (48.8)	
Obesity	205 (36.3)	145 (34.7)	
Hyperlipidemia	140 (24.8)	62 (14.8)	
Hypertension	121 (21.5) 75 (17.9)		
Posttraumatic stress disorder	105 (18.6)	142 (34.0)	
Alcohol use disorder	93 (16.5)	72 (17.2)	
Intentional self-inflicted injury	79 (14.0)	58 (13.9)	
Type 2 diabetes mellitus	65 (11.5)	30 (7.2)	
Last antipsychotic use before index date, n (%)			
Any second-generation oral	473 (83.9)	369 (88.3)	
Any first-generation oral	36 (6.4)	9 (2.2)	
Any second-generation LAI	43 (7.6)	9 (2.2)	
Any first-generation LAI	11 (2.0)	0) 1 (0.2)	
None			
Other common medications taken during baseline, n (%)			
Antidepressant	381 (67.6)	307 (73.4)	
Mood stabilizer	316 (56.0)	321 (76.8)	
Antihypertensive	222 (39.4)	185 (44.3)	
Anxiolytic	269 (47.7)	254 (60.8)	
Metformin	79 (14.0)	47 (11.2)	
Patients with type 2 diabetes mellitus	34 (52.3)	16 (53.3)	

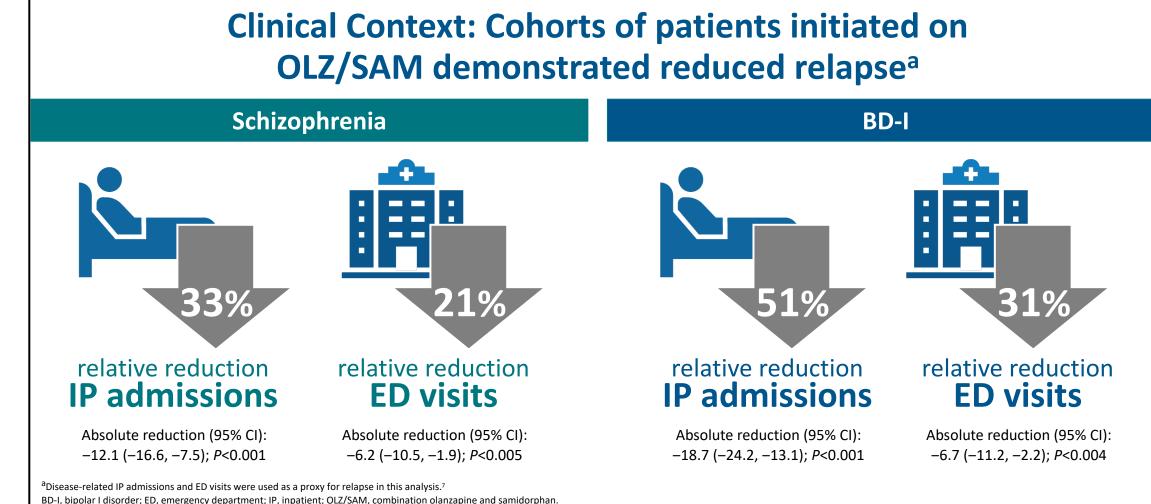


Figure 2. Disease-Related Acute Care Events^a in the Young Adult Subgroup

^aAbsolute changes observed within groups between the baseline and follow-up periods. Results are presented descriptively; no statistical tests

were conducted to compare the young adult subgroup and the full analysis set.

ED, emergency department; IP, inpatient; OLZ/SAM, combination olanzapine and samidorphan

