

CLINICAL STUDY

Efficacy and advantages of modified Traditional Chinese Medicine treatments based on "kidney reinforcing" for chronic aplastic anemia: a randomized controlled clinical trial

Wu Dijiong, Shen Yiping, Ye Baodong, Fang Bingmu, Lin Shengyun, Chen Zhilu, Jiang Huifang, Feng Changwei, He Lüyuan, Gao Yanting, Liu Yonglin, Liu Yonghua, Zhu Jiajia, Wu Liqiang, Shao Keding, Zhou Yuhong

Wu Dijiong, Shen Yiping, Ye Baodong, Lin Shengyun, Gao Yanting, Liu Yonglin, Zhu Jiajia, Wu Liqiang, Shao Keding, Zhou Yuhong, Department of Hematology, Zhejiang Provincial Hospital of Traditional Chinese Medicine, Hangzhou 310006, China

Fang Bingmu, Liu Yonghua, Department of Hematology, People's Hospital of Lishui City, Lishui 323000, China

Chen Zhilu, Jiang Huifang, Department of Hematology, Tongde Hospital of Zhejiang Province, Hangzhou 310007, China

Feng Changwei, Department of Hematology, Taizhou Hospital of Zhejiang Province, Taizhou 318000, China

He Lüyuan, Department of Hematology, Jinhua Hospital of Traditional Chinese Medicine, Jinhua 321017, China

Supported by Special Item of Important Disease of Zhejiang Province Traditional Chinese Medicine Sic-Tech Innovation Platform (Effect and Mechanism of Traditional Chinese Medicine on the Treatment of Aplastic Anemia and the Funding of Traditional Chinese Medicine Assessment Criterion, No. 2009ZDJB01); Subject of Key Sic-Tech Innovation Team of Zhejiang Province (Clinical Study on Treatment of Chronic Aplastic Anemia by Tonifying Kidney and Promoting Blood Circulation, No. 2011R09042-02); Special Research Funds for Traditional Chinese Medicine Industry (Effect of Traditional Chinese Medicine on the Treatment of Risk Factors of Chronic Aplastic Anemia, No. 201107001); Special Research Funds for Traditional Chinese Medicine Industry (Clinical Study on the Diagnosis and Treatment of Aplastic Anemia Based on the Syndrome And Stage Differentiation, No. 201407001); Zhejiang Provincial Traditional Chinese Medicine Administration Bureau Program (Establishment of Traditional Chinese Medicine Clinical Pathway on Aplastic Anemia, No. 2010ZA039)

Correspondence to: Prof. Shen Yiping, Department of Hematology, Zhejiang Provincial Hospital of Traditional Chinese Medicine, Hangzhou 310006, China. shenyp_@126.com; **Prof. Ye Baodong**, Department of Hematology, Zhejiang Provincial Hospital of Traditional Chinese Medicine,

Hangzhou 310006, China. 13588453501@163.com

Telephone: +86-571-87073569

Accepted: February 22, 2016

Abstract

OBJECTIVE: To compare the efficacy of modified treatments based on "kidney reinforcing" in the management of chronic aplastic anemia (CAA), and explore their advantages and specialties.

METHODS: One hundred and eleven patients with CAA were randomly divided into three groups: kidney reinforcing alone (KA), "kidney reinforcing and Qi tonifying" (KQ), and "kidney reinforcing and blood circulation invigorating" (KC). Normal and positive control groups were also formed. All patients were treated for 6 months (two courses). Hemograms, Traditional Chinese Medicine (TCM) syndrome scores, and therapeutic effects were assessed, and changes in T-lymphocyte subsets, regulatory T cells and cytokines were detected.

RESULTS: The KQ and KC groups had lower TCM syndrome scores than the positive control group after 6 months ($P < 0.05$). The KQ group had a higher overall efficacy than the positive control group after 3 months ($P < 0.05$), while platelet counts increased in the KC group after 6 months ($P < 0.05$). CD3+ T-lymphocyte ratios decreased only in the KQ group, while CD3 + CD4 + CD8 – Tlymphocytes increased only in the KC group after 6 months ($P < 0.05$). Levels of interferon- γ , tumor necrosis fac-

tor- α , interleukin (IL)-2 and IL-6 decreased and levels of IL-4 and IL-10 increased in all treated groups after 6 months. Levels of IL-6 in the KQ and KC groups were lower than those in the positive control group ($P < 0.05$).

CONCLUSION: Treatments based on kidney reinforcing have a rebalancing effect on cytotoxic and T helper cells, and regulate expression of interferon- γ , IL-2, IL-6 and IL-4. KQ may be more effective in treating CAA, and KC may have an advantage in platelet recovery.

