INPLASY PROTOCOL

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Corresponding author:
Yibin Hu

1301163720@qq.com

Author Affiliation:
Shandong University of Traditional Chinese Medicine, Jinan, China.

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None declared.

Effectiveness Comparison of Chinese Medicine Decoction for Vascular Dementia: A Systematic Review and Network Meta-analysis

Hu, Y[1]; Zhang, L[2]; Ma, Y[3]; Hou, H[4]; Bi, S[5]; Liu, C[6]; Li, M[7]; Wang, K[8].

Review question / Objective: **Which Chinese medicine decoction would be more effective in the treatment of vascular dementia(VaD)?**
Eligibility criteria: **(1) Randomized controlled trials on VaD were included, including English and Chinese literature. (2) Patients who are diagnosed with VaD according to the clinical diagnostic criteria of VaD. There was no specific restriction on age, gender, and race. (3) The experimental groups were treated with Chinese medicine decoction alone or combined with western medicine , while the control groups were treated with western medicine. (4)The clinical total effective rate,mini-mental status examination (MMSE) score, Hasegawa's dementia scale (HDS) score, adverse reactions were all adopted to estimate and compare therapeutic efficacy and safety of different Chinese medicine decoction alone or combined with western medicine in the treatment of VaD.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 August 2022 and was last updated on 03 August 2022 (registration number INPLASY202280015).

INTRODUCTION

Review question / Objective: **Which Chinese medicine decoction would be more effective in the treatment of vascular dementia(VaD)?**

Condition being studied: **Vascular dementia(VaD) often occurs after stroke and other cerebrovascular diseases, or after low blood flow perfusion caused by heart and circulation disorders. Its pathological feature is that the brain function of cerebral infarction or bleeding site is limited, which leads to the**

impairment of cognitive and motor functions of patients. VaD is the second leading cause of dementia, only secondary to Alzheimer's disease(AD). The incidence of VaD is generally faster than that of AD, but the clinical symptoms are roughly the same as that of AD, so the rate of misdiagnosis and missed diagnosis is relatively high. VaD causes a huge burden for patients and their caregivers because of its damage to intelligence. Research shows that the incidence rate of VaD is increasing with the incidence rate of cerebrovascular diseases and circulatory diseases. By 2050, the number of patients with VaD will reach 15million worldwide. There is no specific drug for VaD yet. At present, the drugs against VaD mainly include cholinesterase inhibitors and memantine, but their effects are unstable and have side effects such as gastrointestinal reactions and insomnia. As a kind of alternative medicine, traditional Chinese medicine(TCM) has been widely used in clinic in China and even the world. VaD belongs to the category of "dementia" in traditional Chinese medicine. A variety of traditional Chinese medicine prescriptions have been used in clinic as drugs for the treatment of vascular dementia, which are often used alone or in combination with western medicine, acupuncture, moxibustion and other therapies, At present, a number of randomized controlled studies have evaluated the efficacy and safety of traditional Chinese medicine prescriptions used alone or in combination with western medicine in the treatment of VaD, and a number of systematic evaluations have confirmed the effectiveness and safety of classic prescriptions, but there is still a lack of research on horizontal comparison between various prescriptions. This study uses the method of network meta-analysis to select five representative clinical randomized controlled trials related to classic prescriptions (Buyang Huanwu Decoction, Dihuang Yinzi Decoction, Tongqiao Huoxue Decoction, Qifuyin Decoction, Yiqi Congming Decoction), and compare the effectiveness and safety of TCM classic prescriptions in the treatment of VaD alone or in combination with Western Medicine through network meta-analysis, so as to provide evidence-based medical evidence for the treatment of clinical prescriptions.

METHODS

Participant or population: Patients who are diagnosed with vascular dementia according to the clinical diagnostic criteria of DSM-V or other diagnostic criteria for VaD will be included. There was no specific restriction on age, gender, and race.

Intervention: Chinese medicine decoction alone or combined with western medicine will be the main intervention.

Comparator: Western medicine or regular treatment will be the main comparator.

Study designs to be included: Randomized controlled trials(RCTs) will be included.

Eligibility criteria: (1) Randomized controlled trials on VaD were included, including English and Chinese literature. (2) Patients who are diagnosed with VaD according to the clinical diagnostic criteria of VaD. There was no specific restriction on age, gender, and race. (3) The experimental groups were treated with Chinese medicine decoction alone or combined with western medicine , while the control groups were treated with western medicine. (4)The clinical total effective rate,mini-mental status examination (MMSE) score, Hasegawa's dementia scale (HDS) score, adverse reactions were all adopted to estimate and compare therapeutic efficacy and safety of different Chinese medicine decoction alone or combined with western medicine in the treatment of VaD.

Information sources: China National Knowledge Infrastructure (CNKI), Wanfang database (Wanfang), Chinese Science and Technology Periodical Database (VIP), China Biology Medicine disc (CBM), MEDLINE, EMBASE, and Cochrane Library.

Main outcome(s): Clinical efficacy, mini-mental state examination (MMSE) score will be the main outcomes.

Quality assessment / Risk of bias analysis: Two researchers extracted the data independently and assessed the quality of the included trials. The literature's inclusion and exclusion criteria were strictly followed. If two researchers disagreed on the selection of a literature, the literature would be given to a third researcher who would analyze it and decide whether or not to keep it. To assess the quality of evidence in each comparison, we used the GRADE system. The risk of publication, heterogeneity, indirectness, imprecision, and publication bias were all evaluated, and the results were classified as high, moderate, low, or very low.

Strategy of data synthesis: We will use RevMan 5.3 software for meta-analysis and heterogeneity test of literature. I square test will be used to detect the heterogeneity among included trials. The trials with significant heterogeneity ($P < 0.10$, $I2 > 50\%$) will be analyzed by random effects model; For the trials with small heterogeneity ($P > 0.10$, $I2 < 50\%$), the fixed effects model will be used for analysis.

Subgroup analysis: If the number of studies in each comparison is small, there will be no subgroup analysis performed. Otherwise, We will record treatment duration of every RCT as the basis for subgroup analysis.

Sensitivity analysis: We will use the method of excluding each study one by one for the sensitivity analysis.

Language restriction: English.

Country(ies) involved: China.

Keywords: Chinese medicine decoction; Vascular dementia.

Contributions of each author:

Author 1 - Yibin Hu.
Email: 1301163720@qq.com
Author 2 - Lijuan Zhang.
Email: zhlj-8103@163.com
Author 3 - Yizheng Ma.
Email: 1562965267@qq.com
Author 4 - Hanru Hou.
Email: houhanruxx@163.com
Author 5 - Shuyue Bi.
Email: bishuyue9227@163.com
Author 6 - Changning Liu.
Email: lcnjk966@qq.com
Author 7 - Mingxiang Li.
Email: leemingxiang@126.com
Author 8 - Kangfeng Wang.
Email: wkfszy@163.com