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A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL OF PALIPERIDONE ER VERSUS ORAL OLANZAPINE IN PATIENTS WITH SCHIZOPHRENIA

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Objective: To compare the longer-term metabolic effects and efficacy of paliperidone ER and olanzapine in patients with schizophrenia.

Methods: Prospective 6-month randomized study evaluating flexible doses of paliperidone ER and oral olanzapine (OLA). Primary endpoint was the change in triglyceride to high-density lipoprotein (TG:HDL) ratio, a sensitive measure of insulin resistance. Additional endpoints were the Positive and Negative Syndrome Scale (PANSS), body weight, lipids, homoeostasis model of insulin resistance (HOMA-IR) and adverse events (AEs).

Results: 239 patients were randomized to paliperidone ER, 220 to olanzapine. Demographics and baseline characteristics were comparable. Mean doses were 6.9±1.3 mg/day for paliperidone ER and 11.6±2.3 mg/day for olanzapine. The TG:HDL ratio for olanzapine significantly worsened from baseline to endpoint (0.42±1.19;p< 0.0001); it remained unchanged for paliperidone ER (-0.08±1.10;p=0.4718; between-group difference p< 0.0001). PANSS total scores at endpoint significantly improved (olanzapine -16.6±15.0; paliperidone ER -13.5±15.9; both p< 0.0001 vs. baseline); the between-group difference met prespecified non-inferiority criteria. Endpoint weight change was 3.8±5.9kg for olanzapine and 1.2±4.6kg for paliperidone ER (p< 0.0001). Insulin resistance in HOMA-IR did not change with paliperidone ER (p=0.1507) but significantly worsened with olanzapine (p=0.003 vs. baseline). The most frequently reported treatment-emergent AEs (>=5%) were weight increase (OLA 18.2%;Pali ER 9.6%), insomnia (OLA 1.4%;Pali ER 9.6%), somnolence (OLA 9.5%;Pali ER 3.3%) and schizophrenia (OLA 1.8%;Pali ER 5.0%).

Conclusion: In this randomized controlled study paliperidone ER was superior to olanzapine with regards to insulin resistance, weight gain, lipid changes and other relevant metabolic endpoints. Efficacy was non-inferior between paliperidone ER and olanzapine.

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