



Baoyuan Decoction in the Treatment of Chronic Heart Failure: Formula Composition, Chemical Constituents, Anti-CHF Mechanisms, and Clinical Research Progress

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Abstract: Chronic heart failure (CHF) represents the terminal stage of various cardiovascular diseases and remains one of the most lethal diseases worldwide. As a classical traditional Chinese medicine (TCM) formula for benefiting Qi and warming Yang, Baoyuan Decoction has demonstrated favorable clinical efficacy and safety in the treatment of CHF, particularly in patients presenting with the Qi deficiency and blood stasis pattern. The present review systematically consolidates the formula composition, chemical constituents, anti-CHF mechanisms, and clinical research progress of Baoyuan Decoction, with the aim of providing a theoretical basis for its rational clinical application and promoting the development of TCM in the prevention and treatment of cardiovascular diseases.

Keywords: Chronic Heart Failure, Baoyuan Decoction, Traditional Chinese Medicine, Qi Deficiency And Blood Stasis Pattern, Chemical Constituents, Anti-CHF Mechanisms, Clinical Research, Systematic Review.

1. Introduction

Chronic heart failure (CHF) is a clinical syndrome characterized by dyspnea, fluid retention, and other manifestations resulting from impaired ventricular filling or ejection due to structural or functional abnormalities of the heart. Epidemiological surveys indicate that against the backdrop of accelerating population aging, the weighted prevalence of heart failure among Chinese residents aged ≥ 35 years is approximately 1.3%, with an estimated 8.9 million affected individuals, imposing a heavy burden on the public health system [1]. Although modern medicine has made significant progress in CHF treatment—such as the clinical application of angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), and β -blockers [2]—the rates of rehospitalization and mortality among CHF patients remain persistently high. In this context, traditional Chinese medicine (TCM) has garnered increasing attention for its holistic regulatory and multi-target intervention characteristics. TCM classifies CHF under categories such as “palpitations,” “dyspnea,” and “edema,” considering the disease location to be in the heart while involving multiple organs including the lung, spleen, and

kidney. In TCM syndrome differentiation, the pathogenesis of CHF is characterized by root deficiency and branch excess, which can be summarized into three dimensions: “deficiency,” “stasis,” and “water.” The core of the root deficiency lies in heart Qi deficiency, often accompanied by heart Yang insufficiency in later stages; the branch excess primarily manifests as blood stasis, frequently complicated by fluid retention and phlegm turbidity [3]. As a representative formula for benefiting Qi and warming Yang, Baoyuan Decoction is commonly used in combination with other formulas or Western medicines for CHF treatment. This review systematically summarizes its formula composition, chemical constituents, mechanisms of action, and clinical research progress, with the aim of providing a reference for its rational clinical application and future research.

2. Formula Composition Analysis of Baoyuan Decoction

Baoyuan Decoction, first recorded in Bo'ai Xinjian by Wei Zhi of the Ming Dynasty, is one of the first batch of ancient classic formulas announced by the National Administration of Traditional Chinese Medicine (NATCM). The formula is composed of four principal herbs: Ginseng Radix et Rhizoma (Renshen), Astragali Radix (Huangqi), Cinnamomi Cortex (Rougui), and Glycyrrhizae Radix et Rhizoma (Gancao), with a single slice of ginger added as an adjuvant during decoction [4]. Within this formula, Ginseng powerfully tonifies primordial qi and serves as the monarch drug. Astragalus, acting as the minister drug, tonifies qi, lifts yang, and consolidates the exterior. It works synergistically with Ginseng to enhance the efficacy of tonifying qi and cultivating primordial qi. A small amount of Rougui serves as the assistant drug to warmly unblock blood vessels and warm the kidney to tonify yang. Licorice, sweet in flavor and neutral in nature, acts as both assistant and guide drug to harmonize the various herbs and tonify the middle. Collectively, the formula exerts effects of tonifying qi, warming yang, activating blood circulation, and unblocking collaterals. Based on the TCM theory that “Qi is the commander of Blood, and Blood is the mother of Qi,” a deficiency of heart qi leads to insufficient propulsion for blood circulation, readily resulting in blood stasis and vessel obstruction. By tonifying qi to restore blood circulation and warming yang to dissipate cold coagulation, Baoyuan Decoction addresses both the manifestation and the root cause. This aligns precisely with the pathogenesis of CHF, which is characterized by the “coexistence of deficiency and stasis.”