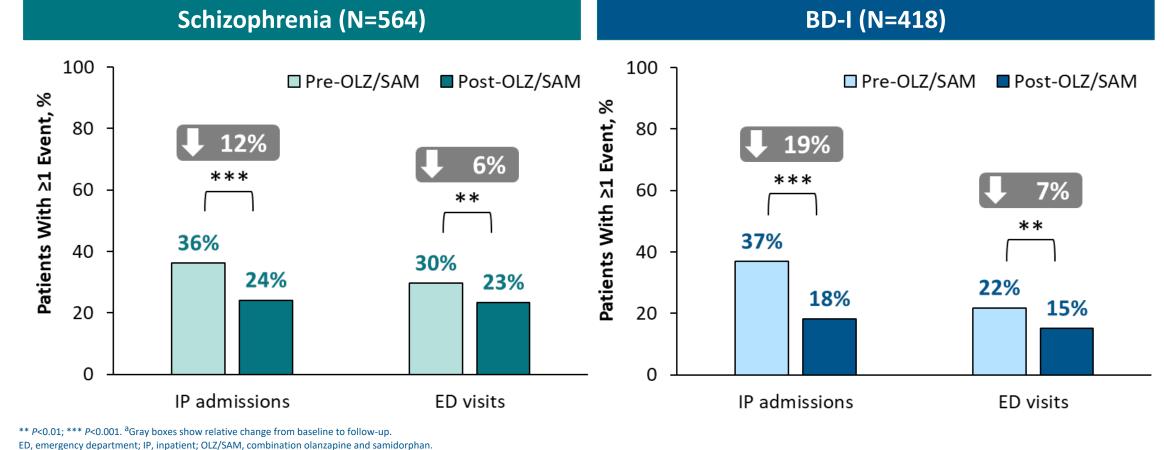


Figure 3. Changes^a in Disease-Related Acute Care Events After Initiation of OLZ/SAM in the Young Adult Subgroup Compared With the Full Analysis Set

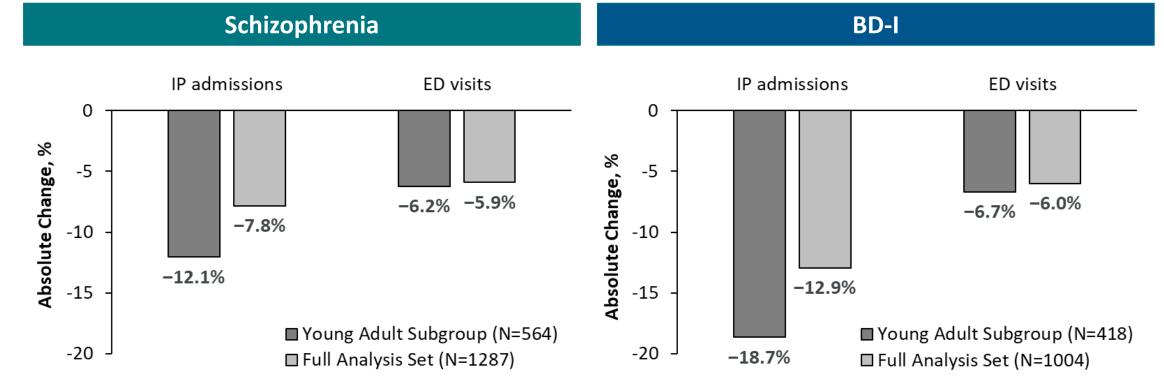


Table 3. All-Cause and Mental Health-Related Acute Care Events in the Young Adult Subgroup Compared With the Full Analysis Set

	S	Schizophrenia Cohort (N=564)		
Event, n (%)	Baseline	Follow-up	Difference	Difference
All cause				
Proportion with ≥1 IP admission, n (%)	282 (50.0)	183 (32.5)	-17.6	-11.3
Proportion with ≥1 ED visit	355 (62.9)	281 (49.8)	-13.1	-7.8
Mental health related				
Proportion with ≥1 IP admission, n (%)	266 (47.2)	171 (30.3)	-16.8	-11.7
Proportion with ≥1 ED visit	286 (50.7)	186 (33.0)	-17.7	-11.7
		BD-I Cohort (N=418)		Overall (N=1004)
	Baseline	Follow-up	Difference	Difference
All cause				
Proportion with ≥1 IP admission, n (%)	210 (50.2)	116 (27.8)	-22.5	-14.0
Proportion with ≥1 ED visit	269 (64.4)	215 (51.4)	-12.9	-9.8
Mental health related				
Proportion with ≥1 IP admission, n (%)	193 (46.2)	103 (24.6)	-21.5	-14.6
Proportion with ≥1 ED visit	180 (43.1)	116 (27.8)	-15.3	-12.4

