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THE EFFICACY AND SAFETY OF THE NOVEL ANTIPSYCHOTIC CARIPRAZINE IN ACUTE EXACERBATION OF SCHIZOPHRENIA

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Introduction: Cariprazine is a potent D_3/D_2 partial agonist with preferential binding to D_3 receptors.
Objectives/aims: To evaluate the efficacy and safety of cariprazine versus placebo in acute exacerbation of schizophrenia.
Methods: A multinational, multicenter, double-blind, randomized, placebo- and active-controlled, fixed-dose trial in patients aged 18-60 years with DSM-IV-TR-defined schizophrenia, current psychotic episode < 2 weeks, and PANSS total score between 80 and 120. After 1-week washout, patients received 6-weeks treatment (cariprazine 1.5, 3.0, or 4.5 mg/d, risperidone 4.0 mg/d, or placebo) and 2-week safety follow-up. Risperidone was used to assess assay sensitivity. Primary and secondary efficacy: baseline to Week 6 change (LOCF) in PANSS total and CGI-S scores, respectively. Safety: adverse events (AEs), vital signs, laboratory measures, extrapyramidal symptom (EPS) scales.
Results: Of 732 randomized patients, 64% completed the study. Mean baseline PANSS (98) and CGI-S scores (4.8) were similar across groups. PANSS total score improvement at Week 6 was statistically significant versus placebo for cariprazine 1.5 mg/d, 3.0 mg/d, and 4.5 mg/d (placebo-adjusted improvements: -7.5, -8.9, -10.4, respectively; $P< .001$; LOCF) and risperidone (-15.0, $P< .001$, LOCF); significant improvement on CGI-S was demonstrated for all active treatments ($P< .05$). The most common cariprazine AEs were insomnia, EPS, akathisia, sedation, nausea, dizziness, and constipation. AE discontinuation rates were 15% for placebo, 10%, 5% and 8% for cariprazine 1.5, 3.0, and 4.5 mg/d, respectively, and 9% for risperidone 4.0 mg/d.
Conclusions: Cariprazine significantly improved PANSS and CGI-S scores versus placebo in acute exacerbation of schizophrenia and was generally well tolerated.

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