Treatment Patterns From OASIS: Observational Study of Long-Acting Injectables in Schizophrenia

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INTRODUCTION

- Atypical long-acting injectable (aLAI) antipsychotic formulations have been associated with reduced relapse rates and hospitalization risk, but they may be underused in patients with schizophrenia[1,2]
- OASIS (Observational Study of Long-Acting Injectables in Schizophrenia; NCT03919994) was an assessment of real-world treatment patterns and clinical, socioeconomic, and patient-reported outcomes in patients with schizophrenia initiating an aLAI antipsychotic

OBJECTIVE

- To present the treatment patterns observed with aLAI antipsychotic use in OASIS
  - Please see poster 157 for baseline patient demographics and locations of care characteristics and poster 163 for clinical outcomes observed in OASIS

METHODS

Study Design

- OASIS was a prospective, noninterventional, multicenter cohort study, conducted between March 2019 and January 2023, that enrolled adults with schizophrenia following their clinician's decision to initiate 1 of 4 of the most commonly prescribed aLAI antipsychotics (2019): aripiprazole lauroxil, aripiprazole monohydrate, paliperidone palmitate, or risperidone LAI

Assessments and Analysis

- Index aLAI was given in the 10 days before to 30 days after the baseline visit (study day 1)
- Key outcomes assessing treatment patterns were evaluated prospectively for up to 12 months from baseline visit
  - Patterns of aLAI antipsychotic use included the number, timing, and reasons for treatment switches and discontinuations

RESULTS

Table 1. Reported Reasons for Initiating aLAI Antipsychotics (>1 response was allowed)

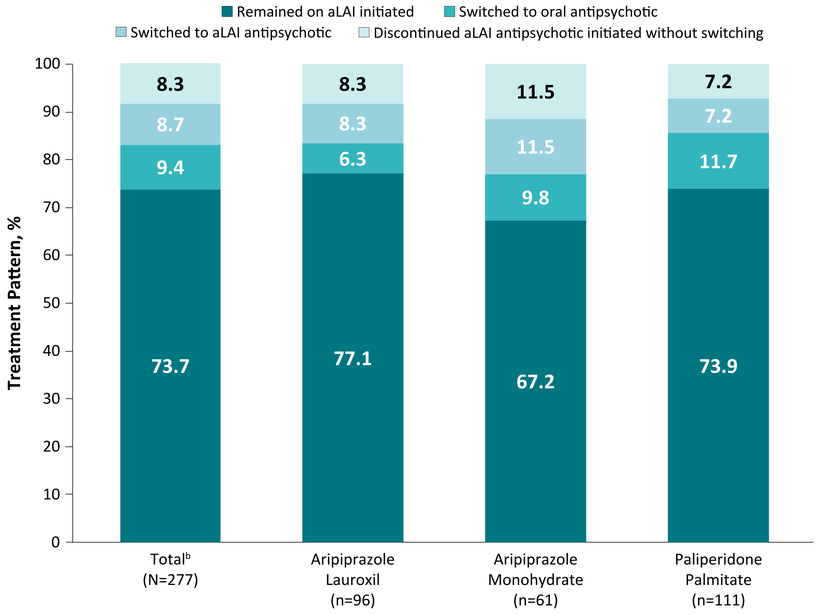
	Total[a] (N=277)	Aripiprazole lauroxil (n=96)	Aripiprazole monohydrate (n=61)	Paliperidone palmitate (n=111)
Reasons for initiating any aLAI antipsychotic,[b] n (%)				
Persistent psychotic symptoms	139 (50.2)	57 (59.4)	25 (41.0)	55 (49.6)
Need for better monitoring due to suboptimal adherence	123 (44.4)	43 (44.8)	20 (32.8)	55 (49.6)
Patient request	72 (26.0)	23 (24.0)	15 (24.6)	32 (28.8)
Family request	38 (13.7)	13 (13.5)	3 (4.9)	22 (19.8)
History of improvement on aLAI antipsychotics	37 (13.4)	10 (10.4)	12 (19.7)	15 (13.5)
Recommended by case manager or another clinician	34 (12.3)	10 (10.4)	8 (13.1)	16 (14.4)
Persistent psychotic symptoms in setting of substance abuse problems	22 (7.9)	4 (4.2)	9 (14.8)	9 (8.1)
Recent or anticipated change in living situation	19 (6.9)	6 (6.3)	5 (8.2)	8 (7.2)
Other	14 (5.1)	3 (3.1)	2 (3.3)	9 (8.1)
Reasons for selecting a specific aLAI antipsychotic,[b] n (%)				
Past clinical experience with a specific aLAI over others	112 (40.4)	53 (55.2)	20 (32.8)	39 (35.1)
Efficacy history with oral version	101 (36.5)	26 (27.1)	25 (41.0)	44 (39.6)
Patient's preference for injection interval	44 (15.9)	16 (16.7)	10 (16.4)	18 (16.2)
Tolerability history	41 (14.8)	12 (12.5)	11 (18.0)	15 (13.5)
Patient's history of efficacy or tolerability problems with another medication	35 (12.6)	15 (15.6)	7 (11.5)	13 (11.7)
Easily accessible	17 (6.1)	5 (5.2)	2 (3.3)	10 (9.0)
Clinician's experience with oral equivalent over others	14 (5.1)	5 (5.2)	2 (3.3)	6 (5.4)
Clinician's preference for dosing options	9 (3.3)	7 (7.3)	1 (1.6)	0
Other	30 (10.8)	7 (7.3)	3 (4.9)	20 (18.0)

[a]The risperidone LAI group was included in total N and percentages but is not reported individually because of the low number of observations (n=9).
[b]Multiple responses allowed; therefore, responses may not sum to 100%.
aLAI, atypical long-acting injectable.

