



## Review article

## Herbal medicine (Shaofu Zhuyu decoction) for treating primary dysmenorrhea: A systematic review of randomized clinical trials



Hoyoung Lee<sup>a,c,1</sup>, Tae-Young Choi<sup>b,1</sup>, Chang-Seon Myung<sup>c</sup>, Ju Ah Lee<sup>a</sup>,  
Myeong Soo Lee<sup>b,\*</sup>

<sup>a</sup> KM Fundamental Research Division, Korea Institute of Oriental Medicine 483 Expo-ro, Yuseong-gu, Daejeon 34054, Republic of Korea

<sup>b</sup> Clinical Research Division, Korea Institute of Oriental Medicine 483 Expo-ro, Yuseong-gu, Daejeon 34054, Republic of Korea

<sup>c</sup> Department of Pharmacology, Chungnam National University College of Pharmacy, 99 Daehakno, Yuseong-gu, Daejeon 34134, Republic of Korea

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## ABSTRACT

Shaofu Zhuyu decoction (SFZY) or Sobokchugeo-tang, a traditional herbal formula, is used as a treatment for primary dysmenorrhea. We searched four English, seven Korean, three Chinese, and one Japanese database from inception through January 2016 without a language restriction. All randomized controlled trials (RCTs) of SFZY or modified SFZY (MSFZY) were included. Data extraction and risk of bias assessments were performed by two independent reviewers. A total of 51 potentially relevant studies were identified, and 9 RCTs met our inclusion criteria. Seven RCTs tested the effects of SFZY or modified SFZY in treating dysmenorrhea. Three RCTs showed superior effects of (M)SFZY on the response rate, while the other three RCTs failed to do so ( $n = 531$ , RR: 1.17, 95% CI: 1.09 to 1.26,  $P < 0.0001$ ,  $I^2 = 0\%$ ). Three RCTs showed favorable effects of MSFZY for pain reduction compared with conventional drugs ( $n = 340$ , SMD:  $-1.39$ , 95% CI:  $-2.23$  to  $-0.55$ ,  $P = 0.01$ ). Two RCTs examined the effects of modified SFZY plus conventional drugs and conventional drugs alone. The meta-analysis showed favorable effects of MSFZY ( $n = 206$ ; RR, 1.12; 95% CI 1.08 to 1.36;  $P = 0.0009$ ,  $I^2 = 0\%$ ). Our systemic review and meta-analysis provide suggestive evidence of the superiority of SFZY over conventional drugs for treating primary dysmenorrhea. However, the level of evidence is low because of a high risk of bias.

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\* Corresponding author at: Clinical Research Division, Korea Institute of Oriental Medicine, Daejeon, 34054, Republic of Korea. Fax: +82 0 42 868 9622.

E-mail addresses: [drmslee@gmail.com](mailto:drmslee@gmail.com), [mslee@kiom.re.kr](mailto:mslee@kiom.re.kr) (M.S. Lee).

<sup>1</sup> HYL and TYC equally contributed.

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## 1. Introduction

Dysmenorrhea is a common gynaecological complaint in adolescent and young females characterized by lower abdominal pain that occurs during menstruation [1]. Several studies have found a consistently high prevalence of dysmenorrhea in women of different ages and nationalities, with an estimated prevalence ranging from 45% to 95% [2–4].

Non-steroid anti-inflammatory drugs (NSAIDs) are the primary treatment for this condition but are limited by inadequate pain control, gastrointestinal discomfort and an impact on renal function [5]. Combined oral contraceptives are also frequently used but are not universally accepted, possibly due to their potential side effects including induction of endometriosis [6]. Therefore, complementary and alternative medicine (CAM) is in high demand in many countries. In one large study, as many as 48% of women reported the use of CAM as an alternative to prescription medication or to enhance the effectiveness of their prescription medications [7,8].

