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SAFETY, TOLERABILITY AND TREATMENT RESPONSE OF FLEXIBLE DOSES OF PALIPERIDONE ER IN ACUTELY EXACERBATED PATIENTS WITH SCHIZOPHRENIA

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Objective: To explore tolerability, safety and treatment response of flexible doses of oral paliperidone ER in patients with schizophrenia suffering from an acute episode.

Methods: Interim analysis of a 6-week prospective, open-label, international study. Endpoints were the rate of responders defined as a ≥30% improvement in the Positive and Negative Syndrome Scale (PANSS) from baseline to endpoint, the Clinical Global Impression-Severity Scale (CGI-S), weight change and adverse events (AEs).

Results: 100 patients were analyzed (51% male, mean age 39.0±11.6 years). 82% of patients completed the study. Most frequent reasons for early discontinuation were subject choice (10%) and lack of efficacy (7%). The mean dose of paliperidone ER was 5.9 mg/day at baseline and 7.9 mg/day at endpoint. An improvement of ≥30% in total PANSS was observed in 68% of patients (95% confidence interval [CI]58%;77%], with a decrease in mean total PANSS scores from 98.2±16.2 at baseline to 71.1±20.3 at endpoint (mean change -27.1±19.9; 95%CI -31.1;-23.2, p< 0.0001) and onset of efficacy as of day 2. The percentage of patients rated as at least markedly ill in CGI-S decreased from 69% to 20.3%. AEs reported in ≥5% were insomnia (14%), tachycardia (10%), akathisia (6%), extrapyramidal disorder (6%), headache (5%) and schizophrenia (5%). Median weight gain was 0.7 kg (95% CI 0.19;1.96) from baseline to endpoint.

Conclusion: This analysis supports data from recent controlled studies that flexibly dosed paliperidone ER is safe, well tolerated and associated with a clinically meaningful treatment response in patients with an acute schizophrenic episode.

https://doi.org/10.1016/S0924-9338(09)71427-0 Published online by Cambridge University Press