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Research Article

Effect of Zhu-yuan decoction in patients with chronic rhinosinusitis after functional endoscopic sinus surgery☆☆☆

Li Jing^a, Zheng Chunquan^{b,*}, Lin Hai^b, Yang Chen^b, Gu Siyuan^b, Wang Yi^b, Duan Honggang^c^a Department of Otolaryngology, Hangzhou First People's Hospital, Nanjing Medical University, Hangzhou 310006, China^b Department of Otolaryngology, Eye & ENT Hospital of Fudan University, Shanghai 200031, China^c Department of Otolaryngology, The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou 310009, China

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ABSTRACT

Objective: To investigate the effectiveness and safety of Zhu-yuan decoction (ZYD) in patients after the functional endoscopic sinus surgery (FESS).**Methods:** A total of 85 patients were randomized into two groups: 44 were treated with intranasal corticosteroids (INC), and 41 were given Chinese herbal medicine (CHM). Patients with chronic rhinosinusitis (CRS) who underwent FESS were prospectively enrolled in the study. Before surgery, they were evaluated by visual analog scale (VAS), nasal endoscopy, computed tomography (CT), and routine blood test. After surgery, they were randomized to take ZYD or INC for 12 weeks and reevaluated by VAS; nasal endoscopy at 4, 8, and 12 weeks; and CT at 12 weeks after surgery.**Results:** In both the groups, VAS and endoscopy scores decreased significantly at 4, 8, and 12 weeks, and CT scores after treatment declined at 12 weeks compared with baseline scores. No significant differences were observed with regard to postoperative VAS, endoscopy, or CT scores between groups. ZYD, combined with surgery, can reduce VAS, nasal endoscopy, and CT scores and has the same efficacy and safety profile as INC in post-FESS management. No fatalities or major adverse events occurred in either group.**Conclusion:** Our findings suggest that ZYD has similar effects and safety profiles in patients after FESS compared with INC.© 2018 Traditional Chinese Medicine Periodical Press. Published by Elsevier B.V.
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1. Introduction

Chronic rhinosinusitis (with or without nasal polyps) is a common otolaryngologic disease worldwide. The management options for sinonasal polyposis are medication, surgery, or both. Surgical intervention in the treatment of chronic rhinosinusitis (CRS) is considered in patients who fail to improve after a trial of medical treatment for three months. Endoscopic sinus surgery significantly improves the quality of life of patients with chronic rhinosinusitis [1].

Currently, functional endoscopic sinus surgery (FESS) is the standard treatment for CRS, based on the principle established by

Messerklinger, who recommended restoring the natural function of the sinuses [2]. FESS involves clearing polyps and inflammatory tissue and opening the sinus ostia. However, up to 25% of patients with adhesions will require revision surgery [3]. It is common practice to use a topical agent with intranasal corticosteroids (INC) as the first therapeutic choice, followed by surgery. There is good evidence from randomized controlled trials that supports the use of topical nasal corticosteroids to improve endoscopic polyp and symptom scores and reduce the recurrence of polyps [4].

Traditional Chinese herbal medicine (TCM) is also being increasingly used for the treatment of CRS [5–7]. A systematic review has shown that the effects of herbal medicines in the treatment of rhinosinusitis are limited—in particular, for CRS [8]. But, it is opined that postoperative treatment is an interesting area for future studies on this topic. A randomized, double-blind, placebo-controlled study reported no significant benefit of Tsang–Erh–San extract granules, Houttuynia extract powder, or oral amoxicillin in the post-FESS care of CRS patients. Most of the studies above used single herbs or their extracts.

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* Corresponding author.

E-mail address: 12111260015@fudan.edu.cn (Z. Chunquan).

