INPLASY

Efficacy of oral Chinese medicine in regulating the intestinal flora of patients with chronic heart failure: a 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 4 January 2026 and was last updated on 4 January 2026.

INTRODUCTION

Review question / Objective To evaluate the clinical efficacy of oral Chinese medicine containing danshen and rhubarb components in combination with conventional western drugs in the treatment of chronic heart failure.

Condition being studied A large number of evidence-based medical studies have concluded that the combination of TCM and conventional therapy can improve clinical efficacy, reduce side effects and improve cardiac function. However, most of these studies have focused on the regulation of myocardial energy metabolism, inhibition of myocardial fibrosis and cardiomyocyte apoptosis, and suppression of inflammatory responses by TCM or TCM components. In this study, we evaluated the clinical efficacy of oral Chinese herbal preparations containing danshen and rhubarb in the treatment of chronic heart failure and their effects on the quality of life of patients with chronic heart failure from the perspective of regulating intestinal flora by meta-analysis.

METHODS

Search strategy In compliance with the PRISMA2020 statement [13], computerised searches of PubMed, the Dutch Medical Abstracts database (Embase), The Cochrane Library, Web of Science, China Biomedical Literature Database (CBM), China Journal Full Text Database (CNKI), WanFang Database (WanFang Data) and Wikipedia (VIP). The search period was from the establishment of the database to July 2024, regardless of language. The search strategy included the following keywords: 'Chronic heart failure' OR 'CHF' AND 'Traditional Chinese Medicine' OR 'TCM' AND 'Salvia miltiorrhiza' OR 'Rhubarb'. Besides, to broaden the search, we reviewed the references of the included studies to obtain the target literature.

Participant or population Literature study subjects: patients with a clear diagnosis of chronic

heart failure, who need to meet the diagnostic criteria for chronic heart failure in the Chinese Guidelines for the Diagnosis and Treatment of Heart Failure, and patients with heart failure whose cardiac function is graded at grade II or higher according to the New York Heart Association (NYHA) criteria.

Intervention The control group was treated with conventional therapy, including diet and lifestyle improvement, antiplatelet drugs, lipid-regulating and plaque-stabilising drugs, diuretics, angiotensin convertingenzyme inhibitors (ACEI), angiotensin II receptor blockers (ARB), B receptor blockers and nitrates. The test group was based on the drugs of the control group. The experimental group was treated with an oral TCM qi and blood-activating compound formula (containing danshen and rhubarb) on top of the drugs in the control group.

Comparator The control group was treated with conventional therapy, including diet and lifestyle improvement, antiplatelet drugs, lipid-regulating and plaque-stabilising drugs, diuretics, angiotensin convertingenzyme inhibitors (ACEI), angiotensin II receptor blockers (ARB), B receptor blockers and nitrates. The test group was based on the drugs of the control group.

Study designs to be included The type of study included was a clinical randomised controlled trial (RCT).

Eligibility criteria Inclusion criteria: (1) The type of study included was a clinical randomised controlled trial (RCT). (2) Literature study subjects: patients with a clear diagnosis of chronic heart failure, who need to meet the diagnostic criteria for chronic heart failure in the Chinese Guidelines for the Diagnosis and Treatment of Heart Failure, and patients with heart failure whose cardiac function is graded at grade II or higher according to the New York Heart Association (NYHA) criteria. (3) Literature interventions: The control group was treated with conventional therapy, including diet and lifestyle improvement, antiplatelet drugs, lipid-regulating and plaque-stabilising drugs, diuretics, angiotensin convertingenzyme inhibitors (ACEI), angiotensin II receptor blockers (ARB), B receptor blockers and nitrates. The test group was based on the drugs of the control group. The experimental group was treated with an oral TCM qi and blood-activating compound formula (containing danshen and rhubarb) on top of the drugs in the control group. (4) Literature containing the following seven outcome indicators (one or more): ① Effective rate of improvement in cardiac function; ② Six-minute walk test (6MWT); ③ Ventricular diastolic function (E/A); ④ Terminal B-type natriuretic precursor of B-prOBNP (NT-prOBNP); ⑤ Ejection fraction (LVEF); ⑥ Minnesota quality of life scale (MLHFQ); ⑦ Adverse reactions or adverse events recorded : Adverse reactions such as headache, nausea, vomiting, dizziness, etc. or adverse events such as gastrointestinal haemorrhage during the course of the trial.
Exclusion criteria: (1) The TCM used contained neither danshen nor rhubarb. (2) The study subjects suffered from serious primary cardiovascular diseases: acute heart failure patients, cardiogenic shock, obstructive cardiomyopathy, severe ventricular arrhythmia, stenotic pericarditis, hypertensive emergencies, and secondary heart failure due to systemic diseases. (3) Literature study subjects are those suffering from severe liver and kidney insufficiency, hyperthyroidism or other serious systemic diseases, pregnant and lactating women, and those suffering from mental illness. (4) Literature that lacks standardised criteria for assessing the efficacy of the observed indicators. (5) Literature on animal testing. (6) Literature of case study and review. (7) Literature with unreasonable experimental design and incorrect statistical methods. (8) Repeatedly published or similar literature.