3. Chemical Constituent Analysis of Baoyuan Decoction

Identification of active components in TCM formulas is a prerequisite for elucidating pharmacological mechanisms. The chemical composition of Baoyuan Decoction is complex. Currently, studies on the chemical constituents of its individual herbs have been relatively comprehensive [5-8], and in recent years, research on the overall material basis of the formula has also progressively deepened. Among the compounds identified from Baoyuan Decoction, the primary active constituents are flavonoids and saponins, predominantly derived from Renshen, Huangqi, and Gancao [9]. The flavonoid compounds in Baoyuan Decoction mainly include liquiritin, liquiritigenin, isoliquiritin, isoliquiritigenin, formononetin, and calycosin; the saponin components encompass ginsenosides (such as ginsenoside Rb1 and Re), astragaloside IV, glycyrrhizic acid, and others [10].

4. Mechanisms of Baoyuan Decoction in Treating Chronic Heart Failure

4.1 Inflammatory Regulation

Chronic inflammation is a critical driver of CHF progression, characterized by persistently elevated circulating pro-inflammatory factors. Yuan et al. [11] found in a rat model of myocardial infarction that Baoyuan Decoction combined with Taohong Siwu Decoction downregulated the expression of tumor

necrosis factor- α (TNF- α), Toll-like receptor 4 (TLR4), and nuclear factor- κ B (NF- κ B) in lung tissue, confirming the formula's anti-inflammatory effects at the animal experimental level. Further studies by Zhou et al. [12] demonstrated that Baoyuan Decoction combined with Xuefu Zhuyu Decoction effectively reduced plasma levels of pro-inflammatory factors including high-sensitivity C-reactive protein (hs-CRP), interleukin-6 (IL-6), and TNF- α in CHF patients. These basic and clinical studies corroborate each other, suggesting that Baoyuan Decoction combined with other formulas may exert anti-inflammatory effects by downregulating pro-inflammatory factors, thereby delaying CHF progression.

4.2 Anti-oxidative Stress

Oxidative stress is a major pathological mechanism driving the onset and progression of CHF. Under pathological conditions, excessive production of reactive oxygen species (ROS) overwhelms the clearance capacity of the antioxidant defense system, triggering lipid peroxidation, protein oxidation, and DNA damage, ultimately leading to cardiomyocyte injury [13]. Superoxide dismutase (SOD) catalyzes the dismutation of superoxide anion radicals (O_2^-) to hydrogen peroxide (H_2O_2), which is subsequently reduced to water by glutathione peroxidase (GSH-Px), thereby scavenging free radicals and mitigating oxidative damage. Although Sun et al. [14] found that modified Baoyuan Decoction (Baoyuan Decoction with *Schisandrae Chinensis Fructus*) could significantly increase the activities of SOD and GSH-Px in the hippocampal tissue of chronic stress rats, this antioxidant effect provides indirect evidence and suggests a potential direction for further cardiac studies.

4.3 Inhibition of Cardiomyocyte Apoptosis

Cardiomyocyte apoptosis is a significant contributor to the progressive loss of cardiac systolic function. Wang et al. [15] demonstrated that Baoyuan Decoction improves cardiac function and inhibits cardiomyocyte apoptosis, with the molecular mechanism associated with downregulation of angiotensin II type 1 receptor (AT1R) and cardiac ankyrin repeat protein (CARP) expression. Additionally, Baoyuan Decoction upregulates the anti-apoptotic protein B-cell lymphoma-2 (Bcl-2) in myocardial tissue while suppressing pro-apoptotic molecules including p53, Bcl-2-associated X protein (Bax), and cleaved caspase-3. These findings suggest that Baoyuan Decoction may exert cardioprotective effects by modulating the AT1R-CARP signaling pathway to inhibit cardiomyocyte apoptosis.

