Clinical and functional response to paliperidone palmitate in early schizophrenia—a retrospective observational study in newly diagnosed patients treated over a 12-month period

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Background
- Data on the use of long-acting injectable antipsychotic therapy (LAT) in newly diagnosed patients with schizophrenia are sparse, despite findings that this population may significantly benefit from LAT1
- Rehospitalization in the early stages of schizophrenia has been identified as a significant predictor of poorer outcome,2 while clinical gain upon treatment of early psychosis predicts long-term outcome3
- Reducing symptom severity and achieving improvements in functioning are important goals for early treatment of schizophrenia4

Therefore, optimizing treatment response and providing continuous treatment through LAT may result in favourable long-term outcomes

Objectives
- The objective of the study was to retrospectively evaluate the clinical and functional response of patients treated with paliperidone palmitate (PP) for 12 months and the number of hospitalizations following PP initiation

Methods
- Retrospective, non-interventional, multicentre, exploratory study of adult, newly diagnosed patients with schizophrenia who received continuous treatment with PP for at least 12 months
- The evaluation period started from documentation of the first PP injection (baseline) and ended after the first 12 months of continuous treatment (endpoint)

Written informed consent was collected from all patients

Here we present the clinical response outcomes. Data on the baseline characteristics, dosing, and hospitalizations are reported elsewhere

Results
- Overall 90 patients were documented, 84 met the eligibility criteria and were included in the full analysis set (FAS). Of the six patients not meeting the eligibility criteria, four had documented use of PP and were therefore included in the safety set (SS, n=88)

Mean age was 24.1 years, 69.0% male

In total, 69.0% of patients received PP according to the initiation regimen recommended in the summary of product characteristics (150 mg Day 1, 100 mg Day 8, ± 4 days, both in deltoid muscle)

From Month 1 onwards, 76 (69.7%) patients did not change their dose, 5 (6.0%) patients had a dose increase and 24 (26.6%) patients had a dose decrease.

Hospitalizations
- Overall, 81 (91.4%) patients had no new hospitalization during the 12-month documentation period

Three (3.6%) patients had one new hospitalization for management of an episode/relapse, lasting 10, 12, and 25 days, respectively

All three new hospitalizations during the study occurred for management of an episode/relapse

Clinical response
- In patients with PANSS assessment (n=72), 79% achieved a clinical response as indicated by a PANSS improvement of ≥20% from baseline to endpoint (Figure 1)

Safety and tolerability
- Adverse drug reactions (ADRs) as documented in the patients’ medical records

Several patients (n=45) had a clinical response as indicated by a PANSS improvement of ≥20% from baseline to endpoint (Figure 1)

In patients with PSP assessment (n=72), 79% achieved a clinical response as indicated by a PANSS improvement of ≥20% from baseline to endpoint (Figure 1)

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Amenorrhea, n (%) 2 (2.3)

Table 1. ADRs occurring in ≥2% of patients (SS) n=88

Weight increased, n (%) 8 (9.1)

Hyperprolactinaemia, n (%) 2 (2.3)

Somnolence, n (%) 2 (2.3)

Depression, n (%) 2 (2.3)

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Conclusions
- In this newly diagnosed population of patients with schizophrenia, the majority of patients achieved clinically relevant improvements in illness severity and functioning over the 12 months following initiation of LAT

At last PP administration, the majority of patients were deemed to have a clinically relevant improvement in illness severity (clinical response, 97%) or functioning (functional response, 65%) (Figure 4)

Objectives
- The objective of the study was to retrospectively evaluate hospitalization, drug utilization, patterns of paliperidone palmitate (PP) use, and clinical outcomes from the medical records of newly diagnosed patients with schizophrenia

Here we present the clinical response outcomes. Data on the baseline characteristics, dosing, and hospitalizations are reported elsewhere

Methods
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The evaluation period started from documentation of the first PP injection (baseline) and ended after the first 12 months of continuous treatment (endpoint)

Written informed consent was collected from all patients before data collection and analysis

Key selection criteria
- Patients aged 18–29 years at time of first PP injection with diagnosis of schizophrenia (International Classification of Diseases (ICD)-10 or Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV))

First psychotic episode suggestive of schizophrenia must have occurred not longer than 1 year before the first PP injection

Documentation of continuous treatment (defined as regular consecutive injections as prescribed by the treating clinician), with not more than one missed injection within the 12-month documentation period) for PP for at least 12 months (365 ± 31 days) administered for the first time as part of clinical practice

Not having been treated with any LAT prior to PP initiation or with an LAT other than PP during the 12-month documentation period

Patients (%)

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Conclusions
- In this newly diagnosed population of patients with schizophrenia, the majority of patients achieved clinically relevant improvements in illness severity and functioning over the 12 months following initiation of PP

The number of hospitalizations following PP initiation was low, and in line with a previous study of first episode patients treated with long-acting risperidone5

Using an atypical long-acting antipsychotic early in the disease course may help to reduce relapse, promote sustained remission and achieve better long-term outcomes6

References

Deliverables
- LH, PB, PC, and AS are employees of Janssen-Cilag.
- This poster was first presented at the EFA Congress, 12-15 March 2016, Madrid, Spain
- Information was last updated on June 1, 2016

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Disclosures
- LH, PB, PC, and AS are employees of Janssen-Cilag.

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