

INPLASY PROTOCOL

Clinical efficacy of Integrative Chinese-Western Medicine in treatment of Ischemic stroke: a meta-analysis

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None declared.

Review question / Objective: Ischemic stroke is recognized as a major public health problem worldwide. The treatment of ischemic stroke in modern medicine is mainly based on thrombolysis, anticoagulation, intracranial pressure reduction, nutritional support and other symptomatic treatments, although the clinical symptoms of patients can be reduced in the short term, but the overall efficacy needs to be improved. Compared with Western medicine, traditional Chinese medicine has the characteristics of high safety, multi-channel, multi-level and multi-target, and has unique advantages in improving collateral circulation. However, neither a single medical surgery nor a single TCM treatment can achieve the best results, so the integration of Chinese and Western medicine is a new trend in development. However, up to now, the clinical efficacy of integrated traditional Chinese and Western medicine in the treatment of ischemic stroke is not clear, and the purpose of this study is to explore and analyze the clinical efficacy of integrated traditional Chinese and Western medicine in the treatment of ischemic stroke and the efficacy of Western medicine alone. The method chosen for this review was RCT trials.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 January 2023 and was last updated on 12 January 2023 (registration number INPLASY202310035).

INTRODUCTION

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anticoagulation, intracranial pressure reduction, nutritional support and other symptomatic treatments, although the clinical symptoms of patients can be reduced in the short term, but the overall efficacy needs to be improved. Compared with Western medicine, traditional Chinese

medicine has the characteristics of high safety, multi-channel, multi-level and multi-target, and has unique advantages in improving collateral circulation. However, neither a single medical surgery nor a single TCM treatment can achieve the best results, so the integration of Chinese and Western medicine is a new trend in development. However, up to now, the clinical efficacy of integrated traditional Chinese and Western medicine in the treatment of ischemic stroke is not clear, and the purpose of this study is to explore and analyze the clinical efficacy of integrated traditional Chinese and Western medicine in the treatment of ischemic stroke and the efficacy of Western medicine alone. The method chosen for this review was RCT trials.

Condition being studied: Ischemic stroke refers to a type of clinical syndrome in which local brain tissue avascular necrosis or softening, resulting in cerebral blood circulation disorders and tissue ischemia and hypoxia, and rapid occurrence of corresponding neurological deficits. It is a major public health issue recognized worldwide. Studies show that stroke was the second leading cause of death worldwide (66 million deaths) until 2019. "Four highs": High incidence (70% increase in absolute stroke incidence globally over the past 30 years), high prevalence (85% increase in prevalence), high disability (32% increase in disability) and high mortality (43% increase in mortality) are important features of the disease. In China, the socio-economic burden caused by stroke is also quite serious. Studies have shown that ischemic stroke is also the most common stroke event, accounting for 66.8%~80% of all stroke events, which is particularly worthy of attention. Ischemic stroke refers to narrowing or occlusion of cerebral blood supply arteries, blood dysfunction, and then affecting blood supply disorders, resulting in brain tissue necrosis in the arterial blood supply area, with sudden dizziness, diplopia, limb numbness as the main clinical manifestations, severe hemiplegia, aphasia, and even life-threatening. Studies have reported that the recurrence rate of new-onset ischemic

stroke within 1~2 years is as high as 14.7%, and the risk of recurrence is increasing with the increase of the number of attacks. At present, the treatment of ischemic stroke in modern medicine is mainly based on thrombolysis, anticoagulation, reduction of intracranial pressure, maintenance of blood pressure, nutritional support and other symptomatic treatments, although in the short term can reduce the clinical symptoms of patients and restore neurological function, but the overall efficacy needs to be improved. Compared with Western medicine, traditional Chinese medicine has the characteristics of high safety, multi-channel, multi-level and multi-target, and has unique advantages in improving collateral circulation. However, neither a single Western medicine treatment nor a single TCM treatment can achieve the best results, so the integration of Chinese and Western medicine is a new trend in development. The purpose of this study is to explore and analyze the clinical efficacy of integrated traditional Chinese and Western medicine in the treatment of ischemic stroke.

METHODS

Search strategy: Search of CNKI, VIP, Wanfang Data Knowledge Service Platform, PubMed, EMBase, Cochrane Library, web of science for randomized clinical trials published from database inception through December 31, 2022, that evaluated the association of Integrative Chinese-Western Medicine on treatment of ischemic stroke.

