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Efficacy of Chinese herbal medicine on health-related quality of life (SF-36) in hypertensive patients: A systematic review and meta-analysis of randomized controlled trials

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Summary

Objectives: This study aims to evaluate published randomized controlled trials (RCTs) of Chinese Herbal Medicine (CHM) improving health-related quality of life (HRQL) in hypertensive patients that employ the Short-Form 36-Item Health questionnaire (SF-36) as an outcome measure.

Methods: Five electronic databases were searched up to October 2013 to identify RCTs of CHM for hypertension. The primary outcome was SF-36. Trial selection, data extraction, methodological quality assessment, and data analyses were conducted according to the Cochrane handbook.

Results: Eleven RCTs with total of 1043 participants were identified. The majority of the included trials were assessed to be of poor methodological quality and high clinical heterogeneity. Meta-analysis shows a significant improvement both in physical component summary (PCS) measure and mental component summary (MCS) measure of SF-36, with physical functioning (WMD = 8.54[5.34, 11.74], $p < 0.001$), role physical (WMD = 13.32[7.03, 19.61], $p < 0.001$), bodily pain (WMD = 10.53[6.46, 14.60], $p < 0.001$), general health (WMD = -5.56[2.09, 9.02], $p < 0.001$), vitality (WMD = 6.84[4.33, 9.53], $p < 0.001$), social functioning (WMD = 7.50[2.63, 12.36], $p < 0.001$), role emotional (WMD = 12.06[4.45, 19.68], $p < 0.001$) and mental health (WMD = -5.68[2.90, 8.47], $p < 0.001$). CHM can also decrease systolic blood pressure (WMD = -4.45 [-6.71, -2.19], $p < 0.001$) and relieve symptoms related to hypertension.

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Conclusions: CHM appears to have beneficial effects on improvement of HRQL in hypertensive patients. However, the findings should be interpreted with caution due to the poor methodological quality and high clinical heterogeneity of the included trials. Further clinical trials should be carried out to provide more reliable evidence.

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Introduction

Hypertension is the most common condition in primary health care and about one third of adults in most communities in the developed and developing world suffered from hypertension.¹ It is not only a leading cause of cardiovascular events, strokes, and kidney disease, but also decreases health-related quality of life (HRQL). A systematic review and meta-analysis of observational studies of HRQL in hypertensive patients concluded that hypertension reduced HRQL.² A self-administered questionnaire survey using SF-36, which was conducted in a general population in Shanghai, China, found that hypertension markedly impairs quality of life in terms of both physical and mental health.³ Another study conducted in patients attending hospital clinics in China found that hypertensive patients scored lower in most questions on the SF-36 than those without hypertension.⁴ Several studies had proved that pharmacologic interventions may play an important role in maintaining and possibly improving HRQL of hypertensive patients.^{5–8} However, on the contrary, a cross-sectional study found that individuals with hypertension have worse quality of life, particularly when their blood pressure is controlled by drugs.⁹ Other therapies, for example, yoga¹⁰ and physical exercise^{11,12} may have a positive effect on HRQL in hypertensive patients.

In China, the integrative treatment of conventional medicine and Chinese herbal medicine (CHM) for hypertension is commonly used and developed as a treatment model.¹³ Recently years, a number of RCTs assessing the efficacy CHM on HRQL in hypertensive patients have been published. However, to our knowledge, a comprehensive review about the current evidence is not available. Therefore, this study aims to systematically evaluate the results of these RCTs.

Materials and methods

Study design

This study is a systematic literature review and meta-analysis of randomized controlled trials.

Database and search strategy

The literature searches were conducted in the following five databases: China Knowledge Resource Integrated Database (CNKI), Chinese Biomedical Database (CBM), Wanfang Database, PubMed and the Cochrane Controlled Trials Register. Databases in Chinese were searched to retrieve the maximum possible number of trials as CHM is mainly used and researched in China and published in Chinese journals.

The following search strategy was used for Pub Med, and modified to suit other databases. These terms (translated into Chinese) were used as key words to search the three Chinese databases. All searches were completed before October, 2013.

PubMed search strategy:

- No. 1 Chinese medicine.
- No. 2 Chinese drug.
- No. 3 herb.
- No. 4 Chinese herbal.
- No. 5 herbal medicine.
- No. 6 Chinese herbal medicine.
- No. 7 traditional Chinese medicine.
- No. 8 Chinese plant extracts.
- No. 9 OR no. 1–8.
- No. 10 hypertension.
- No. 11 high blood pressure.
- No. 12 hypertensive.
- No. 13 OR nos. 10–12.
- No. 14 quality of life.
- No. 15 life quality.
- No. 16 health-related quality of life.
- No. 17 SF-36.
- No. 18 OR nos. 14–17.
- No. 19 no. 9 and no. 13 and no. 18.

Selection of trials

Two authors (J.-Q. Ju and H.-C. Jiao) independently screened the information contained in each searched paper according to the following inclusion and exclusion criteria. The inclusion criteria were presented below in PICOS format recommended by the PRISMA statement.¹⁴

- (1) Participants: Trials including adult patients with primary hypertension.
- (2) Interventions: Oral administration of CHM formulae in any form (decoction, capsule, pill, liquid, granule etc.) with or without antihypertensive drugs.
- (3) Comparators: Antihypertensive drugs recommended by Chinese guidelines for the management of hypertension with or without placebo.
- (4) Outcome: The efficacy of CHM on HRQL in hypertensive patients was assessed by SF-36.
- (5) Study design: Randomized controlled trials with or without blinding.

The exclusion criteria were the following: (1) Quasi-randomized trials whose methods of allocation use date of birth, date of admission, hospital numbers, or alternation; (2) Interventions using CHM in combination with other

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