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

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BACKGROUND

- Olanzapine/samidorphan (OLZ/SAM) provides the antipsychotic efficacy of olanzapine while mitigating olanzapine-associated weight gain in patients with schizophrenia or bipolar I disorder (BD-I)[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 an extended duration[3]
- 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 relapse[7]
  - 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 relapse[8]

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, and pharmacy claims data from October 18, 2020, to December 31, 2023, from Komodo Healthcare Map

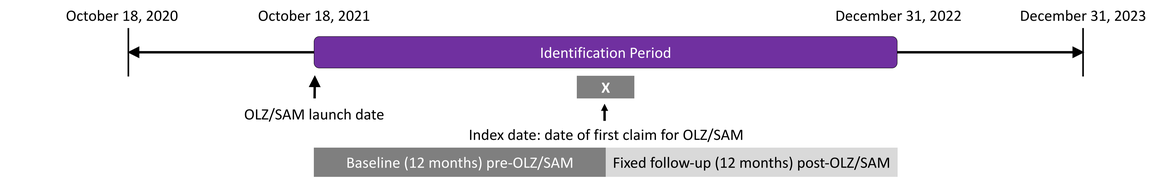
Main Study Criteria

- 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 follow-up 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



OLZ/SAM, combination olanzapine and samidorphan.

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 test was 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

Patients

- 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 with BD-I
- 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)

BD-I, bipolar I disorder.

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)	1 (0.2)
None	16 (2.8)	31 (7.4)
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)

BD-I, bipolar I disorder; LAI, long-acting injectable.

RESULTS

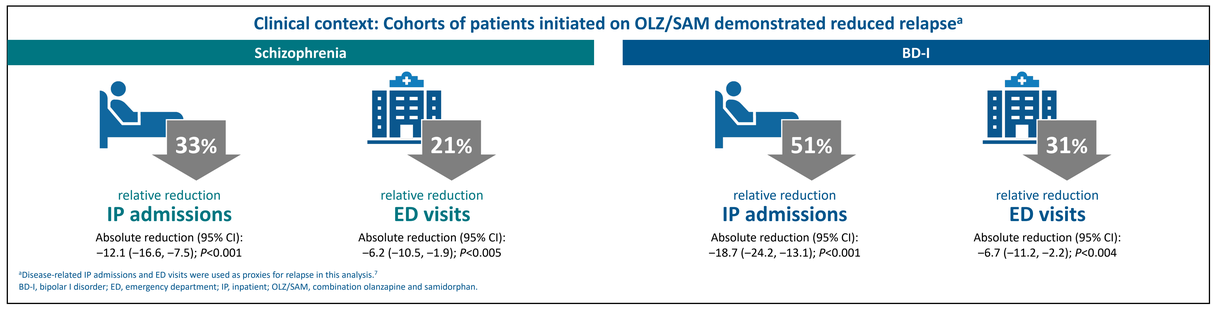
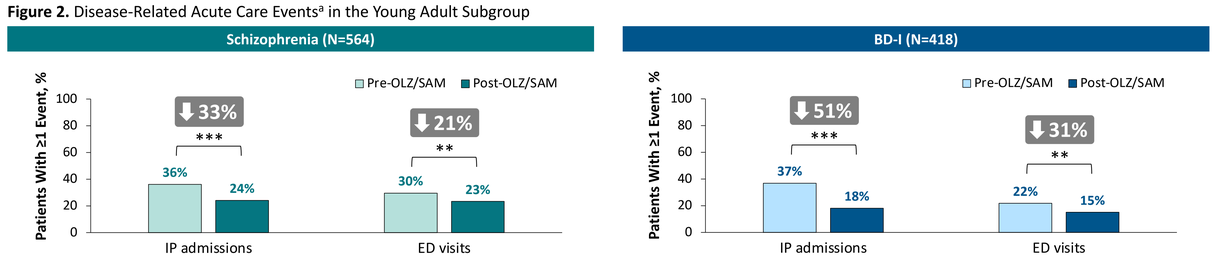
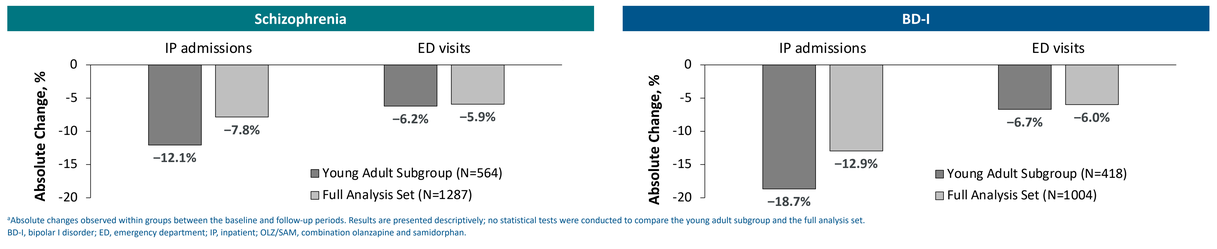


Figure 2. Disease-Related Acute Care Events[a] in the Young Adult Subgroup



** P<0.01; *** P<0.001. [a]Gray boxes show relative change from baseline to follow-up.
BD-I, bipolar I disorder; 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



[a]Absolute 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.
BD-I, bipolar I disorder; ED, emergency department; IP, inpatient; OLZ/SAM, combination olanzapine and samidorphan.