Herbal medicine is currently used in hospitals and clinics for the treatment of primary dysmenorrhea in East Asian countries including Korea, China, Taiwan, and Japan [9–11]. Shaofu Zhuyu decoctions (SFZY) have shown an effect on uterine muscles and may help to prevent and cure dysmenorrhea. SFZY decoction also improved hemorheological factors of blood stasis and regulation in rat ovaries [12,13]. SFZY decoction was first described in the *Yi Lin Gai Cuo* in a famous formula that has been used for treating primary dysmenorrhea in China since the Qing dynasty [14]. This decoction is used, particularly in gynaecology, for blood stasis accompanied by masses and gatherings in the lower abdomen [15]. Clinically, it has been used for the treatment of chronic pelvic inflammatory disease, infertility, endometrial hyperplasia, myoma uteri, and uterine cancer [16–18].

One Cochrane Review of Chinese herbal medicine showed promising evidence for the use of traditional Chinese medicine (TCM) in reducing menstrual pain in primary dysmenorrhea [19]. However, the quality of the included studies was poor, and the review is also outdated. Currently, no relevant systematic reviews have been performed to examine the efficacy of SFZY for treating primary dysmenorrhea, and prescription of SFZY was not included in the previous systematic review.

Therefore, the aim of this study was to systematically review the available literature regarding the efficacy of SFZY in treating primary dysmenorrhea.

## 2. Methods

### 2.1. Protocol registration

The protocol for this systemic review was registered in PROSPERO 2015 (CRD42015016386) [20], and the full protocol was published [21].

### 2.2. Data source

The following databases were searched from their inception through January 2016: PubMed, AMED, EMBASE, the Cochrane Library, seven Korean medical databases (Korean Studies Information, DBPIA, Oriental Medicine Advanced Searching Integrated System, Research Information Service System, KoreaMed, the Town Society of Science Technology and the Korean National Assembly Library), three Chinese medical databases (the Chinese Medical Database [CNKI], Chongqing VIP Chinese Science and Technology Periodical Database [VIP], and WanFang Database) and one Japanese Database (J global). The search terms used were as follows: (Shaofu Zhuyu decoction OR Shaofu Zhuyu formula OR Shaofu Zhuyu tang) AND (dysmenorrhea OR menstruation disturbances OR menstruation disorders OR menstrual disorder OR pelvic pain OR painful menstruation OR painful period OR period pain OR primary dysmenorrhea) AND (randomized controlled trial) in Korean, Chinese, Japanese and English. In addition, the reference lists of all retrieved articles were hand-searched for further relevant literature. Hard copies of all included articles were read in full. Because all of the various databases used for this study possessed their own subject headings, each database was searched independently.

### 2.3. Study selection

#### 2.3.1. Type of studies

All randomized controlled trials (RCTs) and quasi-RCTs were included. Observational, cohort, case-control, case series, and qualitative studies, uncontrolled trials and laboratory studies were excluded.

#### 2.3.2. Type of participants

Women of reproductive age with primary dysmenorrhea, i.e., individuals with no identifiable pelvic pathology as indicated by a pelvic examination, ultrasound scans and laparoscopy, or women self-reporting a diagnosis of primary dysmenorrhea were included. Exclusion criteria consisted of identifiable pelvic pathology and dysmenorrhea resulting from the use of an intra-uterine contraceptive device.

#### 2.3.3. Types of interventions

Studies that used an SFZY or a modified SFZY were included. SFZY included the following 10 formulas: Fructus Foeniculi, Rhizoma Zingiberis, Cortex Cinnamomi, Radix Paeoniae Rubra, Radix Angelica Sinensis, Radix Ligustici Wallichii, Myrrh, Rhizoma Corydalis, Pollen Typhae, and Faeces Trogopteri [15]. MSFZY prescribed according to TCM syndrome definitions was acceptable and defined by practitioners as adding only herbs to the original herbs, resulting in nearly the same actions as the original SFZY. Trials in which the SFZY was used as an adjunct to conventional treatment, usual

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