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A FLEXIBLE-DOSE STUDY OF PALIPERIDONE ER IN NON-ACUTE PATIENTS WITH SCHIZOPHRENIA PREVIOUSLY UNSUCCESSFULLY TREATED WITH ORAL RISPERIDONE

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Objective: To explore tolerability, safety and treatment response of flexible doses of paliperidone ER in adult non-acute patients with schizophrenia previously unsuccessfully treated with oral risperidone.

Methods: International prospective 6-month open-label study. Endpoints were the Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression-Severity Scale (CGI-S), adverse events (AEs), extrapyramidal symptoms (Extrapyramidal Symptom Rating Scale; ESRS) and weight change.

Results: 694 patients were included (59.2% male, mean age 40.0±12.8 years, 74.8% paranoid schizophrenia); most were enrolled because of lack of efficacy (n=366) or lack of tolerability (n=178) with prior oral risperidone treatment. 74.1% of patients (n=514) completed the 6-month study. Most frequent reasons for early discontinuation were patient choice (7.3%) and lack of efficacy (5.2%). The median mode dose of paliperidone ER was 6 mg/day, independent of the reason for switching. For all patients, mean total PANSS decreased significantly from 78.6±20.5 at baseline to 65.6±22.5 at endpoint (mean change -13.0±19.4; 95% confidence interval -14.5;-11.5, $p < 0.0001$). The percentage of patients rated mildly ill or less in CGI-S increased from 28.3% to 52.5% at endpoint, and the rate of patients with mild functional impairment increased from 16.5% to 36.6%. AEs reported in greater-than-or-equal-to 5% of patients were insomnia (8.8%) and anxiety (7.3%). Extrapyramidal symptoms in ESRS decreased significantly from 3.8±6.1 to 2.3±5.1 ($p < 0.0001$). Mean weight gain from baseline to endpoint was 0.4±4.3kg.

Conclusion: These data support results from recent randomized controlled studies that paliperidone ER is safe, well tolerated and effective in patients previously unsuccessfully treated with oral risperidone.

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