interaction, family functioning, education/employment, sexual functioning, and leisure activities. Additionally, panellists reached consensus that dimensions should be minimally impairing, if present (excluding sexual functioning) and asked about at every encounter with the patient (excluding sexual functioning and leisure activities). In summary, this Delphi panel yielded agreement that functional recovery is multidimensional and should be assessed regularly as part of usual care on an individual patient level in FEP and EP schizophrenia patients.
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Delphi Panel on the Relationship Between Long-Acting Injectable Antipsychotics and Longer-Term Functional Recovery in First-Episode and Early-Phase Schizophrenia Patients

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Abstract

Schizophrenia is among the top ten causes of years lost due to disability. Goals of treatment are evolving beyond remission of psychotic symptoms to include physical and mental functioning, quality of life, and long-term functional recovery. Evidence has shown long-acting injectables (LAIs) are beneficial for schizophrenia patients by increasing treatment adherence and decreasing relapse and rehospitalisation. This potentially reduces disease progression and facilitates functional recovery. However, LAIs are underused and often seen as a last resort for first-episode (FEP) and early-phase (EP) patients, due to physicians' lack of familiarity and stigma.

A three-round modified Delphi panel was held to gain expert consensus on an approach to functional recovery in FEP and EP patients with LAIs. A literature review and input from a steering committee of 5 experts in psychiatry informed the development of statements. Round one was carried out via one-to-one video conference interviews, and the subsequent rounds were conducted via electronic surveys, which enabled international collaboration. Delphi panellists were 17 psychiatrists with schizophrenia treatment experience, practicing in 7 countries (France, Italy, US, Germany, Spain, Denmark, and UK). Several analysis rules determined whether a statement could progress to the next round and specified the level of agreement required to achieve consensus. Measures of central tendencies (mode, mean) and variability (interquartile range) of aggregated responses from the previous round were reported to panelists to understand their response in relation to the group.

There was consensus (defined a priori as ≥80% agreement) on the 8 statements relating to long-term treatment goals and LAI links to functional recovery. LAI treatment in FEP and EP patients increases adherence and reduces treatment burden and functional decline compared to the same and other oral medication. Additionally, there was consensus that LAIs lead to better treatment outcome and functional recovery. Other important factors to achieving functional recovery include patient attitude towards treatment and psychoeducation. Furthermore, consensus was reached that functional recovery and quality of life are linked. In summary, this Delphi panel yielded agreement that functional recovery is a reachable goal for FEP and EP patients and can be enhanced using LAIs.
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A Prospective Observational Study Examining the Real-World Clinical and Treatment Outcomes of Parkinson's Disease Psychosis in the United States

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Abstract

Introduction. Psychosis is a common feature of Parkinson's Disease (PD), affecting approximately 50% of PD patients during their disease course. The INSYTE study was the first prospective, real-world, observational study examining the outcomes of both treated and untreated patients with PD Psychosis (PDP).
Methods. PDP patients were enrolled from 76 US academic centers and community sites from 03/21/2017 to 03/08/2021. Patients were included in the final analytical cohort if they had a baseline visit and at least 1 follow-up visit within 3 years; due to the variability of follow-up for each patient within the 3-year period, all study outcomes were assessed in patients with at least one baseline and two follow-up visits within 1 year. No specific visit schedule was imposed; all interactions were established by the investigators. Questionnaires were completed at follow-up visits and assessments focused on PDP treatment utilization, treatment patterns, clinical outcomes, caregiver burden, quality of life, and resource utilization.
Results. 760 patients were initially enrolled; 635 patients (84%) were included in the final study group, and 441 patients (69%) were included in the analysis. 281 patients (64%) had no antipsychotic treatment at enrollment (untreated group) vs 160 (36%) who had received an antipsychotic at enrollment (treated group).

