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Shenfu decoction as adjuvant therapy for improving quality of life and hepatic dysfunction in patients with symptomatic chronic heart failure



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ABSTRACT

Ethnopharmacological relevance: Shenfu decoction (SFD) is a water extract of the dried root or root stalk of *Panax ginseng* C. A. Mey (Asian ginseng) and the lateral root of *Aconitum carmichaeli* Debx (prepared by Fuzi, Heishunpian in Chinese). It has been used to treat heart failure for over a thousand years. The main active components of SFD, ginsenosides and higenamine, enhance heart contractility, increase the coronary blood supply, improve ischemic myocardial metabolism, scavenge free radicals and protect myocardial ultrastructure.

Aim of the study: To investigate the effect of SFD on quality of life (QOL) and hepatic function in symptomatic chronic heart failure (CHF) patients.

Materials and methods: Forty patients enrolled in the study were randomized into two groups: an SFD group (18 cases) and a control group (22 cases). All the patients received standard heart failure therapy, and the SFD group patients were also treated with Shenfu granules for 14 days as an adjunctive therapy. The effects of SFD on QOL, plasma alanine aminotransferase (ALT) level, cardiac function, left ventricular ejection fraction (LVEF) and tumor necrosis factor- α (TNF- α) level were studied. ALT threshold in hepatic injury are 21 U/L for men and 17 U/L for women.

Results: Minnesota Living with Heart Failure Questionnaire (MLHFQ) scores were improved by 35.27 ± 10.72 vs. 23.87 ± 11.96 in the SFD and control groups respectively ($p < 0.01$). Subgroup analysis of the MLHFQ results demonstrated that both physical and emotional scores were significantly higher in the SFD group (21.00 ± 5.66 vs. 16.75 ± 6.25 , $p < 0.05$; 4.64 ± 4.84 vs. 1.13 ± 2.85 , $p < 0.05$). Circulating ALT was significantly decreased by SFD (13.3 IU/L vs. 0.6 IU/L, $p < 0.01$). The grading of cardiac function and LVEF were increased by 1.6 ± 0.5 vs. 1.1 ± 0.3 and $18\% \pm 13\%$ vs. $8\% \pm 8\%$ in the SFD and control groups respectively ($p < 0.05$ and $p < 0.05$). The level of TNF- α declined more in SFD than control group (64.8 ± 5.0 to 57.6 ± 4.1 , $p < 0.05$; vs. 61.6 ± 5.9 vs. 57.7 ± 3.2 , $p > 0.05$).

Conclusion: Compared with standard heart failure treatment, oral SFD as an adjuvant therapy significantly improved QOL and hepatic injury in CHF patients.

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1. Introduction

Cardiovascular disease is the greatest noninfectious health hazard to confront the human race. Of all cardiovascular

diseases, heart failure accounts for most deaths, especially in adults over the age of 65 years. Despite advances in the treatment of heart failure, it is estimated that ≈ 6.6 million US adults ≥ 18 years of age had heart failure in 2010, and the value is expected to increase by 25% in 2030 (Roger et al., 2012). Given the steady growth of morbidity and aging populations, new therapeutic approaches are needed. SFD, a traditional Chinese formulation first documented in 1465 (Luo et al., 2008), consists mainly of extracts of *Radix ginseng* and *Radix aconitum Carmichael* roots. Approximately 40 ginsenosides were identified in ginseng roots, and it is likely that ginseng-mediated cardioprotective effects are achieved by a combined effect orchestrated by

Abbreviations: SFD, Shenfu decoction; SFI, Shenfu injection; QOL, Quality of life; CHF, Chronic heart failure; ALT, Alanine aminotransferase; LVEF, Left ventricular ejection fraction; TNF- α , Tumor necrosis factor- α ; MLHFQ, Minnesota Living with Heart Failure Questionnaire; ACEI, Angiotensin-converting enzyme inhibitors; ARBs, Angiotensin II receptor blockers; NYHA, New York Heart Association; LFT, Liver function test; ROS, Reactive oxygen species

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multiple components of ginseng rather than by any single ginsenoside alone (Kim, 2012). Both in vitro and vivo models, ginseng have potential cardiovascular benefits through diverse mechanisms, including antioxidation, improving cardiovascular function, modifying vasomotor function, altering autonomic neurotransmitters release and regulating intracellular ion channels (Li et al., 2010). *Aconitum carmichaeli* Debx (Fu zi, heishunpian in Chinese) was another herbal drug which has been used in Asia for 2000 years. Studies have shown that Fuzi and its active components can improve left ventricular systolic and diastolic function (Liu et al., 2012). Cardioprotective effect of Fuzi may be related to scavenging of hydroxyl radicals, increasing nitric oxide production and inhibition of lipid peroxidation (Yu et al., 2015). Shenfu injection (SFI), a form of SFD used for intravenous injection, and SFD itself have been widely used in clinical practice for treating cardiac diseases; it protects against conditions such as myocardial infarction, coronary heart disease, cardiac insufficiency, cardiac arrhythmia and congestive heart failure (Dong et al., 2004; Li et al., 2007; Zhang et al., 2005; Zheng et al., 2004). Moreover, some studies have proved that SFD and SFI help to protect against ischemia/reperfusion injuries in many organs such as the spinal cord, brain, liver and especially the heart (Wang et al., 2006; Xiong et al., 2007; Zhu et al., 2006).

