

Clinical Study on the Treatment of Primary Dysmenorrhea of Cold-congealed Qi Stagnation and Blood Stasis Type with the Addition and Subtraction of Regulating Menstruation and Relieving Pain Soup

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Keywords: Menstruation Regulating and Pain Relieving Soup, Primary Dysmenorrhea, Traditional Chinese Medical Treatment

Abstract: To evaluate the clinical efficacy of regulating menstruation and relieving pain in treating primary dysmenorrhea of cold-congealed qi stagnation and blood stasis type. 60 patients were divided into two groups by randomized numerical table method: Chinese medicine treatment group (30 cases) and western medicine treatment group (30 cases). The traditional Chinese medicine group was given oral menstruation regulating and pain relieving soup 5 days before menstruation, one dose twice/day for 7 days; the western medicine group was given oral ibuprofen extended-release capsule for a maximum of 5 days. Course of treatment: three consecutive menstrual cycles. Comparison of pain scores and TCM evidence points before and after treatment was carried out for the two groups. The VAS score of the TCM group was lower than that of the posttreatment score before treatment, and the difference was statistically significant compared with that of the Western medicine group ($p < 0.05$); the TCM evidence points of the TCM group before and after treatment improved compared with that before treatment, and the improvement of the TCM group was more obvious than that of the Western medicine group. (The total effective rate of TCM group was higher than that of the control group ($p < 0.05$)). Regulating menstruation and relieving pain soup can relieve symptoms of dysmenorrhea with high safety, it is a good prescription for the treatment of primary dysmenorrhea.

Primary dysmenorrhea (PD) refers to the cyclic lower abdominal pain that occurs during or around menstruation and accompanies the onset of the menstrual cycle for more than three consecutive times, with no obvious organic lesions of the reproductive organs by gynecological examination [1]. PD is a common gynecological disease, and according to a survey, the incidence of dysmenorrhea in China is as high as about 33%, with primary dysmenorrhea accounting for 36% of the total, which has seriously endangered the physical and mental health of women. For the treatment of primary dysmenorrhea, Western medicine mainly uses contraceptive pills and painkillers to reduce uterine contractions, thereby reducing pain. Although the therapeutic effect is

good, but easy to produce drug resistance is easy to repeat after stopping the drug; and China's traditional Chinese medicine treatment of this disease has a unique advantage through the dialectical treatment to choose the appropriate treatment method, which has achieved significant clinical efficacy [2]. The author's self-proposed method of activating blood and regulating menstruation and relieving pain has achieved good efficacy in the treatment of PD, which is now reported as follows.

1. Introduction

General information, Sixty cases of PD patients in the gynecology outpatient clinic of Xi'an Hospital of Traditional Chinese Medicine from January 2022 to December 2022 were selected as the study subjects, and the random numbers were generated by random number generation algorithm using SPSS22.0 statistical software, and the included subjects were randomly assigned to A: Traditional Chinese medicine group and B: Western medicine group in the proportion of 1:1 according to the random numbers corresponding to the code of each subject. The age of the traditional Chinese medicine group ranged from 15 to 44 years, with a mean age of (23.95 ± 9.23) years; the duration of the disease ranged from 0.4 to 11 years, with a mean duration of (4.07 ± 2.15) years, and the body mass index ranged from 18.8 to 26, with a mean body mass index of (21.28 ± 1.34) ; and the age of the western medicine group ranged from 13 to 45 years, with a mean age of (22.55 ± 10.75) years; the duration of the disease ranged from 0.5 to 9 years, with a mean Duration of disease (3.85 ± 3.18) years, body mass index 18.9-27, average body mass index (21.72 ± 1.95) ; the difference between the basic data of the two groups is not statistically significant ($P > 0.05$), and is comparable.

Inclusion criteria ① patients with PD who met the clinical diagnostic criteria of Western medicine; ② patients who met the criteria for primary dysmenorrhea in the cold-congealed qi stagnation and blood stasis category in Chinese Medicine Gynecology [3]; ③ patients who voluntarily enrolled in the study and signed the informed consent form; ④ Patients who had undergone hormonal drugs or conservative surgical therapies but had stopped using the drugs or surgery for at least three months; or Patients who had undergone traditional Chinese medicine but had stopped using the drugs for at least one month, and still meet the above diagnostic criteria.

Exclusion criteria ① gynecological examination or ultrasound found to have organic lesions; ② combined with serious uterine fibroids, cardiovascular and cerebrovascular diseases, hepatic and renal diseases, and hematopoietic system diseases; ③ patients with mental illness; ④ patients who are allergic to the drug and the control drug; ⑤ do not meet the inclusion criteria, not in accordance with the standard use of medication, unable to determine the effectiveness of the treatment, or incomplete data and so on, in order to affect the judgment of the efficacy and safety.