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At enrollment, patients in the untreated vs treated group, respectively, had a mean PD duration of 8.05 vs 10.23 years, mean duration of PDP features of 2.20 vs 3.10 yrs, and had a PDP diagnosis for a mean of 1.42 vs 2.16 yrs. Most patients in the untreated group (n=221, 77%) received no antipsychotics through follow-up. The groups were balanced in terms of age (mean 73.9 vs 73.4 yrs) and sex (65.1% vs 63.1% male). The untreated group had higher rates of hypertension (44.5% vs 36.8%) and diabetes (12.8% vs 8.8%); however, the treated group had higher rates of depression (25.6% vs 41.3%) and anxiety (22.8% vs 26.9%). The percent change from baseline at 12 months in total psychosis, hallucination, and delusion scores for the untreated group showed greater worsening than the treated group: 32.3% vs 29.3%; 29.3 % vs 25.0%; and 29.3 % vs 25.0%, respectively, as did daytime sleepiness scores (51.6% vs 40.8%). Measures of PD severity (non-motor and motor MDS-UPDRS scores) and health-related quality of life showed less worsening for the untreated group vs treated group at 12 months. Caregiver burden (per the ZBI) was lower in the untreated group vs the treated group (81.5% vs 90.0%).

Conclusions. In this descriptive analysis, untreated patients had shorter duration of PD, fewer PDP symptoms at baseline, and lower rates of mental health comorbidities vs treated patients. The untreated PDP patients had greater worsening in their psychosis and sleepiness scores at 12 months versus the treated group, yet remained untreated. Future studies are needed to better understand clinicians' rationale for withholding PDP treatment.

Funding. Acadia Pharmaceuticals, Inc

Study Outcomes Among Patients with Parkinson's Disease Treated for Psychosis Residing in the Long-Term Care Setting and Newly Initiating Pimavanserin or Off-Label Atypical Antipsychotics

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Abstract

Introduction. Psychosis is a common feature of Parkinson's Disease (PD), with an estimated 50% of PD patients experiencing psychosis (i.e., hallucinations [H] or delusions [D]) at some time during the course of their illness. Pimavanserin (PIM) is the only medication approved in the US for the treatment of H&D associated with Parkinson's disease psychosis (PDP); however, off-label atypical antipsychotics (AAP) are continuously used. Currently, there are very few real-world studies which evaluate the patient characteristics and clinical outcomes among PD patients residing in the long-term care (LTC) setting within the US, newly initiated on PIM or other AAPs to treat psychosis.

Methods. A national LTC database consisting of diagnoses (DX), pharmacy orders (RX), and EHR data linked with the Minimum Data Set (MDS) was used to identify PD patients with a PD DX and 1 PD RX from 01/01/2017 to 09/30/2021 retrospectively. Patient groups were created: PIM group (patients with a PIM RX); AAP group (patients with an AAP RX [and no PIM RX]); and no treatment (No Tx) group (no PIM or AAP RX). All patients were required to have at least 100 days in LTC to be labelled as a resident (≤7 days between discharge and admission were included as LTC stay). Psychosis diagnosis was required at any time for the AAP and No Tx groups. Other medical causes of psychosis beyond PD were not excluded. The index dates were the first RX identified during the study time period for the PIM and AAP groups; and the psychosis DX date for the No Tx group. Incident treatment patients were defined as having no history of PIM or AAP in the 6 months prior to the index date. Patient/clinical characteristics, treatment patterns, and study outcomes were reported using means (SD) and frequencies during the post index period.

Results. There were: PIM group (N=3,120; N=870 incident), AAP group (N=5,880; N=2,396 incident), and No Tx group (N=1,802). The PIM and AAP groups had an average of 415 days and 383 days between the admitting date and the date of RX. The mean age among all groups was 76–77 years and 48–50% were female. PIM group patients were observed to be sicker with higher rates of concomitant dementia, depression, diabetes, and hypertension versus the AAP group or No Tx group. Initial treatments in the AAP group were mostly quetiapine (49%), risperidone (21%), or olanzapine (12%). The descriptive analysis during the 6 months post index showed the outcomes for the incident AAP group to have: higher proportion of falls and aggression events; higher incidence of new DX (physical changes, anxiety disorders, cognitive decline, insomnia, depression, and anticholinergic effects); and higher proportion of new medication orders (anticonvulsants, antidepressants, and benzodiazepines) compared with the incident PIM group.

Conclusions. In this descriptive LTC retrospective analysis, incident PIM patients were shown to have better outcomes versus the AAP group. These findings are subject to study limitations.

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Hyperammonemia and First-Degree Atrio-Ventricular Block in Adult Male from Valproic Acid Toxicity

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Abstract

Introduction. The purpose of this case study is to review the clinical presentation and medical work of an adult male who experienced symptomatic hyperammonemia and first-degree atrio-ventricular block in the setting of valproic acid toxicity.

Method. This case involves a 28-year-old African American male with a past psychiatric history of bipolar 1 disorder with psychotic

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