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CARIPRAZINE 3 MG/DAY IN BIPOLAR DEPRESSION: POST HOC ANALYSIS OF POOLED STUDY DATA

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1.5 and 3 mg cariprazine are effective doses to treat general symptoms of bipolar depression.

The higher dose of 3 mg cariprazine is beneficial in more severely ill patients and in the presence of manic symptoms.

OBJECTIVE

To examine options of personalized treatment related to dosing, symptom type and severity.

METHODS

Post-hoc analysis of pooled data from three randomized, double-blind, placebo-controlled trials in bipolar I depression (NCT01396447, NCT02670538, NCT02670551) were analyzed regarding the mean change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS) total scores for pooled cariprazine 1.5 mg/d and 3 mg/d versus placebo by:

- (1) baseline MADRS severity scores of <31 (less severely ill) and ≥31 (more severely ill) – with a rationale of 31 being the median – and
- (2) concurrent manic symptoms [5] (baseline YMRS total score ≥4) versus without (YMRS total score <4)

RESULTS: BASELINE SEVERITY

In patients with **higher baseline depression severity** (Figure 1A):

- Both doses of cariprazine resulted in a significant decrease in MADRS score compared to placebo.
- The higher dose (3 mg/day) resulted in a numerically greater, 1.3-fold reduction of MADRS score compared to the lower dose.

In patients with **lower depression severity at baseline** (Figure 1B):

- CAR 1.5 mg/d showed a significant reduction in MADRS score vs placebo, while the 3mg/d dose led to only a numerical decrease.

Figure 1A
Higher baseline depression severity

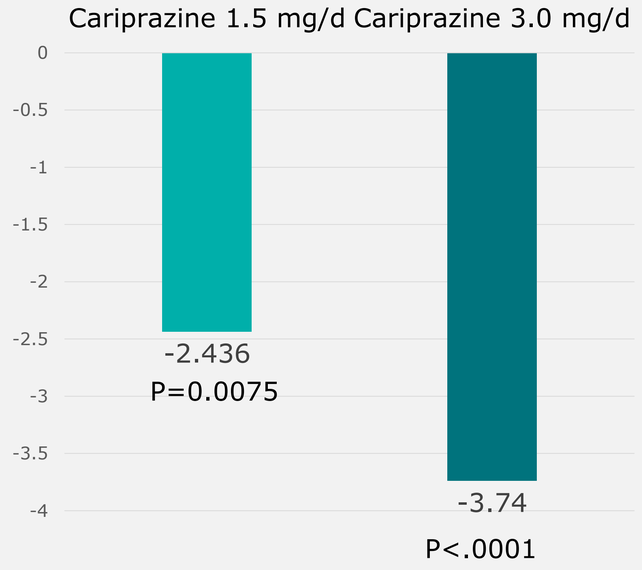
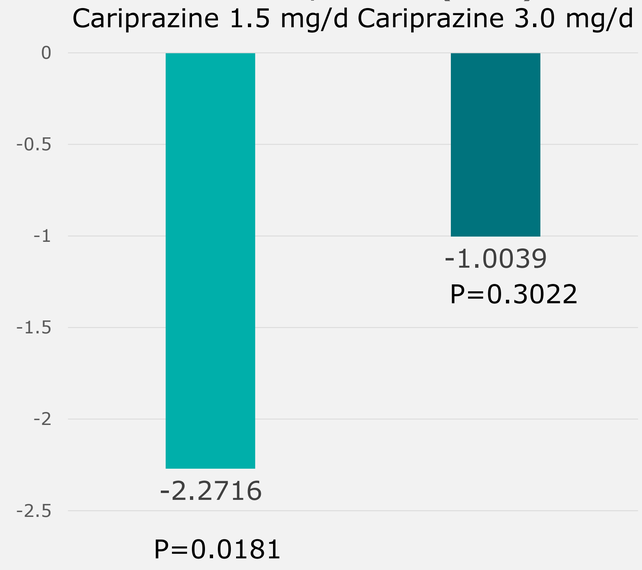


