Article: 1736
Topic: 69 - Schizophrenia

LONG-ACTING INJECTABLE RISPERIDONE AND ORAL ANTIPSYCHOTICS IN PATIENTS WITH SCHIZOPHRENIA - A PROSPECTIVE ONE-YEAR NON-INTERVENTIONAL STUDY (INORS)

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Introduction and objectives: To explore safety, tolerability, treatment response and hospitalizations in adult patients with schizophrenia treated with long-acting injectable risperidone (RLAI) or oral antipsychotic standard of care (oAP) in routine clinical practice.
Methods: Prospective one-year open-label non-interventional study exploring flexible doses of RLAI and oAPs. Primary outcome was the number of hospitalizations from baseline to endpoint. Additional outcomes were changes in the Clinical Global Impression of Schizophrenia (CGI-SCH), patient functioning (Global Assessment of Functioning) and treatment-emergent adverse events (TEAEs).
Results: The intent-to-treat analysis included 561 patients on RLAI and 522 patients on oAPs (44% female gender, mean age (±SD) 42.2±13.1 years) . Demographics and baseline characteristics were comparable, yet RLAI-treated patients had higher disease severity, lower baseline functioning and more substance abuse. The number of hospitalizations did not differ between the two groups while median duration of hospitalization was significantly shorter with RLAI (12.3 vs 20.6 days). Positive, negative, cognitive symptoms, disease severity, patient functioning and medication satisfaction improved significantly better with RLAI than oAPs. The most frequently reported TEAEs (≥2% in any group) for RLAI and oral APs were increase of body weight (5.0%; 5.6%), psychotic disorder (2.7%; 4.0%), schizophrenia (2.5%; 3.1%), anxiety (2.3%; 2.7%), insomnia (0.9%; 3.1%) and somnolence (0.4%; 2.5%), respectively.
Conclusion: This one-year non-interventional study supports results of recent randomized controlled trials that treatment with RLAI is associated with less days spent in hospital, better symptomatic and functional outcomes and higher patient satisfaction with medication compared to oral APs.

https://doi.org/10.1016/S0924-9338(13)76716-6 Published online by Cambridge University Press