Key Message: Among patients with schizophrenia receiving care in mostly community, outpatient settings and receiving aLAIs, most patients remained on the aLAI they initiated

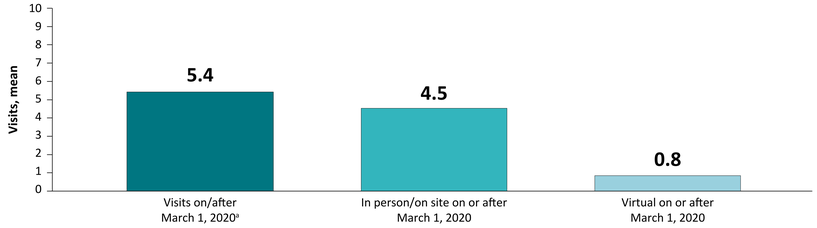
- Overall, 46.9% of patients who were enrolled in OASIS completed the study
  - Mean (SD) time on the study was 249.3 (146.7) days
  - The most common reason for patients ending participation was loss to follow-up, while the second most common was patient decision
- Mean (SD) time on the initiated treatment was 210.0 (145.3) days, with nearly 74% remaining on the aLAI antipsychotic that was initiated (**Figure 1**)
- Most visits occurred after the COVID-19 pandemic began and were in person/on site (**Figure 2**)

Figure 1. Treatment Patterns[a]



[a]Does not account for patients who stopped the study before 12 months.
[b]Risperidone LAI group was included in total percentages but not reported individually because of the low number of observations (ie, n=9).
aLAI, atypical long-acting injectable.

Figure 2. Visit Patterns During the COVID-19 Pandemic; N=277



[a]Approximate start of the COVID-19 pandemic.

LIMITATIONS

- Because of the nonrandomized, observational design of OASIS, outcomes were evaluated descriptively and no statistical comparisons were conducted
- Overall sample size was lower than anticipated, in part because of challenges associated with the COVID-19 pandemic; the low enrollment of patients initiating risperidone treatment may not reflect real-world patterns of use
- Some patients were lost to follow-up and/or did not contribute complete data
- The study goal was to capture "real-world" clinician and patient decisions made regarding aLAI choice; the possibility that participation in this research study affected treatment decisions made cannot be excluded

CONCLUSIONS

- The baseline demographic and location-of-care characteristics of OASIS are presented in poster 157 and show that patients with schizophrenia enrolled in the study received care mostly in community, outpatient settings
- Previous research has highlighted the minimal impact of the COVID-19 pandemic on demonstrated aLAI antipsychotic adherence[3]
- The observed treatment patterns, including time on aLAI antipsychotic treatment, are generally consistent with those observed in other observational studies[4-6]
- The frequency of patients remaining on their index aLAI antipsychotic and attending in-person visits reinforces the utility of using these formulations for patients with schizophrenia, even during periods of hardship such as a pandemic

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AUTHOR DISCLOSURES

LNS, MJD, CA, and **JAM** are or were employees of Alkermes, Inc., and may own stock/options in the company.

PJW is a former employee of Alkermes, Inc., and has been a consultant for Alkermes, Inc., Lyndra, MapLight, and Teva.

EDA has consulted or served on advisory boards for Alkermes, Atheneum, Janssen, Karuna, Lundbeck/Otsuka, Neurocrine Biosciences, Roche, Sunovion, and Teva and has received research funding from Alkermes, Astellas, Biogen, Boehringer Ingelheim, CMS, InnateVR, Janssen, National Network of Depression Centers, Neurocrine Biosciences, Novartis, Otsuka, Pear Therapeutics, and Takeda.

PDH has received fees for consulting and travel from Alkermes, BioXcel, Boehringer Ingelheim, Karuna, Minerva, and Sunovion; royalties for Brief Assessment of Cognition in Schizophrenia (owned by VeraSci, Inc.); and grant support from Stanley Medical Research Foundation and Takeda; and is chief scientific officer with i-Function, Inc.

JMK has been a consultant for or received honoraria from Alkermes, Boehringer Ingelheim, Click Therapeutics, Intra-Cellular Therapies, Janssen, Johnson and Johnson, Karuna, LB Pharmaceuticals, Lundbeck, Lyndra, Merck, Neurocrine Biosciences, Newron, Otsuka, Pierre Fabre, Reviva, Roche, Saladax, Sunovion, Takeda, and Teva; has received grant support from Janssen, Lundbeck, and Otsuka; and is a shareholder of LB Pharmaceuticals and Vanguard Research Group.

SRS is an employee of The University of Texas at Austin College of Pharmacy; was appointed to the Texas Health and Human Services Commission, San Antonio State Hospital, and UT Health San Antonio Long School of Medicine; has consulted for Alkermes, BioXcel, Genomind, Janssen, Karuna, and Otsuka; has participated on speakers bureaus for BioXcel, Neurocrine, Otsuka PsychU, Teva, and Texas Society of Health-System Pharmacists and several professional organizations; serves on the Business Development Council for the College of Psychiatric and Neurologic Pharmacists; has served as a defendant and plaintiff expert witness; and has no direct stock ownership in any pharmaceutical corporation.

JT was an employee of Worldwide Clinical Trials.

DIV has served as a consultant for and has received research grant funding from Alkermes; has served as a consultant, speaker, and advisory board participant for Otsuka; has served as a consultant and speaker for Janssen and Teva; and has served as an advisory board participant for Lyndra.

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