Treatment ① Traditional Chinese medicine group: oral menstrual regulation and pain relief soup: 12g of angelica, 15g of fried white peony, 10g of chuanxiong, 12g of fennel, 10g of cinnamon branch, 15g of fried hedgehog's nest, 15g of Sichuan hyssop, 15g of motherwort, 3g of cinnamon, 12g of yuanhu, 10g of scented adenophorbia, 9g of ouyao, 6g of roasted licorice, 12g of Pu huang (decoction), 10g of wuling yu, 6g of roasted licorice, and in the event of liver and kidney deficiency, add 12g of baji tian, 12g of baji tian, 6g of roasted licorice. Add *Bacopa monnieri* 12g, *Semen Cuscutae* 15g; for those with weak qi and blood, add *Radix Codonopsis Pilosulae* 15g, *Rhizoma Atractylodis Macrocephalae* 15g. Decoctions are made in the Pharmacy Center of Xi'an Hospital of Traditional Chinese Medicine, and tonics are supplied by the Chinese Medicine Decoction Room of Xi'an Hospital of Traditional Chinese Medicine, and the treatment is to be taken orally starting from 5 days before menstruation, with 1 dose per day, 2 times/day, for 7 days. Note: During the treatment

period, other medicines for this condition should not be taken at the same time. The intake of oily and stimulating foods should also be minimized during the medication. If pregnancy occurs during treatment, the medication should also be stopped immediately. Allergic to Chinese medicine is prohibited, allergic people should be cautious. ② Western medicine group: Oral ibuprofen extended-release capsules in the middle of the disease, up to 5 days. A continuous course of treatment for three menstrual cycles is required. During treatment, the use of other drugs with similar effects is prohibited.

Observation indicators Pain score: patients record their own "pain assessment form", including: menstrual abdominal pain, menstrual breast distension, pre-and post-menstrual lumbar pain, menstrual anal irritation, etc., and record the degree of menstrual pain before and after treatment in the two groups of patients by using VAS scoring method.

Efficacy Evaluation Criteria In clinical control, dysmenorrhea symptoms were categorized according to the recovery of dysmenorrhea symptom scores. Complete recovery: the dysmenorrhea symptom score recovered to 0 after treatment, abdominal pain and other symptoms completely disappeared [4]; significant effect: the dysmenorrhea symptom score was reduced to less than 1/2 of the pretreatment score after treatment, abdominal pain was significantly reduced, the rest of the symptoms improved, and the patients were able to work normally without relying on painkillers; Effective: the dysmenorrhea symptom score was reduced to between 1/2 and 3/4 of the pre-treatment score after treatment Effective: after treatment, dysmenorrhea symptom score is reduced to more than 3/4 of the pre-treatment score, abdominal pain is reduced, the rest of the symptoms are improved, and patients need to rely on painkillers to continue working; Ineffective: after treatment, dysmenorrhea symptom score is reduced to more than 3/4 of the pre-treatment score, and abdominal pain and the rest of the symptoms are unchanged [5].

Statistical methods: The obtained data were processed using SPSS 22.0 statistical software. For the general information of the two groups of patients, the chi-square test was used to analyze the count data, and the t-test was used for comparison between the groups, and the difference was considered statistically significant at $p < 0.05$.

2. Results

2.1 Comparison of Clinical Outcomes between the 2 Groups See Table 1

Table 1: Comparison of clinical efficacy between 2 groups

Groups	Number of cases	clinical control	Significantly	effective	Ineffective	Total effective rate
Traditional Chinese medicine group	30	14	10	4	2	93.3%
Western medicine group	30	12	8	6	4	86.7%

(compared with western medicine group, $p < 0.05$) (compared with western medicine group)

2.2 Comparison of VAS Scores between the 2 Groups is Shown in Table 2

Table 2: Comparison of VAS scores in 2 groups ($\bar{x} \pm s$, points)

Groups	Number of cases	Before treatment	After treatment	Difference between before and after treatment
Traditional Chinese medicine group	30	5.83 \pm 1.45	2.8 \pm 1.05	3.03 \pm 1.45
Western medicine group	30	5.70 \pm 2.14	3.15 \pm 1.22	2.60 \pm 0.92

($p < 0.05$ compared with the pretreatment of this group, and $p < 0.05$ after treatment of the traditional Chinese medicine group compared with the posttreatment of the western medicine group)

As can be seen from Table 2, the VAS scores of patients in the two groups before treatment were reduced compared with those after treatment, and the difference between before and after treatment in the traditional Chinese medicine group was greater than that between before and after treatment in the western medicine group, which indicated that the effect of improving pain symptoms in the traditional Chinese medicine group was better than that in the western medicine group.