© 2016 JTCM. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

Key words: Anemia, aplastic; Reinforcing *Qi* strengthening kidney; Reinforcing kidney nourishing blood; Randomized controlled trial

INTRODUCTION

Aplastic anemia (AA) is a commonly encountered hematological disease that presents with bone marrow failure and pancytopenia.¹ AA can be divided into acute AA and chronic AA (CAA), according to the development and severity of the disease. CAA characteristics include long disease course, predisposition to relapse and refractoriness, and poor quality of life; these are ascribed to the maintenance of drug therapy and the persistent risk of infection and bleeding. It is reported that the incidence of AA is $2/10^6$ per year in western countries, while in China, the rate is nearly triple ($\sim 7.4/10^6$); CAA comprises almost 80% of these cases.²

In Traditional Chinese Medicine (TCM), AA is called "Suilao", which means exhaustion of marrow. The application of TCM in the treatment of AA began 50 years ago. Before the 1980s, it was claimed that treatment of CAA should be based on "spleen (Pi)", and "fortify the spleen and replenish *Qi*" was emphasized, although limited effectiveness was achieved. After the 1980s, the consensus was that treatment of CAA should be based on "kidney reinforcing", and the method of "kidney warming and essence replenishing" was recommended.³ To date, many studies have explored the mechanisms behind "kidney deficiency" in the development of AA, such as "*Qi* deficiency", "*Yin* deficiency", "blood stasis", and "stagnation of liver-*Qi*",⁴ yet no consensus has been achieved, and the actual efficacy is not well established.

In our center, we treat CAA with the unification of disease and syndrome differentiation. Reinforcing *Qi* and activating blood is highlighted, followed by kidney reinforcing.^{5,6} To clarify and compare the efficacy and advantages of modified TCM treatments based on kidney reinforcing with or without "*Qi* tonifying" or "blood activating", a multicenter randomized controlled trial was conducted.

MATERIALS AND METHODS

General data

From April 2010 to April 2012, 158 patients with CAA visited Zhejiang Provincial Hospital of Traditional Chinese Medicine, People's Hospital of Lishui, Tongde Hospital of Zhejiang Province, Taizhou Hospital of Zhejiang Province, and Jinhua Hospital of Traditional Chinese Medicine. One hundred and eleven of these patients were enrolled in this study (31 patients were excluded for not meeting the inclusion criteria, and the other 16 declined to receive TCM treatment). Simple randomization was used following a computer-generated random number sequence. Participants and practitioners were not blinded to allocation. All 111 patients were randomly divided into three groups of 37: kidney reinforcing alone (KA), kidney reinforcing and *Qi* tonifying (KQ), and kidney reinforcing and blood circulation invigorating (KC). Fifteen healthy people were enrolled in a normal control group, and another 16 patients without TCM treatment were enrolled as a positive control group. This study followed the Declaration of Helsinki and was approved by the Institution Committee of Ethics of Zhejiang Traditional Chinese Medicine Hospital. All the patients gave informed consent to treatment.

Diagnostic standards

Diagnostic standards in Western Medicine: AA was diagnosed according to the "Diagnosis and Treatment Standards of Hematology Disease (third edition)".⁷ Patients with CAA present with: (a) slower progression than acute AA, and slight manifestation of anemia, infection and hemorrhage; (b) decreased hemoglobin, reticulocyte, neutrophil and platelet counts (but not to the same extent as that seen in acute AA); (c) decreased proliferation of two or three hematopoietic cell lines in the bone marrow, dysplasia at more than one site, significantly reduced numbers of megakaryocytes, and increased numbers of nonhematopoietic cells; and (d) a type of severe AA diagnosed upon confirmation of progressive disease.

Kidney *Yang* deficiency syndrome differentiation in TCM: Patients presented with soreness and weakness in the waist and knees, cold body and limbs, pale complexion, poor appetite, diarrhea, plump tongue with whitish and slippery furring and bearing dental indentations on the margin, and a forceless deep pulse, which were diagnosed with kidney *Yang* deficiency according to "Guidelines for Diagnosis and Treatment of Common Internal Disease in Chinese Medicine".⁸

Standards for inclusion

(a) Patients conformed to AA diagnostic criteria in Western Medicine and kidney *Yang* deficiency syndrome differentiation in TCM. (b) Patients with no other diseases present with pancytopenia, such as myelodysplastic syndrome, primary myelofibrosis, paroxys-

Download English Version:

<https://daneshyari.com/en/article/4200904>

Download Persian Version:

<https://daneshyari.com/article/4200904>

[Daneshyari.com](https://daneshyari.com)