Although there has been considerable research into the effects of SFD or SFI in vitro and in animal models, clinical research has been relatively limited, so much less is known about the effect of SFD on QOL in patients with CHF and no data on the improvement of hepatic dysfunction in these patients have been reported. In the present study, we therefore investigated the effects of SFD on QOL and liver function in CHF patients.

2. Methods

2.1. Study population

In a prospective randomized controlled trial, patients were included if they met the following criteria: (1) New York Heart Association (NYHA) classification II, III and IV were enrolled. (2) A 2D-guided M-mode echocardiogram was performed on each subject by an expert sonographer. Left ventricular diameters were measured according to American Society of Echocardiography guidelines. An additional 2D echocardiogram from the apical view was used to determine the systolic ejection fraction by planimetry of the left ventricle (modified Simpson method). Systolic dysfunction was LVEF < 50%. (3) ≥ 18 years of age on test data. Exclusion criteria were the presence of acutely decompensated heart failure, severe renal or liver dysfunction, thyroid diseases, a history of other severe chronic diseases or cancer, or unwillingness to participate. All study procedures were conducted in accordance with the guidelines of the Declaration of Helsinki and Tokyo for humans, and were also approved by the institutional ethics committee. All patients enrolled gave written informed consent.

In this randomized controlled trial, 40 patients (≥ 18 years) with symptomatic CHF who fulfilled all inclusion criteria were assigned to a control group or SFD group using random numbers (Fig. 1). All patients received standard heart failure therapy for 14 days at the time of randomization, including angiotensin-converting enzyme inhibitors (ACEI) or angiotensin II receptor blockers (ARBs), and β -blockers. Depending on the stage of heart failure, an aldosterone antagonist and/or digitalis glycoside were also used, and a diuretic was deployed to relieve symptoms according to ACCF/AHA guidelines for the diagnosis and management of heart failure in adults. In addition, the patients in the

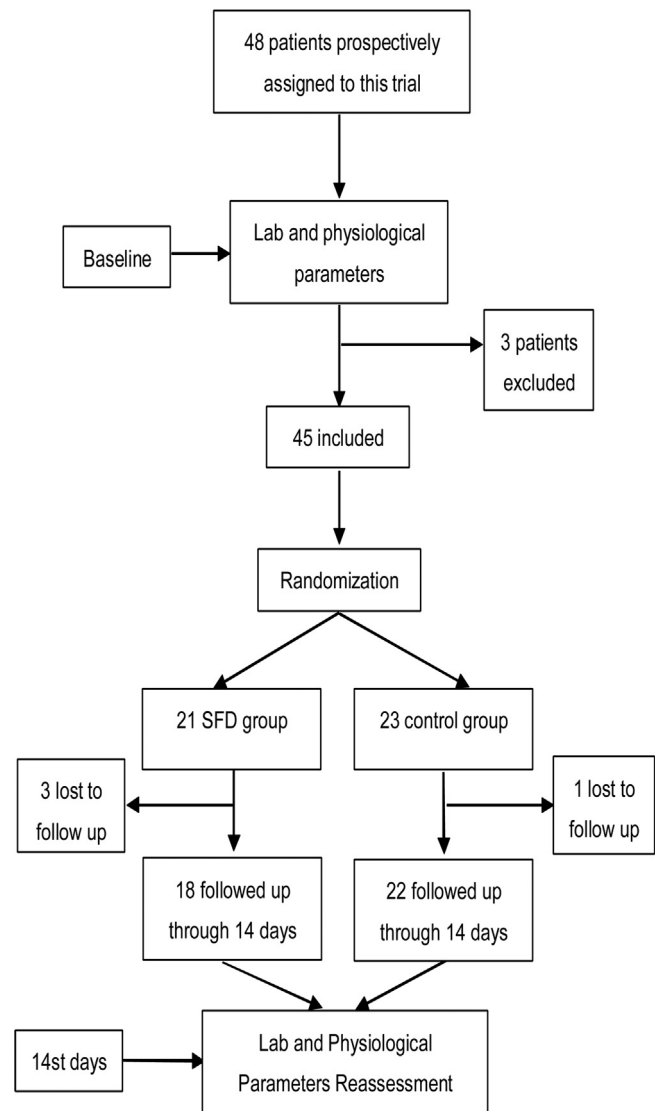


Fig. 1. Disposition of patients in the study.

SFD group received shenfu granules (equal to Ginseng 10 g, Heishunpian 10 g) once a day. MLHFQ scores, NYHA classification, and LVEF were recorded at the beginning and end of the study period. Patients were recorded as showing worsened, unchanged, improved, or markedly improved NYHA classification. 'Worsened' was defined as death or worsening of heart failure class by more than 1. 'Unchanged' was defined as lack of or insufficient therapeutic response, or improvement of heart failure class less than 1. 'Improved' and 'markedly improved' were defined as improvement in heart failure class of 1–2 and ≥ 2 , respectively. The plasma ALT level was also recorded as an indicator of hepatic injury. We also noted the safety and tolerability of SFD for CHF patients. Safety was assessed by adverse events, laboratory parameters (serum urea nitrogen, serum creatinine), hematology (hemoglobin, red blood cell count, and platelet count), serum electrolytes (potassium, sodium), blood pressure and heart rate. All physiological parameters and biochemical indices were determined immediately before as well as after treatment. The endpoint of the study comprised the changes in QOL, LVEF, NYHA classification and ALT after 14 days. All data were obtained by a cardiologist blinded to the patient information.

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