4.4 Improvement of Mitochondrial Function and Energy Metabolism

Mitochondria serve as the core site of energy supply for cardiomyocytes, and mitochondrial dysfunction accelerates myocardial injury. Wan et al. [16] employed proteomic techniques to screen for target proteins mediating the cardioprotective effects of Baoyuan Decoction, identifying 46 potential binding target proteins, the majority of which were localized to mitochondria. KEGG pathway enrichment analysis indicated that these target proteins are primarily involved in the tricarboxylic acid cycle and amino acid metabolic pathways. Furthermore, JC-1 fluorescence staining confirmed that Baoyuan Decoction significantly alleviated mitochondrial damage. These findings suggest that Baoyuan Decoction may effectively attenuate myocardial injury and exert cardioprotective effects by modulating mitochondrial function and ATP energy metabolism pathways.

4.5 Inhibition of Cardiac Hypertrophy and Ventricular Remodeling

Pathological cardiac hypertrophy and ventricular remodeling represent the core pathological basis of CHF progression. Ankyrin repeat domain 1 (ANKRD1) [17], a biomarker that has recently attracted considerable attention, can promote pathological cardiac hypertrophy induced by neurohumoral factors such as angiotensin II or catecholamines by activating the extracellular signal-regulated kinase (ERK)/GATA-binding protein 4 (GATA4) signaling pathway. Previous studies [18] have shown that Baoyuan Decoction reverses various CHF-related biological abnormalities in rats with heart failure post-acute myocardial infarction, with the mechanism primarily involving regulation of the ANKRD1-ERK/GATA4 signaling pathway. In vitro experiments further confirmed that Baoyuan Decoction inhibits cardiac hypertrophy and delays ventricular remodeling progression by downregulating AT1R, ANKRD1, p-ERK1/2, calpain 1, and p-GATA4 expression.

5. Clinical Research Progress on Baoyuan Decoction in Treating Chronic Heart Failure

5.1 Improvement of Clinical Efficacy

Multiple studies have observed the clinical efficacy of Baoyuan Decoction in CHF treatment. Jian et al. [19] reported that adding modified Baoyuan Decoction to conventional Western medicine treatment increased the total effective rate to 98.00%, significantly higher than the 82.00% observed with Western medicine alone ($P < 0.05$). Wang et al. [20] demonstrated that in elderly CHF patients with heart-lung Qi deficiency and heart blood stasis pattern, the combination of Baoyuan Decoction with Xuefu Zhuyu Decoction plus conventional Western drugs achieved a total effective rate of 90.00%, superior to the 66.67% in the conventional Western drugs alone group ($P < 0.05$). These studies consistently indicate that Baoyuan Decoction combination therapy has a favorable clinical effect in CHF patients. Furthermore, Huo et al. [21] conducted a meta-analysis of 12 RCTs (involving 976 CHF patients) to summarize the clinical efficacy of Baoyuan Decoction combined with conventional Western drugs. The results showed that compared with conventional Western drugs alone, the combination therapy significantly improved the overall clinical response rate ($RR = 1.23$, 95% CI [1.16, 1.31], $P < 0.00001$).