Participant or population: A total of 869 patients participated in the study after searching according to search terms from seven major databases: CNKI, VIP, Wanfang Data Knowledge Service Platform, PubMed, EMBase, Cochrane Library, and web of science. The cases met the inclusion criteria. A total of 869 patients participated in the study after searching according to search terms from seven major databases: CNKI, VIP, Wanfang Data Knowledge Service Platform, PubMed, EMBase, Cochrane Library, and web of science.

Intervention: Integrative Chinese and Western medicine.

Comparator: Western medicine alone.

Study designs to be included: RCT.

Eligibility criteria: Inclusion criteria(1) Study type: consistent with the randomized controlled trial of integrated traditional Chinese and Western medicine in the treatment of ischemic stroke, the baseline data of the two groups in the study were statistically compared, and the balance between the two groups was good.(2) Research subject: Western medicine diagnostic criteria are based on the diagnostic criteria for ischemic stroke in the "Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke 2014". New stroke diagnosed by CT or MRI. There are no age or gender restrictions. Diagnostic criteria for traditional Chinese medicine: refer to the diagnostic criteria in the 2002 edition of the "Guidelines for Clinical Research of New Chinese Medicines (Trial)".(3) Intervention: the experimental group received integrated traditional Chinese and Western medicine intervention; The control group was treated with conventional western medicine.(4) Outcome indicators: NIHSS score, MRS score activities of daily living, Barthel index for cognitive function (MMSE score, MoCA score), vascular recanalization rate, complications, clinical indicators, etc.Exclusion criteria(1) Reviews, case reports, reviews, meeting minutes, etc.:(2) Non-randomized controlled trials(3) Animal experiments(4) The full text is not available or the data report is incomplete;(5) retrospective studies,(6) including other control groups;(7) The diagnostic criteria or efficacy evaluation criteria are not clear;(8) Adopt topical treatment methods such as acupuncture, cupping, and rehabilitation training.

Information sources: 7 major databases: CNKI, VIP, Wanfang Data Knowledge Service Platform, PubMed, EMBASE, Cochrane Library, web of science.

Main outcome(s): NIHSS score, MRS score activities of daily living, Barthel index for cognitive function (MMSE score, MoCA score), vascular recanalization rate, complications, clinical indicators, etc.

Quality assessment / Risk of bias analysis: According to the Cochrane Handbook Quality Evaluation Criteria, the literature quality evaluation includes: (1) whether the random method is correct; (2) whether the allocation is hidden; (3) whether blinding is used; (4) reports of cases of withdrawal or loss to follow-up, including the number and reasons for loss to follow-up; (5) whether intention-to-treat analysis is used; (6) Comparability of baseline data. Grade A: Fully meets the above criteria with minimal risk of bias; Grade B: Moderately likely to be biased if the above criteria are partially met; Grade C: Completely does not meet the above criteria and the potential for bias is high.

Strategy of data synthesis: This study used STATA16.0 statistical software for meta-analysis. Relative risk (RR) and confidence interval (CI) were used as the pooled effect size to measure efficacy for qualitative measures. The quantitative data measure used the standardized mean difference (SMD) as the pooled effect size to measure efficacy. The test for heterogeneity uses the Q-statistic test and the I² statistic. Pooling methods were selected according to the test of heterogeneity: if there was no heterogeneity between the results of the studies ($P \geq 0.1$), the fixed-effect model was used to combine the data; If there was heterogeneity between study results ($I^2 > 50\%$ and $P < 0.1$), a random-effects model was used for data analysis. Begg's test, Egger's test, and funnel chart were used to test for publication bias at $\alpha = 0.05$ is the inspection level.

Subgroup analysis: If data are available, a subgroup analysis will be performed to detect sources of obvious heterogeneity regarding the types of participants, and outcome indicators Subgroup analyses

were performed according to disease duration < 1 month and ≥ 1 month.

Sensitivity analysis: In the case of sufficient data, a sensitivity analysis will be conducted to test the robustness of study findings regarding the methodological quality and missing data of all eligible studies.

Country(ies) involved: China.

Keywords: Integrative Chinese-Western Medicine; Ischemic stroke; Clinical efficacy.

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