

AN OPEN-LABEL, PROSPECTIVE STUDY TO EVALUATE SOCIAL FUNCTION AND OVERALL IMPROVEMENT FROM PALIPERIDONE ER IN THAI SCHIZOPHRENIA PATIENTS

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Objectives:

- To evaluate social function and overall improvement of paliperidone ER treatment in Thai schizophrenia patient.
- To collect the safety data of Paliperidone ER.

Methods: Patients were at least 18 years old and had been diagnosed with schizophrenia according to DSM-IV criteria. Patients were unsatisfied with previous treatment and had been previously or currently on oral atypical antipsychotics. Eligible patients were initiated on a dose of paliperidone ER (3, 6, 9, 12 mg/day) based on tolerability of previous medication. Flexible maintenance dosing during the 10 week study duration was allowed for all participants based on individual tolerability. The primary outcome is social function, determined by Personal and Social Performance Scale (PSP). Patients were also rated for overall severity of illness using Clinical and Global Impressions-Severity (CGI-S) scale.

Results: In total, 40 patients were enrolled. The statistical significant improvements from baseline in PSP total score were observed at all time points. An improvement of greater than or equal to 1 category (classified as a 10-point interval) on PSP scale is considered as clinical relevant response. Improvement in CGI-S were observed at endpoint ($p < 0.001$). The mean reduction \pm SD at endpoint was for 0.8 ± 1.04 (95% CI 0.48-1.16). The most commonly reported adverse events ($\approx 5\%$ of patients) were daytime drowsiness (15%) and headache (15%). Three subjects (7.5%) discontinued due to adverse events.

Conclusion: This study suggests that paliperidone ER is well tolerated in schizophrenic patient. Paliperidone ER showed improvement in schizophrenic symptom control and social functioning.