Information sources The searched literature was imported into EndNote literature management software by two researchers independently. The software was used first to eliminate duplicates, then to screen the literature by reading the titles and abstracts according to the established inclusion and exclusion criteria, and finally by reading the full text of the literature to be included in this study. When there was a difference of opinion, the decision was made by a third researcher. All the literature included was read in its original language and then extracted using an Excel sheet, which included (1) the basic information of the data: the name of the study, the name of the first author, and the year. (2) Number of study subjects. (3) Intervention mode. (4) Outcome indicators.

Main outcome(s) ① Effective rate of improvement in cardiac function; ② Six-minute walk test (6MWT); ③ Ventricular diastolic function (E/A); ④ Terminal B-type natriuretic precursor of B-prOBNP (NT-prOBNP); ⑤ Ejection fraction (LVEF); ⑥ Minnesota quality of life scale (MLHFQ); ⑦ Adverse reactions or adverse events recorded : Adverse reactions such as headache, nausea,

vomiting, dizziness, etc. or adverse events such as gastrointestinal haemorrhage during the course of the trial.

Quality assessment / Risk of bias analysis The Cochrane Collaboration Network Risk Assessment Tool was used to evaluate the quality of the literature, which was evaluated in terms of random allocation method, allocation scheme concealment, blinding, completeness of outcome data, selective reporting of findings and other sources of bias. The Newcastle-Ottawa Scale (NOS) for quality assessment of observational studies was used. The scale was evaluated in terms of eight items: representativeness of the study population, comparability between groups, adequacy of the study's evaluation of the outcome, adequacy of the follow-up period, and completeness of follow-up, respectively. The scale was scored out of 9, with a total score of 7 and above as high-quality literature and 5 and below as low-quality articles.

Strategy of data synthesis The Cochrane Collaboration Network Risk Assessment Tool was used to evaluate the quality of the literature, which was evaluated in terms of random allocation method, allocation scheme concealment, blinding, completeness of outcome data, selective reporting of findings and other sources of bias. The Newcastle-Ottawa Scale (NOS) for quality assessment of observational studies was used. The scale was evaluated in terms of eight items: representativeness of the study population, comparability between groups, adequacy of the study's evaluation of the outcome, adequacy of the follow-up period, and completeness of follow-up, respectively. The scale was scored out of 9, with a total score of 7 and above as high-quality literature and 5 and below as low-quality articles.

Subgroup analysis Statistical analysis was performed using RevMan 5.3 statistical software. The effective rate of cardiac function improvement belonged to dichotomous count data using oddsratio (OR), while LVEF, E/A, NT-prOBNP, 6MWT, MLHFQ belonged to continuous variable data using weightedmean difference (WMD), and the statistical results were expressed as 95% confidence intervals (95% CI). When $P > 0.10$, $I2 < 50\%$, it indicates that there is no statistical heterogeneity among the included studies, and the fixed effects model was used for analysis. When $P < 0.10$ and $I2 > 50\%$, it indicates the existence of heterogeneity among the included studies. The source of heterogeneity was first analysed to see if there was a significant change in the results after removing each study individually through sensitivity analysis. If the heterogeneity was due to an individual study, the study was excluded and the Meta-analysis was repeated. If the source of heterogeneity could not be clarified then the data were combined using a random effects model. When the combined factor $P < 0.05$, it was statistically significant.

Sensitivity analysis Statistical analysis was performed using RevMan 5.3 statistical software. The effective rate of cardiac function improvement belonged to dichotomous count data using oddsratio (OR), while LVEF, E/A, NT-prOBNP, 6MWT, MLHFQ belonged to continuous variable data using weightedmean difference (WMD), and the statistical results were expressed as 95% confidence intervals (95% CI). When $P > 0.10$, $I2 < 50\%$, it indicates that there is no statistical heterogeneity among the included studies, and the fixed effects model was used for analysis. When $P < 0.10$ and $I2 > 50\%$, it indicates the existence of heterogeneity among the included studies. The source of heterogeneity was first analysed to see if there was a significant change in the results after removing each study individually through sensitivity analysis. If the heterogeneity was due to an individual study, the study was excluded and the Meta-analysis was repeated. If the source of heterogeneity could not be clarified then the data were combined using a random effects model. When the combined factor $P < 0.05$, it was statistically significant.

Country(ies) involved China.

Keywords Traditional Chinese medicine; Chronic heart failure; Meta-analysis; Clinical efficacy; Cardiac function; BNP level.

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