

PATIENT FUNCTIONING WITH FLEXIBLE DOSES OF PALIPERIDONE ER - A 6-MONTH PROSPECTIVE STUDY

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Objective: To explore changes in functioning with flexible doses of paliperidone ER in a large international study in patients with schizophrenia previously unsuccessfully treated with other oral antipsychotics.

Methods: Prospective 6-month open-label study. Functioning was assessed using the Personal and Social Performance Scale (PSP), including four domains:

- (1) personal and social relationships,
- (2) socially useful activities including work and study,
- (3) self care and
- (4) disturbing and aggressive behavior.

Results: 1812 patients were included (59.9% male, mean age 40.1±12.6 years, 75.8% paranoid schizophrenia); most were enrolled because of lack of efficacy (n=1026) or lack of tolerability (n=490) with prior antipsychotic treatment. The median mode dose of paliperidone ER was 6 mg/day. 70.7% of patients completed the study. Most frequent reasons for early discontinuation were patient choice (8.8%), lack of efficacy or adverse event (5.1% each). AEs reported in >= 5% of patients were insomnia (9.2%) and anxiety (7.2%). Mean total baseline PSP score was 57.7±14.5, which improved to 64.1±15.6 at endpoint (mean change +6.4±13.5; 95% confidence interval 5.8;7.0, p< 0.0001); 49.0% of patients improved by at least one 10-point category in PSP. At baseline, 84.3% of patients had moderate to severe functional impairment, mostly driven by at least marked difficulties in socially useful activities (46.4.%) and personal and social relationships (36.4%). These percentages decreased to 30.6% and 22.9%, respectively.

Conclusion: In this large prospective flexible-dose study, results from recent randomized controlled studies are supported that paliperidone ER is associated with a clinically meaningful improvement of functioning in patients with schizophrenia.