5.2 Improvement of Cardiac Function

The meta-analysis by Huo et al. [21] also indicated that combination therapy significantly improved cardiac function in CHF patients compared with conventional Western drugs, manifested as increased left ventricular ejection fraction (LVEF) and decreased plasma N-terminal pro-B-type natriuretic peptide (NT-proBNP) and brain natriuretic peptide (BNP) levels. A systematic review and meta-analysis by Ma et al. [22], including 26 RCTs and 1,857 patients, evaluated the effects of modified Baoyuan Decoction on cardiac function in CHF patients with Qi deficiency and blood stasis pattern, with conclusions consistent with the aforementioned studies. The results indicated that combination therapy significantly improved LVEF ($MD = 5.88$, 95% CI [5.46, 6.30], $P < 0.00001$), reduced BNP ($MD = -151.66$, 95% CI [-154.92, -148.40], $P < 0.00001$), and decreased logarithmically transformed NT-proBNP levels ($MD = -0.22$, 95% CI [-0.37, -0.06], $P = 0.007$). Combination therapy also further improved echocardiographic parameters, specifically reducing left ventricular end-systolic and end-diastolic internal diameters (LVESD and LVEDD) while increasing left ventricular fractional shortening (LVFS). These mutually reinforcing studies demonstrate that Baoyuan Decoction combination therapy can improve cardiac function in CHF patients from multiple dimensions.

5.3 Improvement of TCM Syndromes

The same systematic review and meta-analysis by Ma et al. [22] also demonstrated that modified Baoyuan Decoction combined with conventional Western medicine significantly improved TCM syndrome scores in CHF patients with Qi deficiency and blood stasis pattern (MD = -4.12, 95% CI [-5.09, -3.15], $P < 0.00001$). Furthermore, Li et al. [23], focusing on CHF patients with heart-lung Qi deficiency pattern, confirmed that adding Baoyuan Decoction combined with Bufe Decoction to standardized CHF treatment significantly reduced TCM syndrome scores for palpitations, fatigue, shortness of breath, pallor, and cough with exhaustion, with all individual symptom scores in the study group significantly lower than those in the control group ($P < 0.05$). These two studies targeting different TCM patterns (Qi deficiency with blood stasis vs. heart-lung Qi deficiency) both confirmed the advantages of Baoyuan Decoction combination therapy in improving TCM syndromes in CHF patients.

5.4 Improvement of Exercise Tolerance

Duan et al. [24] demonstrated in elderly CHF patients with coronary heart disease that adding modified Baoyuan Decoction to conventional Western drugs significantly increased the 6-minute walk distance (6MWD). In addition, Zhang et al. [25] investigated the effect of Baoyuan Decoction combined with modified Taohong Siwu Decoction on exercise tolerance in CHF patients with Qi deficiency and blood stasis pattern. Patients were randomly divided into a control group (receiving the new quadruple therapy) and a treatment group (receiving the new quadruple therapy plus Baoyuan Decoction combined with modified Taohong Siwu Decoction) for a 4-week course. The results indicated that after the intervention, the 6MWD of the treatment group significantly increased compared to before, and the increase was greater than that of the control group ($P < 0.05$). These two studies consistently demonstrated that the Baoyuan Decoction combination treatment is beneficial in improving the exercise tolerance of patients with CHF.

5.5 Improvement of Quality of Life

Chen et al. [26] used the Minnesota Living with Heart Failure Questionnaire (MLHFQ) as an assessment tool to observe the effects of Baoyuan Decoction combined with Tingli Dazao Xiefei Decoction on the quality of life of patients with heart failure with reduced ejection fraction (HFrEF). In this study, the patients were divided into a basic Western drugs treatment group and a combination therapy group. The MLHFQ results showed no significant differences between the two groups in physical, emotional, and other domain scores before treatment ($P > 0.05$); after 2 weeks of treatment, the combination therapy group showed greater reductions in all domain scores compared with the control group ($P < 0.05$). In addition, Meng et al. [27] used the 36-Item Short Form Health Survey (SF-36) to evaluate the impact of recombinant human brain natriuretic peptide (rhBNP) combined with Baoyuan Decoction on various quality-of-life dimensions in patients with refractory heart failure. The results showed that after intervention, the observation group had superior scores in emotional function, physiological function, and social function compared with the control group ($P < 0.05$). Although these two studies employed different assessment tools, both indicated that Baoyuan Decoction combination therapy has a positive effect on improving quality of life in CHF patients.