BD-I, bipolar I disorder; ED, emergency department; IP, inpatient

LIMITATIONS

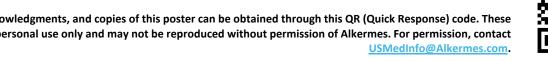
- Results from this population may not be generalizable to uninsured populations
- A claim for a filled prescription does not indicate that the medication was taken as prescribed
- The presence of a diagnosis code may not accurately reflect the presence of disease, and it does not provide any indication of disease severity

CONCLUSIONS

- In this subgroup analysis of young adult patients with schizophrenia or BD-I, initiating OLZ/SAM was associated with statistically significant reductions in disease-related acute care events that serve as a proxy for relapse
- In the schizophrenia and BD-I cohorts, reductions in proportions of patients with diseaserelated IP admissions and ED visits were clinically relevant and numerically larger than those reported previously for the main study
- For young adults with schizophrenia or BD-I who may be in an earlier stage of their illness, initiating OLZ/SAM may be an effective strategy for reducing relapse

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¹Department of Psychiatry, SUNY Upstate Medical University, Syracuse, NY, USA; ¹Neuroscience Education Institute, Lakewood Ranch, FL, USA; ²Neuroscience Education Institute, Lakewood Ran

DISCLOSURES

AJC has been a consultant or on an advisory board for AbbVie, Acadia, Alfasigma, Alkermes, Anavex Life Sciences, Autobahn Therapeutics, Axsome, Biogen, Biohaven, BioXcel, Boehringer Ingelheim, Bristol Myers Squibb, Cerevel, Collegium Pharmaceutical, Corium, Delpor, 4M Therapeutics, Intra-Cellular Therapies, J&J Innovative Medicine, Jazz Pharma, Karuna, Knight Therapeutics, LivaNova, Lundbeck, Luye Pharma, MapLight Therapeutics, Mentavi, Neumora, Neurocrine, NeuroSigma, Noven, Otsuka, PaxMedica, Relmada, Sage Therapeutics, Supernus, Teva, Thynk, Tris Pharma, Vanda Pharmaceuticals, and VistaGen; is on the speakers' bureau for AbbVie, Alfasigma, Alkermes, Axsome, Boehringer Ingelheim, Bristol Myers Squibb, Collegium Pharmaceutical, Corium, Innovative Medicine, Intra-Cellular Therapies, J&J, Knight Therapeutics, Lundbeck, Neurocrine, Noven, Otsuka, Supernus, Teva, Tris Pharma, and Vanda Pharmaceuticals; is on a data safety monitoring board for COMPASS Pathways; holds stock options from 4M Therapeutics; and receives no royalties. HRP and MJD are or were employees of Alkermes, Inc., a health services innovation company that received funding from Alkermes, Inc., to conduct this study and analyze the data used for this publication. HEO has been a consultant for Alkermes, Biogen, Bristol Myers Squibb, Intra-Cellular Therapies, Janssen, Karuna, Neurocrine, Otsuka, Sage Therapeutics, and Sunovion; is on the speakers' bureau and has received honoraria from Alkermes, Bristol Myers Squibb, Intra-Cellular Therapies, Lundbeck, Neurocrine, Otsuka, Neurocrine, Otsuka, Pamlab, Pfizer, Sage Therapeutics, Supernus, Takeda, Teva, Transcend Therapeutics, Otsuka, Pamlab, Pfizer, Sage Therapeutics, Sunovion, Takeda, Tris Pharmaceuticals, and Viatris; served on an advisory board for Adamas, Alkermes, Corium, Eisai, Janssen, Lilly, Lundbeck, Merck, Neos Therapeutics, Otsuka, Pamlab, Pfizer, Shire, Sunovion, Takeda, Tris Pharmaceuticals, and Teva; and received research funding from AbbVie, Lilly, Lundbeck, Otsuka, Pfizer, Shire, Sunovion,

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