cariprazine + ADT (94%) experienced only mild or moderate akathisia. The incidence of restlessness was 3.8% for patients treated with cariprazine 3 mg/d + ADT, 3.6% for cariprazine 1.5 mg/d + ADT, and 1.8% for placebo + ADT. The incidence of EPS excluding akathisia and restlessness was 4.4% for patients treated with cariprazine 3 mg/d + ADT, 4.6% for cariprazine 1.5 mg/d + ADT, and 3.2% for placebo + ADT. For patients treated with cariprazine + ADT and placebo + ADT, respectively, EPS-related study discontinuations were 1.4% and 0.4% due to akathisia, 0.2% and 0.0% due to restlessness, and 0.1% and 0.4% due to EPS excluding akathisia and restlessness. Rescue medications were used to treat EPS-related TEAEs during the double-blind treatment period in 3% of cariprazine-treated patients and 0.4% of placebo-treated patients. The mean time to resolution of akathisia during treatment was slightly shorter in cariprazine-treated patients (15.6 days) versus placebo-treated patients (19.5 days).

Importance. Incidence of akathisia was higher for cariprazine than placebo, with a lower incidence observed for patients treated with cariprazine 1.5 + ADT than with cariprazine 3 mg/d + ADT, suggestive of a dose related effect. Most patients experienced mild or moderate akathisia. Rates of study discontinuation and rescue medication use due to akathisia were low, suggesting that akathisia was tolerated by most patients.

This data was previously presented at the CINP World Congress; Montreal, Canada; May 7-10, 2023.

Funding. AbbVie

Effect of Adjunctive Cariprazine Treatment on Anxiety and Somatization Symptoms in Patients with Major Depressive Disorder: A Post Hoc Analysis

Maurizio Fava[1], Vladimir Maletic[2], Jun Yu[3], Simranpreet Waraich[3], Julie L. Adams[3], Ken Kramer[3] and Majid Kerolous[3]

[1]Department of Psychiatry, Massachusetts General Hospital, Boston, MA, USA; [2]University of South Carolina School of Medicine, Columbia, SC, USA and [3]AbbVie, Madison, NJ, USA

Introduction. Patients with major depressive disorder (MDD) commonly experience comorbid anxiety and somatization, which can complicate treatment. Adjunctive therapy with atypical antipsychotics can be an effective treatment option for patients with MDD who had inadequate responses to antidepressant therapy (ADT) alone. Cariprazine is a dopamine D_3-preferring D_3/D_2 and serotonin 5-HT_{1A} receptor partial agonist that is approved as an adjunctive treatment for MDD. This post hoc analysis examined the effect of adjunctive cariprazine therapy on anxiety and somatization symptoms in patients with MDD.

Methods. A post hoc analysis was conducted using data from a phase 3, double-blind, placebo-controlled, fixed-dose study of patients with MDD who had inadequate responses to ADT alone. Patients were randomized (1:1:1) to receive ADT plus cariprazine 1.5 mg/d, 3 mg/d, or placebo for 6 weeks. The least squares (LS) mean change from baseline to week 6 in Hamilton Rating Scale for Depression (HAM-D) Anxiety/Somatization subscale was measured. The Anxiety/Somatization subscale includes six HAM-D items: anxiety-psychic, anxiety-somatic, gastrointestinal somatic symptoms, general somatic symptoms, hypochondriasis, and insight. The modified intent to treat population included 751 patients (placebo=249; cariprazine 1.5 mg/d=250; cariprazine 3 mg/d=252).

Results. The LS mean change from baseline in HAM-D Anxiety/Somatization subscale at week 6 was significantly greater than placebo + ADT for both cariprazine + ADT dose groups (placebo: -3.22; cariprazine 1.5 mg/d: -4.00, $P<.001$; 3 mg/d: -3.75, $P<.05$). LS mean change from baseline in the cariprazine 1.5 mg/d + ADT group was also significantly greater than placebo + ADT on the anxiety-psychic (placebo: -0.88; cariprazine 1.5 mg/d: -1.08, $P<.01$) and anxiety-somatic (placebo: -0.78; cariprazine 1.5 mg/d: -0.96, $P<.05$) items. In patients treated with cariprazine 3 mg/d + ADT, LS mean changes from baseline on anxiety-psychic and anxiety-somatic items were numerically larger than placebo + ADT but not statistically significant. Both cariprazine + ADT dose groups had significantly larger LS mean changes compared with placebo + ADT on the gastrointestinal somatic symptoms item (placebo: -0.51; cariprazine 1.5 mg/d: -0.66, $P<.01$; cariprazine 3 mg/d: -0.68, $P<.01$). General somatic symptoms, hypochondriasis, and insight items showed no significant difference between placebo + ADT and cariprazine + ADT groups.

Conclusions. Patients treated with adjunctive cariprazine demonstrated greater improvements than patients treated with adjunctive placebo on HAM-D Anxiety/Somatization subscale scores, as shown by reduced scores on anxiety-psychic, anxiety-somatic, and gastrointestinal items. These findings suggest adjunctive cariprazine therapy may be effective in reducing anxiety and somatization symptoms in patients with MDD.

Funding. AbbVie

Study Registration Number: NCT03738215

Role of External Factors in the Severity of Dissociation Experienced by Treatment-Resistant Depression Patients Following Esketamine Administration

Maria M. Vento-Correa, PharmD, BCPP, CPh[1], Vidhya Meyyappa, MD, PGY4[2], Alberto Augsten, PharmD, MS, BCPP, DABAT[1], Samantha Sotelo, PharmD, BCPP[1] and Gil Abramovici, MD[1]

[1]Memorial Healthcare System, Hollywood, Florida and [2]Psychiatry Residency Program, Memorial Healthcare System, Hollywood, Florida

Introduction. Esketamine nasal spray is an NMDA receptor antagonist which is FDA approved, in conjunction with an oral antidepressant, for treatment- resistant depression (TRD) in

https://doi.org/10.1017/S1092852924001615 Published online by Cambridge University Press