INPLASY

The Efficacy and Safety of Ginkgo Terpene Lactone Preparations combined with Antiplatelet Aents in the Treatment of Ischemic Stroke: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

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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 25 December 2024 and was last updated on 25 December 2024.

INTRODUCTION

Review question / Objective This meta-analysis aimed to assess the efficacy and safety of ginkgo terpene lactone preparations including diterpene ginkgolides meglumine injection (GDMI) and ginkgolide injection combined with antiplatelet drugs in the treatment of ischemic stroke (IS).

Condition being studied Ischemic stroke is a significant cause of disability and mortality worldwide. Data from the Global Burden of Disease study indicate that ischemic stroke impacts millions of patients annually, imposing significant financial and emotional burdens on individuals, families, and society at large. Currently, the primary treatments for ischemic stroke include thrombolytic therapy and antiplatelet therapy. While thrombolytic therapy can effectively reopen occluded vessels in patients with ischemic stroke, it is constrained by a strict time window for administration and carries risks, such as bleeding. Antiplatelet drugs, such as aspirin, clopidogrel, and tirofiban, are crucial for the secondary prevention of ischemic stroke. However, the efficacy of these single agents in enhancing long-term prognosis is limited, and issues such as drug resistance persist. Consequently, there is an urgent need to investigate and validate novel treatment combinations to enhance recovery following a stroke. Ginkgo terpene lactones are a class of natural compounds derived from the leaves of Ginkgo biloba, known for their various pharmacological activities, including antioxidant, anti-inflammatory effects, and the enhancement of cerebral blood flow.Numerous clinical trials have demonstrated that ginkgo terpene lactone preparations, such as DGMI and ginkgolide injection, are significantly effective in treating cerebrovascular diseases. Consequently, they are widely regarded as a potentially effective adjuvant treatment option, offering a novel perspective for improving the therapeutic outcomes of ischemic stroke.

METHODS

Participant or population Study participants were adults (aged ≥ 18 years) regardless of gender or ethnicity. IS should be diagnosed by computed tomography or magnetic resonance imaging and according to any accepted diagnostic criteria.

Intervention The experimental group was treated with ginkgo terpene lactone preparations combined with antiplatelet drugs on the basis of conventional treatment.

Comparator The control group received only antiplatelet drugs on the basis of conventional treatment.

Study designs to be included Chinese or English randomized controlled trial.

Eligibility criteria The exclusion criteria were as follows: 1) nonclinical randomized controlled trials, including literature reviews, systematic reviews, individual case studies, experience summaries, and basic research; 2) repeated publications; 3) imprecise descriptions of conventional treatment in both the experimental and control groups; 4) studies involving patients treated with thrombolytics or other neuroprotective agents (e.g., edaravone, citicoline); and 5) studies focused on other diseases.

Information sources PubMed, China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Journal Database (VIP), Chinese Biomedical Literature Database (CBM), Wanfang Database, Embase, Web of Science, ClinicalTrials.gov, and Cochrane Library.

Main outcome(s) Our primary outcome measure was the overall clinical response rate to treatment, and adverse drug reactions (ADR).

Quality assessment / Risk of bias analysis funnel plots were generated to evaluate the publication bias present in the literature. Meanwhile, publication bias was also assessed by Egger's test with STATA 17 software.

Strategy of data synthesis Statistical analysis was conducted using Stata 17 software. Hazard ratios (RR) and mean differences (MD) served as effect indicators for dichotomous data and continuous variables, respectively. A 95% confidence interval (95% CI) was calculated for both types of data. The I^2 test was employed to assess the heterogeneity among the included studies. If $p > 0.1$ and $I^2 < 50\%$, it was concluded that there was no heterogeneity among the studies, and a fixed-effect model was selected for analysis. Conversely, in cases of substantial heterogeneity, a random-effects model was utilized, and a sensitivity analysis was conducted to identify the sources of heterogeneity.

Subgroup analysis We categorized patients into three subgroups based on their NIHSS scores prior to treatment: moderate stroke (NIHSS ≤ 15), moderate-severe stroke (15 < NIHSS ≤ 20), and severe stroke (20 < NIHSS ≤ 42).

Sensitivity analysis To assess the accuracy and stability of the meta-analysis results, we performed sensitivity analyses using a row wise exclusion method.

Country(ies) involved China.

Keywords Ischemic Stroke；diterpene ginkgolides meglumine injection； ginkgolide injection,； antiplatelet drugs；meta-analysis1.Introduction.

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