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

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INTRODUCTION

- Atypical long-acting injectable (aLAI) antipsychotic medications are effective treatments for schizophrenia, reducing risk of relapse and hospitalization,[1,2] but they may be underused in the treatment of schizophrenia[3]
- 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 key clinician- and patient-reported outcomes observed with aLAI antipsychotic use in OASIS
  - Please see poster 157 for baseline patient demographics and location-of-care characteristics and poster 161 for treatment patterns observed in OASIS

METHODS

Study Design

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

Assessments and Analyses

- Clinical outcomes
  - The Clinical Global Impressions–Severity (CGI-S) scale—a clinician-rated assessment of mental illness severity scored on a scale of 1 (normal, not at all ill) to 7 (most extremely ill)
  - *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, Clinician-Rated Dimensions of Psychosis Symptom Severity—an 8-item measure capturing individual symptom severity of psychosis in the dimensions of hallucinations, delusions, disorganized speech, abnormal psychomotor behavior, negative symptoms, impaired cognition, depression, and mania scored on a scale of 0 (not present) to 4 (present and severe)
- Patient-reported outcomes
  - Glasgow Antipsychotic Side-Effect Scale—a patient-reported measure with 22 questions assessing side effects in the past week (eg, My legs have felt restless and/or I couldn't sit still [ie, akathisia]) and scored on a scale of 0 (never) to 3 (everyday); total score is reported

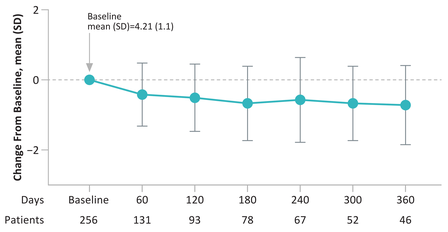
RESULTS

- All cohorts had similar changes across illness severity, symptom severity, and side effects of antipsychotic measures; thus, overall data are presented
- Among 277 patients enrolled in OASIS, overall illness severity was moderate at baseline as assessed by a CGI-S score of 4.21
  - After initiating aLAI treatment, overall illness severity remained stable over time among patients with available data (**Figure 1**)
- Antipsychotic side effects at baseline were absent or mild
  - During follow-up, patient-reported antipsychotic side effects remained absent or mild with aLAI treatment (**Figure 2**)
- Individual symptoms at baseline ranged from equivocal to mild, as assessed by the DSM-5 symptom severity scale
  - Psychotic symptoms remained stable with aLAI treatment across most domains in observed cases (**Figure 3**)

RESULTS

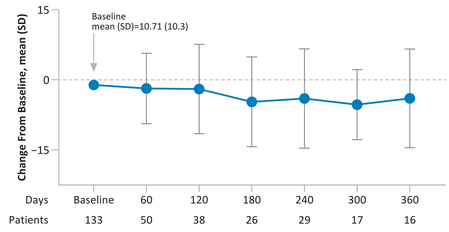
Key Message: Among patients with schizophrenia receiving care in mostly community, outpatient settings and receiving aLAIs, most patients had stability on overall illness and symptom severity

Figure 1. Illness Severity as Assessed by CGI-S[a]



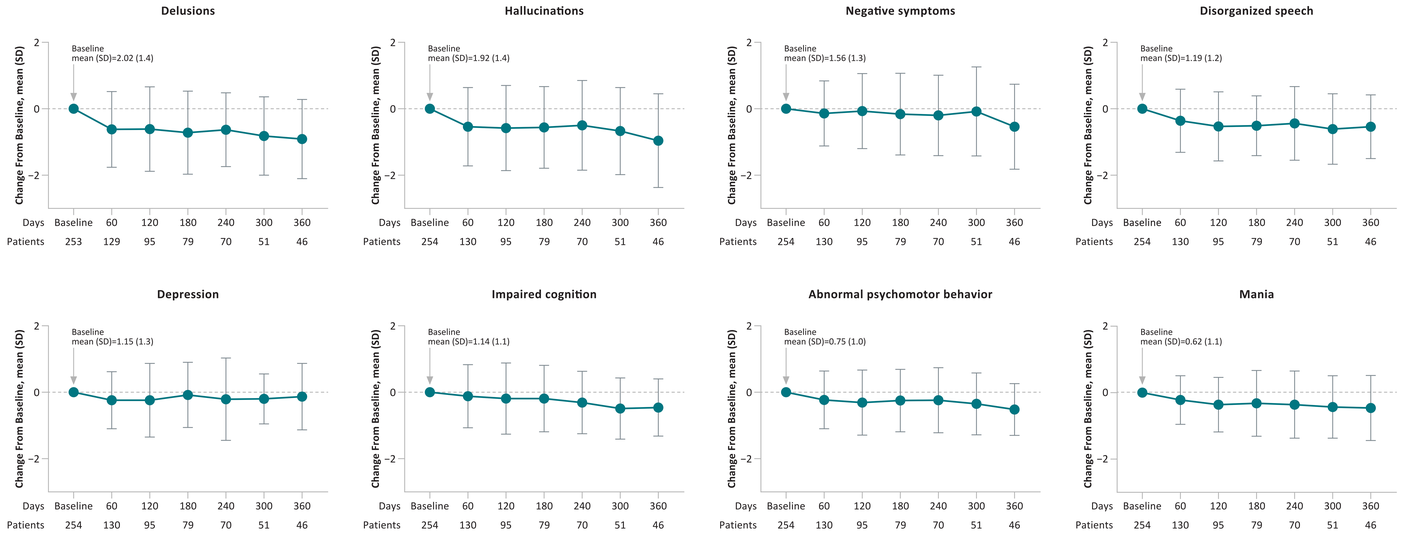
[a]No statistical comparisons were conducted. All cohorts have low numbers at all time points. Presented data are observed cases.
CGI-S, Clinical Global Impression–Severity.

Figure 2. Side Effects of Antipsychotics[a]



[a]Assessed via the Glasgow Antipsychotic Side-Effect Scale. Total score (0–66) can be interpreted continuously or as 0–21=absent or mild, 22–42=moderate, ≥43=severe. No statistical comparisons were conducted. All cohorts have low numbers at all time points. Presented data are observed cases.

Figure 3. Symptom Severity[a]



[a]No statistical comparisons were conducted. All cohorts have low numbers at all time points. Presented data are observed cases.

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
- No study visits were mandated; the frequency of follow-up was determined by clinicians
- Some patients were lost to follow-up and/or did not contribute complete data
- The outcomes observed in OASIS may not be generalizable to the larger population of people living with schizophrenia who are treated with an aLAI antipsychotic

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 in mostly community, outpatient settings
- The treatment patterns of OASIS are presented in poster 161 and show that, overall, 47% of patients who enrolled in OASIS completed the study
- Among patients in the OASIS study who had available data, results suggest that those with schizophrenia who initiated an aLAI antipsychotic had stability on illness severity over 12 months of potential follow-up
- Symptoms of schizophrenia were stable
- Patient-reported antipsychotic side effects were absent or mild

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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, 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, 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 has served as an advisory board participant for Lyndra.

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