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A RANDOMIZED, ACTIVE-CONTROLLED RATER-BLINDED 2-YEAR STUDY OF PALIPERIDONE PALMITATE VERSUS INVESTIGATORS' CHOICE OF ORAL ANTIPSYCHOTIC MONOTHERAPY IN PATIENTS WITH SCHIZOPHRENIA (PROSIPAL)

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Introduction: Recent metaanalyses have reported conflicting results on the efficacy of long-acting compared to oral antipsychotics in the prevention of relapse in patients with schizophrenia.

Methods: 2-year international randomized active controlled, open-label, rater-blinded study evaluating time to relapse, relapse rates, psychotic symptoms (PANSS) and treatment-emergent adverse events (TEAEs) in recently diagnosed patients with schizophrenia (≥1-5 years) treated with a monotherapy of paliperidone palmitate (PP) compared to investigators' choice of oral antipsychotics (oAPs), i.e. aripiprazole, olanzapine, quetiapine, paliperidone ER, risperidone or haloperidol.

Results: 715 patients (58.4% male, mean age 32.5±10.4 years, 86.2% paranoid schizophrenia, no significant differences in baseline characteristics) entered the 2-year study period (352 PP, 363 oAPs). Time to relapse was significantly longer with PP compared to oAPs (mean±SE: 616±10.9 vs 603±13.1 days, p=0.019). Relapse rates were significantly lower with PP vs oAPs (14.8% vs 20.9%; p=0.032), reflecting a relative risk reduction of 29.2%. Reduction of psychotic symptoms in PANSS was significantly superior with PP at treatment day 8 (p=0.021) and showed a trend in favor of PP at endpoint (p=0.074). TEAEs reported in ≥5% in any group (PP vs oAPs) were weight increase (15.9% vs 17.4%), headache (11.1% vs 8.5%), insomnia (9.7% vs 8.0%), schizophrenia (8.2% vs 9.6%), nasopharyngitis (7.1% vs 5.0%), injection site pain (6.8% vs 0%), anxiety (5.7% vs 4.4%), tremor (5.1% vs 2.2%) and suicidal ideation (4.5% vs 5.5%).

Conclusion: In this randomized active controlled 2-year study PP was significantly delaying time to relapse and reducing relapse rates compared to investigators' choice of oral APs.

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