5.6 Prognosis and Safety

Wang et al. [28] randomly divided 120 patients with heart failure with mildly reduced ejection fraction (HFmrEF) into two groups (60 cases in each group). Both groups received conventional heart failure treatment. On this basis, the control group was treated with sacubitril/valsartan, while the study group received an integrated traditional Chinese and Western medicine treatment regimen of sacubitril/valsartan combined with modified Baoyuan Decoction and Bufe Decoction. After a 4-week

treatment course, patients were followed up for 3 months, with all cases completing the follow-up. During the follow-up period, the incidence of major adverse cardiovascular events (MACE) in the study group was significantly lower than that in the control group ($P < 0.05$), suggesting that this combination regimen may help reduce MACE risk in HFmrEF patients and has a positive effect on improving prognosis. Regarding safety, in the systematic review and meta-analysis by Ma et al. [22], 7 of the 26 included RCTs reported safety information. Six reported no adverse reactions during treatment, and only one described adverse reactions in detail, including dry cough and hypokalemia in both the treatment and control groups, with headache additionally reported in the control group. The adverse reaction rate in the treatment group was lower than that in the control group, and no serious adverse events occurred in either group. These findings indicate that adding modified Baoyuan Decoction to conventional Western medicine treatment results in mild, controllable adverse reactions without increasing safety risks. Furthermore, Lin et al. [29], in a study on Qili Qiangxin Capsule combined with Baoyuan Decoction for CHF, randomized patients into an observation group and a control group. Both groups received basic treatment (blood pressure and heart rate control, antiplatelet and lipid-regulating therapy) and cardiac function monitoring; the control group received conventional Western drugs, while the observation group received Qili Qiangxin Capsule combined with modified Baoyuan Decoction. The results showed that the adverse reaction rate in the observation group was 6.67%, significantly lower than the 18.33% in the control group ($P < 0.05$), indicating a superior safety profile for the Baoyuan Decoction combination therapy.

6. Summary and Outlook

As stated in Yilin Gaicuo (Corrections in the Forest of Medicine): “When primordial Qi is deficient, it necessarily fails to reach the vessels; when vessels lack Qi, stasis must remain.” This profoundly reveals the central role of Qi deficiency in CHF pathogenesis, establishing benefiting Qi and warming Yang as the fundamental therapeutic principle for CHF. At the level of formula compatibility, Baoyuan Decoction employs Renshen and Huangqi to greatly supplement primordial Qi to treat the root, supplemented by Rougui to warm and unblock the channels to address the branch. Modern chemical studies indicate that flavonoids and saponins constitute its primary pharmacodynamic material basis. At the mechanistic level, the formula demonstrates synergistic multi-target and multi-pathway intervention advantages, exerting potential cardioprotective effects through multiple pathways including regulation of inflammatory responses, alleviation of oxidative stress, inhibition of cardiomyocyte apoptosis, optimization of mitochondrial energy metabolism, and suppression of cardiac hypertrophy. Moreover, multiple RCTs and meta-analyses suggest that adding Baoyuan Decoction and its modifications to conventional Western medicine treatment can further enhance clinical efficacy, improve cardiac function and TCM syndromes, increase exercise tolerance and quality of life, effectively reduce MACE risk, and exhibit a favorable safety profile. However, current research still has certain limitations: the methodological quality of existing clinical studies is generally low, with most RCTs failing to implement blinding or allocation concealment, and there is a lack of large-sample, multi-center high-quality evidence. Future efforts should focus on conducting rigorously designed, well-executed large-sample multi-center trials to provide evidence for the precise clinical application of Baoyuan Decoction and to promote the in-depth development and application of TCM in cardiovascular disease prevention and treatment.

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