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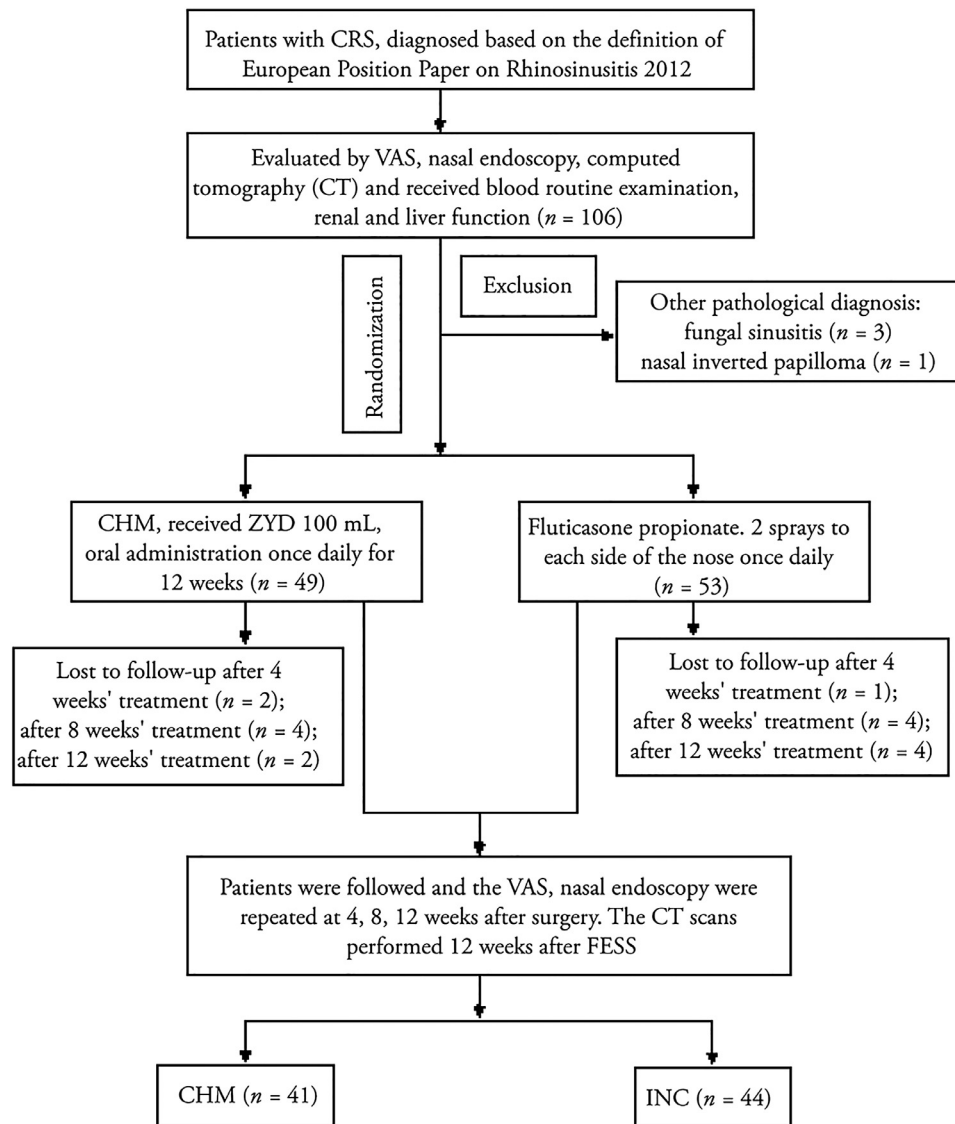


Fig. 1. Flowchart and study design.

CRS: chronic rhinosinusitis; VAS: visual analog scale; CHM: Chinese herbal medicine; ZYD: Zhu-yuan decoction; FESS: functional endoscopic sinus surgery; INC: intranasal corticosteroids.

Based on practices in China and East Asia, the essence of CHM is a herbal formulation that can balance “Yin–Yang” based on TCM theory. Yin–Yang theory is a kind of logic which views things as a whole. The theory is based on two components: Yin and Yang, which are neither materials nor energy. They combine in a complementary manner and form a method for explaining relationships between objects. Gradually, this logic was developed into a system of thought that was applied to other areas. Traditional Chinese Medicine is an example of one area where the theory is used to understand complicated relationships in the body. Usually, Yang is associated with functional aspect of the body and has more energetic qualities, for example, expanding, heat, progressing, active and hyper-functioning states. Yin, on the other hand, is associated with the physical form and has less energetic qualities such as stillness, contracting, cold, degenerating, latent and under-functioning states. We have been studying CRS treatments with CHM for decades. The formulation of Zhu-yuan decoction (ZYD) was developed for postoperative treatment of CRS in the Eye and Ear, Nose, and Throat Hospital of Fudan University in the 1980s. In this study, we aimed to confirm the efficacy and safety of ZYD in patients after FESS.

2. Materials and methods

2.1. Criteria of diagnosis and inclusion

This study was approved by the Institutional Review Board of the Affiliated Eye and Ear, Nose, and Throat Hospital of Fudan University (Ethical registration number: ky-2012-002). Written consent was obtained from each patient. Adults with CRS (with or without nasal polyps) were enrolled in this study. The flowchart and design of this study are shown in Fig. 1.

The diagnosis of CRS was based on a history of RS, the nasal endoscopy findings, and a CT scan. Duration of disease was quantified by continuous symptoms for at least 12 consecutive weeks. The diagnosis of CRS without nasal polyps (CRSwNP) was based on standard criteria issued in the 2012 European Position Paper on Rhinosinusitis and Nasal Polyps guidelines [9]. Any patient who had a history of immunodeficiency or systemic disease was excluded from the study.

ZYD was prepared with Huoxiang (*Herba Agastaches Rugosa*) 9 g, Chenpi (*Pericarpium Citri Reticulatae*) 9 g, Huangqi (*Radix Astragali Mongolici*) 30 g, Yiyiren (*Semen Coicis*) 30 g, Zaojiaoci (*Spina*

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