Categorical Improvement in Depressive Symptom Severity: Results From a Randomized Controlled Trial of Cariprazine for Adjunctive Treatment of MDD

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Abstract

Background. Patients with major depressive disorder (MDD) often do not respond to antidepressant (ADT) monotherapy alone and may require adjunctive treatment to provide adequate symptom relief. Cariprazine (CAR) is a dopamine D3-preferring D3/D2 and serotonin 5-HT1A receptor partial agonist approved to treat adults with schizophrenia and manic, mixed, or depressive episodes of bipolar I disorder. Post hoc analysis of data from a randomized controlled trial evaluated clinically relevant improvements in depressive symptom severity with adjunctive cariprazine in patients with MDD and inadequate response to ADT mono-therapy.

Methods. Post hoc analysis evaluated data from a randomized, double-blind, placebo-controlled MDD trial (NCT03738215) in patients treated with CAR (1.5 mg/d or 3 mg/d) + ADT or placebo + ADT; the primary outcome was change from baseline to week 6 in Montgomery-Åsberg Depression Rating Scale (MADRS) total score. Post hoc analysis evaluated category shifts from baseline to week 6 in MADRS severity (normal ≤6, mild 7–19, moderate 20–34, severe ≥35). MADRS severity shifts were reported as the percentage of patients with no change or worsened severity, 1 category improvement, ≥1 category improvement, and ≥2 category improvement. Examples of categorical shifts in depressive symptoms at week 6 include change from severe at baseline to moderate (1 category improvement) and change from severe at baseline to mild (2 category improvement).

Results. Of the 751 patients in the intent-to-treat (ITT) population (CAR: 1.5 mg/d=250, 3.0 mg/d=252; placebo=249), baseline MADRS severity was mild in 1.5%, moderate in 64%, and severe in 35%. Fewer CAR + ADT patients compared to placebo + ADT had no change or worsened MADRS severity at week 6 (CAR: 1.5 mg/d=32%, 3.0 mg/d=33%; placebo=42%). Approximately 68% of patients treated with CAR + ADT demonstrated a MADRS severity improvement of 1 category or greater by week 6 (CAR: 1.5 mg/d=33%, 3.0 mg/d=7%; placebo=58%). A greater percentage of patients in the CAR 1.5 mg/d group also had a ≥2 or greater category improvement versus CAR 3.0 mg/d or placebo 6 (CAR: 1.5 mg/d=28%, 3.0 mg/d=17%; placebo=19%).

Conclusions. In this post hoc analysis, CAR + ADT was associated with a greater proportion of patients with improvements in depressive symptom severity categories compared with placebo + ADT. These results may suggest that CAR + ADT is associated with clinically meaningful depressive symptom improvement in MDD patients.

Funding. AbbVie

Vilazodone-Induced Glycolimia

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Abstract

Introduction. Glycolimia is observed in a plethora of medical conditions including burning mouth syndrome, opioid withdrawal, as well as from a variety of medications including vortioxetine, 1-methylfolate, lisdexamfetamine, and gabapentin. While vilazodone, an antidepressant with agonist like effects on 5-HT1A receptors, has been found to induce hyperglycemia, it has not heretofore been reported to induce glycolimia. Such a case is described.

Method. Case study: A 60-year-old, left-handed (pathological) male presented with a past history of depression, minimally...