Figure 1B
Lower baseline depression severity



RESULTS: MANIC SYMPTOMS

At week 6, the LS mean difference (LSMD) versus placebo was statistically significant in favour of cariprazine for:

- the 1.5 mg and 3 mg/d dose group in depressed patients **with concurrent manic symptoms** (Figure 2A) and
- the cariprazine 1.5 mg/day dose group in patients **without concurrent manic symptoms** (Figure 2B). [1]

In addition, a significant improvement over placebo was seen in the cariprazine 3 mg/day dose group starting at week 1 (p<.05), which meant a more rapid onset of effect with the 3 mg dose in patients with concurrent manic symptoms. [1]

Figure 2A
With manic symptoms

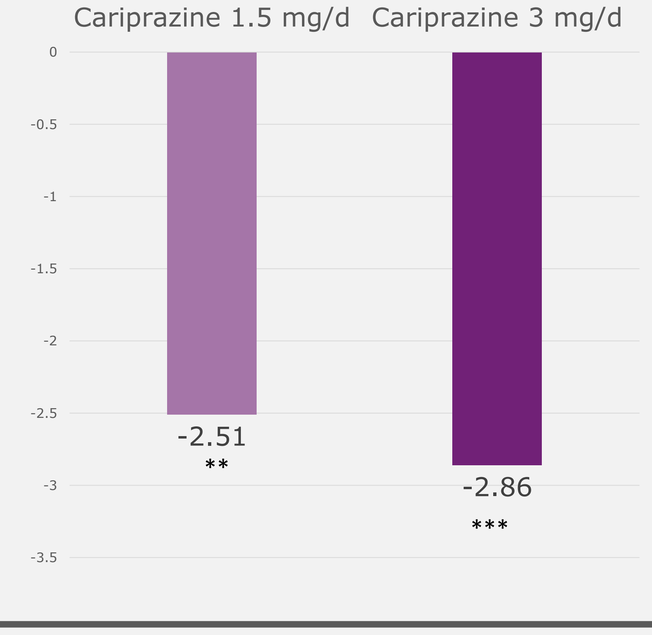
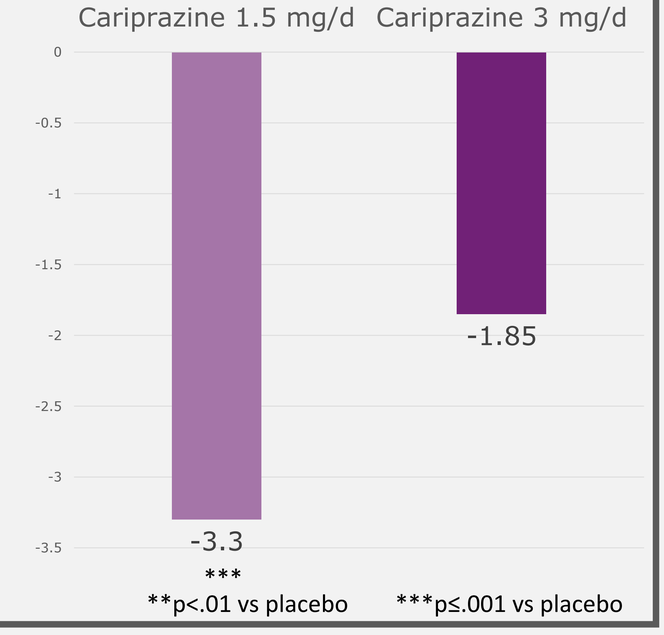


Figure 2B
Without manic symptoms



**p<.01 vs placebo ***p≤.001 vs placebo

Reference: [1] McIntyre, R. S., Suppes, T., Earley, W., Patel, M., & Stahl, S. M. (2019). CARIPRAZINE efficacy in bipolar I depression with and without concurrent manic symptoms: Post hoc analysis of 3 randomized, placebo-controlled studies. CNS Spectrums, 25(4), 502–510. https://doi.org/10.1017/s1092852919001287

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