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CLINICAL STUDY

Multicenter clinical efficacy observation of integrated Traditional Chinese Medicine-Western Medicine treatment in acute onset period of pulmonary heart disease

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Abstract

OBJECTIVE: To evaluate the efficacy of integrated Traditional Chinese Medicine-Western Medicine (TCM-WM) in the treatment of acute onset pulmonary heart disease (PHD).

METHODS: A total of 240 patients met the inclusion criteria and were enrolled. These inpatients were divided into group A (treatment group) and B (control group) in order of admission according to the principles of randomization and control. The research was performed simultaneously in three hospitals. Two groups were given basic treatment that included: controlled oxygen therapy, active and effective anti-infection, maintaining airway patency, correcting O_2 deficiency and CO_2 retention, correcting acid-base imbalance and electrolyte disturbance, reducing pulmonary hypertension and treating right heart failure, nutritional support and treatment of complications. Group A was given basic treatment and integrated Traditional Chinese Medicine (TCM) differentiating therapy; group B was given basic therapy and a placebo that was similar in appearance and taste to TCM medicinal broth of pharmaceutical preparations, provided by Yibin Pharmaceutical Company (Yibin, China, Wuliangye Group).

RESULTS: The mortality in the treatment group decreased by 4.98% compared with the control group. The treatment group reported improved ventilation, corrected hypoxemia, improved nutritional status and promoted digestive functions. It also significantly improved the patient's self-life skills, improved the patient's quality of life and could shorten the length of hospital stay.

CONCLUSION: Comprehensive integrated TCM-WM treatment showed good clinical efficacy toward the acute onset period of PHD patients.

Key words: integrated Traditional Chinese Medicine and Western Medicine; Pulmonary heart disease; Treatment outcome; Multicenter study

INTRODUCTION

Chronic pulmonary heart disease (CPHD) is caused by the persistent presence of pulmonary hypertension, which can result in damage to cardiac function. When the disease progresses to a decompensated state, the situation is normally dangerous, and without timely intervention, death may result.[1,2] The average prevalence rate is 0.46% ,[3] and the hospital mortality rate is 12.5%-14.5% .[4] Chronic obstructive pulmonary disease is

closely related to PHD. The incidence of PHD is increasing, thereby seriously affecting the quality of life for patients.[5-9] In recent years, researchers have carried out studies on the complications of PHD from a pathophysiological aspect.[10-17] Extensive studies have been performed to reduce pulmonary artery pressure and improve respiratory failure and cardiopulmonary functions. However, an effective approach to prevent heart and lung function failure is still not available, and the rates of mortality and mutilation remain high, placing a heavy burden not only on patients and their families but also on society.[18-23] An acute exacerbation of PHD is mostly induced by acute pulmonary infection, which is normally accompanied by respiratory failure and cardiac dysfunction. Complications such as acid-base imbalance and electrolyte disturbance, pulmonary encephalopathy, gastrointestinal bleeding, disseminated or diffuse intravascular coagulation (DIC) and malnutrition are life-threatening.[12,14,15] Several studies investigated integrated Traditional Chinese Medicine-Western Medicine (TCM-WM) for the treatment of acute onset period of PHD; however, the correct scientific methodology was not used and the quality of clinical trials were poor, which consequently affected the authenticity and reproducibility of the conclusions. It is therefore difficult for worldwide medical circles to recognize the results, and thus the promotion and application of this type of treatment is problematic. China is a low-income country, and 70%-80% of patients live in rural areas where PHD accounts for the highest mortality rate. Therefore, it is necessary to develop a reasonable, effective, safe and suitable integrated TCM-WM program. Since 1994, clinical studies have been conducted on integrated TCM-WM in the treatment of acute onset period of CPHD. The results showed that the application of integrated TCM-WM could contribute to patients' recovery from infection, and reduce the period of antibiotic use and hospitalization time. Clinical studies with large samples were carried out to prove the efficacy and explore the value of the program.

MATERIALS AND METHODS

Study subjects

This study included 240 PHD patients who were in the acute onset period. All subjects were inpatients of the Department of Emergency (the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine), Department of Emergency and Internal Medicine (Neijiang Municipal Traditional Chinese Medicinal Hospital) and Department of Internal Medicine (Anyue County Traditional Chinese Medicinal Hospital) from March 2004 to December 2006. These patients were divided randomly into an integrated TCM-WM comprehensive treatment group (treatment group) and Western Medicine (WM) comprehensive treatment group (control group) according to the admission time. Seven cases were excluded from the study because they did not follow their medication, and three cases died within 24 h. A total of 230 cases were included in which 114 cases were in the treatment group and 116 cases were in the control group. Five cases from the treatment group and 10 from the control group did not continue the study. The statistic of comprehensive efficacy was based on the last recorded data and the final data. The baselines of gender, age, disease severity, symptoms and signs integral at the enrolment were homogeneous and comparable. This study was conducted in accordance with the Declaration of Helsinki[24] and with approval from the Ethics Committee of Chengdu University of Traditional Chinese Medicine. Written informed consent was obtained from all participants.

Inclusion criteria

The inclusion criteria were as follows: (a) chronic bronchitis, emphysema and heart disease or other chest diseases caused by cardiovascular disease, pulmonary hypertension, right ventricular enlargement and right ventricular dysfunction, and acute exacerbation; (b) history of chronic bronchitis; (c) aged 40-85 years old; (d) within 72 h of onset; and (e) complied with the TCM differentiating diagnosis of phlegmatic hygrosis retention in lung and closed and depressed lung *Qi*.

Exclusion criteria

Exclusion criteria were as follows: (a) non-chronic bronchitis-caused PHD; (b) < 40 years old or > 85 years old; (c) allergy to test drug; (d) severe liver and kidney dysfunction (alanine aminotransferase, blood urea nitrogen and creatinine were more than twice normal levels); (e) accompanied by severe diseases in the blood system, endocrine and metabolic system, central nervous system and other systems; mental illness; pregnant or lactating women; (f) had serious complications such as coma, shock, gastrointestinal bleeding, DIC, pulmonary encephalopathy, pulmonary embolism, cardiac arrhythmia and coronary heart disease when admitted; (g) died within 24 h of admission; (h) Hb < 6 g/dL; (i) was in the remission period of PHD, and (j) did not comply with inclusion criterion 5. Patients were excluded if any of the 10 criteria were not met.

Grouping

Patient grouping followed the principles of randomization and control. The patients were divided into groups A (integrated TCM-WM comprehensive treatment group, the treatment group) and B (Western Medicine comprehensive treatment group, the control group). Based on the "Chronic Obstructive Pulmonary Disease Treatment Guidelines" published by the Chronic Obstructive Pulmonary Disease Group, Respiratory Diseases Branch of Chinese Society in 2002,[25] patients were divided into light, middle and severe. The inpatients who met the inclusion criteria were dis-