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

Events, n (%)	Schizophrenia Cohort (N=564) Baseline	Schizophrenia Cohort (N=564) Follow-up	Schizophrenia Cohort (N=564) Difference[a]	Overall (N=1287) Difference[a]
All cause				
Proportion with ≥1 IP admission	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	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) Baseline	**BD-I Cohort (N=418)** Follow-up	**BD-I Cohort (N=418)** Difference[a]	**Overall (N=1004)** Difference[a]
All cause				
Proportion with ≥1 IP admission	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	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**

[a]Follow-up vs baseline difference. Bold text indicates statistically significant difference (all *P*≤0.001).
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 proxies for relapse
- In the schizophrenia and BD-I cohorts, reductions in proportions of patients with disease-related 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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DISCLOSURES

AJC has been a consultant or on an advisory board for AbbVie, Acadia, Actinogen, Alfasigma, Alkermes, Anavex Life Sciences, Arrivo BioVentures, Autobahn Therapeutics, Axsome, Aytu Biopharma, BioXcel, Boehringer Ingelheim, Bristol Myers Squibb, Collegium Pharmaceutical, Corium, Definium Therapeutics, Helus Pharma, Incannex Healthcare, Intra-Cellular Therapies, J&J Innovative Medicine, Jazz Pharma, Knight Therapeutics, Kuvatris Therapeutics, Kye Pharmaceuticals, LivaNova, Lundbeck, Luye Pharma, 4M Therapeutics, MapLight Therapeutics, Mentavi, Neumora, Neurocrine Biosciences, Noven, Otsuka, Sensorium Therapeutics, Sirtsei Pharmaceuticals, Supernus, Teva, Thynk, Transneural Therapeutics, Tris Pharma, Vanda Pharmaceuticals, and Vistagen; is on the speakers' bureau for AbbVie, Alfasigma, Alkermes, Axsome, Aytu Biopharma, Bristol Myers Squibb, Collegium Pharmaceutical, Corium, Intra-Cellular Therapies, J&J Innovative Medicine, Knight Therapeutics, Kye Pharmaceuticals, Lundbeck, Luye Pharma, Neurocrine Biosciences, Noven, Otsuka, Supernus, Teva, Tris Pharma, and Vanda Pharmaceuticals; serves on a data safety monitoring board for Compass Pathways; and holds stock options/equity from EMA Wellness, Evolution Research Group, 4M Therapeutics, Sensorium Therapeutics, and Transneural Therapeutics. **HRP** and **MJD** are or were employees of Alkermes, Inc., and may own stock/options in the company. **AGH** is or was an employee of Optum, 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 AbbVie, 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, Johnson & Johnson, Lundbeck, Luye Pharma, Neurocrine, and Teva; receives no royalties; and holds no stock options. **RJ** has been a consultant for AbbVie, Acadia, Adamas, Alfasigma, Alkermes, Almatica, Axsome, Biogen, Boehringer Ingelheim, Cingulate Therapeutics, Corium, Eisai, Evidera, Impel, Janssen, Lilly, Lundbeck, Merck, Neos Therapeutics, Neurocrine Biosciences, Osmotica, Otsuka, Pamlab, Pfizer, Sage Therapeutics, Shire, Sunovion, Supernus, Takeda, Teva, Transcend Therapeutics, and Viatris; received speaker/promotional honoraria from AbbVie, Alkermes, Almatica, Axsome, Corium, Eisai, Intra-Cellular Therapies, Ironshore Pharmaceuticals, Janssen, Lilly, Lundbeck, Merck, Neos Therapeutics, Otsuka, Pamlab, Pfizer, Shire, Sunovion, Takeda, Tris Pharmaceuticals, and Viatris; served on an advisory board for Adamas, Alkermes, Corium, Eisai, Janssen, Lilly, Lundbeck, Merck, Neos Therapeutics, Neurocrine Biosciences, Otsuka, Pamlab, Pfizer, Sage Therapeutics, Shire, Sunovion, Supernus, Takeda, and Teva; and received research funding from AbbVie, Lilly, Lundbeck, Otsuka, Pfizer, Shire, and Takeda.

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