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Adjunctive Cariprazine as a Novel Effective Strategy for Treating Major Depressive Disorder: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 July 2023 and was last updated on 06 July 2023.

INTRODUCTION

Review question / Objective (1) Participants: individuals aged 18 to 65 who have been diagnosed with major depressive disorder; (2) Intervention: patients who were administered cariprazine in addition to their antidepressant medication; (3) Comparison: patients who received a combination of placebo and antidepressant medication; (4) Outcomes: the effectiveness outcomes included the evaluation of changes in various assessment scales, such as the Montgomery-Asberg Depression Rating Scale, the Hamilton Depression Scale (17 items), the Clinical Global Impressions severity, the Clinical Global Impressions improvement, the MADRS response, the MADRS remission, and the CGI-I response. Safety results encompassed the occurrence of adverse events and serious major adverse events; (5) study type: study type was randomized clinical trials.

Condition being studied The objective of this study is to explore the efficacy and safety of cariprazine as an adjunctive treatment for major depressive disorder. Current approaches for patients with insufficient response to first-line antidepressants include combination therapy using multiple antidepressants concurrently, as well as the use of mood stabilizers or atypical antipsychotics to enhance the effectiveness of ADTs. Cariprazine has shown promise as an adjunctive therapy with antidepressants for major depressive disorder. This study involved a comprehensive literature review of cariprazine, utilizing databases such as Embase, PubMed, and the Cochrane Library. Through the comparison of these trials, the aim of this study is to provide valuable insights into the effectiveness of adjunctive cariprazine in managing major depressive disorder.

METHODS

Participant or population Individuals aged 18 to 65 who have been diagnosed with major depressive disorder.

Intervention Patients who were administered cariprazine in addition to their antidepressant medication.

Comparator Patients who received a combination of placebo and antidepressant medicationpatients who were administered cariprazine in addition to their antidepressant medication.

Study designs to be included Randomized clinical trials.

Eligibility criteria (1) Control group: the control group in this study consisted of individuals who received non-pharmacological treatments and psychological treatments.(2) Study type: the study encompassed prospective or retrospective trials, meta-analyses, reviews, protocols, and comments. (3) Studies with unextracted data.(1) Control group: the control group in this study consisted of individuals who received non-pharmacological treatments and psychological treatments.(2) Study type: the study design encompassed prospective or retrospective trials, meta-analyses, reviews, protocols, and comments.(3) Studies that did not have extracted data were also included in the analysis.

Information sources To ensure the review encompassed the latest and most comprehensive literature, an extensive and systematic search was performed on electronic databases, such as PubMed, Embase, and the Cochrane Library. The search was conducted up until May 2023.

Main outcome(s) The effectiveness outcomes included the evaluation of changes in various assessment scales, such as the Montgomery-Asberg Depression Rating Scale, the Hamilton Depression Scale (17 items), the Clinical Global Impressions severity, the Clinical Global Impressions improvement, the MADRS response, the MADRS remission, and the CGI-I response. Safety results encompassed the occurrence of adverse events and serious major adverse events.

Quality assessment / Risk of bias analysis The quality assessment of the included studies was carried out by two independent reviewers who were not involved in data extraction. The evaluation was conducted using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) scale, which consists of five domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias. By employing this approach, the credibility and reliability of the study findings were strengthened.

Strategy of data synthesis The combined data obtained from the studies included in the analysis were assessed using Review Manager 5.4 software (The Cochrane Collaboration, Oxford, UK). The outcomes were analyzed using the risk ratio (RR) and the standard mean difference (SMD), along with their corresponding 95% confidence intervals (95% CI). In instances where the extracted data presented continuous variables as medians, interquartile ranges, or ranges instead of the mean and standard deviation, the data were transformed using the method proposed by Hozo et al. All analyses were two-tailed, and statistical significance was defined as $P < 0.05$.

Subgroup analysis Subgroup analysis was performed to explore the impact of different dosages of cariprazine.

Sensitivity analysis There was no sensitivity analysis in our study.

Country(ies) involved China.

Keywords Major Depressive Disorder, MDD, Cariprazine, Adjunctive, antidepressant.

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