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RESEARCH ARTICLE

Western medication plus Traditional Chinese Medicine preparations in patients with chronic heart failure: a prospective, single-blind, randomized, controlled, and multicenter clinical trial

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Abstract

OBJECTIVE: To assess the efficacy and safety in patients with chronic heart failure (CHF) of Western medication plus Traditional Chinese Medicine (TCM) preparations.

METHODS: This prospective, single-blind, randomized, controlled, and multicenter clinical trial began on September 17, 2008, and was completed on June 25, 2011. A total of 340 inpatients, aged 40-79 years, with exacerbating CHF from 10 hospitals were enrolled and randomly allocated within 24 h of admission. The trial included three intervention periods. During hospitalization, the control group

received western medication for CHF and the treatment group received Danhong injection with Shenfu injection or Shenmai injection. After discharge, all patients were treated with Qiliqiangxin capsules and Buyiqiangxin tablets or a placebo for 6 months. After the 6-month intervention, both groups received only continuous western medication. The primary endpoint was all-cause mortality. The efficacy assessments were as follows: B-type natriuretic peptide (BNP), Lee's HF score, the 6-minute walking test (6MWT), left ventricular ejection fraction (LVEF), and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The safety assessments were as follows: blood and urine routine examination, hepatic and renal function, electrolytes in blood and adverse events.

RESULTS: Compared with the control group, the treatment group showed a 30.99% reduction in all-cause mortality and an improved survival rate. The treatment group showed greater improvement in 6MWT (P = 0.02) than the control group on discharge, after 12-month follow-up, there was a time-group interaction for MLHFQ (P = 0.03). Incidence rate of adverse events and other relevant safety indexes were not statistically significant between the two groups.

CONCLUSION: Western medication plus TCM treatment can increase 6-minute walking distance (improve exercise tolerance) and quality of life with heart failure patients.

Keywords: Heart failure; Medicine, Chinese traditional; Walk test; Randomized controlled trail

INTRODUCTION

In China, patients are often given Traditional Chinese Medicine (TCM) alongside Western medication to treat various diseases. The integration of these two medical approaches has developed into a new treatment model in recent years. For heart failure (HF) in particular, this new treatment model has demonstrated advantages over sole use of western medication in terms of improving patients' quality of life and exercise capacity.[1-8] Prior studies of this treatment approach to HF have been small, single-center trials; thus, larger and more rigorous clinical trials are necessary. Therefore, we undertook an evaluation of the clinical effects of TCM medicine in HF by complex intervention (SECETCM-HF) over a 12-month period to determine the advantages of western medication plus TCM which according to the syndrome differentiation.

METHODS

Participants

Inclusion criteria were as follows: male and female patients aged 40 to 79 years, diagnosed with chronic HF (CHF) and admitted to hospital, presented with HF symptoms such as fatigue and fluid retention (edema) with or without dyspnea for at least 3 months, had an left ventricular ejection fraction (LVEF) of 50% or less according to echocardiography using the modified Simpson method at enrollment and were in the New York Heart Association (NYHA) functional class Ⅱ-Ⅳ. Patients with B-type natriuretic peptide (BNP) levels < 200 pg/mL and those who had acute HF or acute exacerbation of chronic HF were excluded. Additional exclusion criteria included the following: (a) acute coronary syndrome (within the previous 4 weeks); (b) revascularization therapy within 6 months; (c) pulmonary heart disease; (d) severe valvular disease; (e) hypertrophic obstructive cardiomyopathy; (f) congenital heart disease; (g) pulmonary hypertension caused by acute or chronic pulmonary embolism or other factors; (h) pre-excitation syndrome; (i) stroke within the past 6 months; (j) acute myocarditis; (k) severe hepaticin insufficiency [alanine aminotransferase (ALT) > 2 times the upper limit of normal], severe renal insufficiency (serum creatinine > 265 μmol/L) or respiratory insufficiency (partial pressure of arterial oxygen less than 8 kPa (60 mm Hg), or with partial pressure of arterial carbon dioxide higher than 6.65 kPa (50 mm Hg); (l) anemia (hemoglobin level ≤ 90 g/L); (m) severe endocrine diseases like hyperthyroidism; (n) history of malignant tumor; (o) mental disease; (p) pregnant or lactating; (q) suspected or confirmed allergy to the intervention drugs; (r) inability to walk autonomously because of physical disabilities; and (s) participation in other studies within the last 2 months.

Informed consents were signed before enrollment

The investigators were all legally qualified medical practitioners and had been trained specifically for this study.

Trial registration: Chinese Clinical Trial Registry of International Clinical Trials Registry Platform of the World Health Organization (ChiCTR-TRC- 08000059).

Study design

The study was a prospective, single-blind, randomized, controlled, and multicenter clinical trial. The study protocol and informed consent form was approved by the Ethics Committee of the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine. The protocol was conducted according to the International Conference on Harmonization guidelines and other applicable laws and regulations and was approved by the ethics committee on January 30, 2008 (TYLL2008004). The protocol was registered in the Chinese Clinical Trial Registry of the World Health Orga-