2.3 Comparison of Prognostic Recurrence between the Two Groups of Patients is Shown in Table 3

Table 3: Comparison of prognostic recurrence of patients in the two groups

Groups	Number of cases	Recurrence (cases)	No recurrence (cases)	Total effective rate
Traditional Chinese medicine group	30	4	26	86.7%
Western medicine group	30	9	21	70%

($p < 0.05$ compared with western medicine group)

3. Conclusions

Primary dysmenorrhea is a common complication among women, which seriously jeopardizes their physical and mental health. Western medicine believes that the mechanism of this disease is that the contraction of uterine smooth muscle and small arteries in the myometrium is strengthened, and the uterus produces pain due to ischemia and hypoxia [6]. Most of the treatments for this disease take symptomatic treatment, such as antispasmodic and analgesic treatments [7], with significant and rapid efficacy, but the side effects of drug treatment are large, and the treatment of the symptoms is not the root cause of the disease, which is easy to recur. Chinese medicine for the treatment of primary dysmenorrhea in the pathogenesis of "not through pain", "not honor is pain". The doctors of the past dynasties have categorized them into two major groups: deficiency and reality. Deficiency is mainly caused by deficiencies in liver and kidney functions and weakness of qi and blood, while the reality is mainly caused by cold-congealed blood stasis, qi stagnation, and blood stasis, and damp-heat stasis [8]. In the Southern Song Dynasty, Chen Ziming elaborated the causes of primary dysmenorrhea in *The Complete Compendium of Good Prescriptions for Women*, which included factors such as cold Qi stagnation and blood stasis [9]. In recent years, the research on the substance of blood stasis and the mechanism of using blood activation and elimination of blood stasis to deal with this disease has also gained great development and achieved obvious

results. The author has proposed the formula of "Regulating Menstruation and Relieving Pain Tang", in which *Angelica sinensis* is sweet and moist, "a key product for nourishing blood", especially good at regulating menstruation and relieving pain as a key gynecological drug, which is used to nourish and activate blood; *Rhizoma Ligustici Chuanxiong* is a blood qi drug to promote blood qi, to activate blood and eliminate blood stasis, and nourish blood to regulate menstruation; *Paeonia lactiflora* is acidic and bitter with slight coldness, which is good at nourishing blood and astringing yin, and softening the liver to relieve pain; the three medicines are used together to nourish blood, activate blood, and warm up and dissipate the cold stagnation, and together they are used as the king's medicine. Cinnamon, *Cornu Cervi*, *Pantotrichum*, and fennel enhance the power of warming menstruation, dispersing cold and relieving pain, and *Pu huang* and *Wu Ling Lip* are used for the loss of laughter, which can be applied to blood disorders regardless of cold or heat, with or without blood stasis. *Motherwort* activates blood circulation and regulates menstruation, induces diuresis, and reduces swelling; *Yuanhu* is pungent and warm, dredging qi and blood, analgesic and sedative, etc.; *Xiangsui* and *Wuyao* have the function of regulating qi and relieving pain and are used together as adjuvant herbs. *Glycyrrhiza glabra* is the enabler, harmonizing all medicines [10]. The whole formula can warm the uterus to dispel cold and dampness, dredge the meridians to activate blood circulation and remove blood stasis, and has significant efficacy in primary dysmenorrhea of cold-congealed qi stagnation and blood stasis type. In recent years, some studies have shown that *Angelica sinensis* and *Rhizoma Ligustici Chuanxiong* [11] can alleviate uterine smooth muscle spasm, thus playing a role in relieving dysmenorrhea. The total glucoside of white peony [12] also has anti-inflammatory and analgesic effects. *Pu huang*, *danshen* [13] can improve microcirculation and blood flow status and relieve dysmenorrhea. Fragrant herbs have smooth muscle relaxation, analgesic, and estrogen-like effects [14]. *Safflower* is one of the main blood activating and stasis removing herbs, which alleviates blood stasis and circulatory disorders [15]. The combination of the above drugs can activate blood circulation and qi, as well as eliminate blood stasis and relieve pain, thus achieving the purpose of treating primary dysmenorrhea.

The present study showed that after the intervention of regulating menstruation and relieving pain soup, the pain symptoms of patients were significantly improved, and the difference between the traditional Chinese medicine group and the western medicine group was statistically significant ($P < 0.05$); after the treatment, the points of traditional Chinese medicine symptoms of the patients in the two groups improved compared to the pre-treatment period, and the traditional Chinese medicine group had more obvious improvement than the western medicine group ($P < 0.05$); after the treatment, the VAS scores of the patients in the two groups before the treatment were reduced compared to the post-treatment period, and the traditional Chinese medicine group had more significant improvement compared to the western medicine group. After treatment, the VAS scores of both groups before treatment were lower than those after treatment, and the difference between before and after treatment in the traditional Chinese medicine group was greater than that in the western medicine group, which indicated that the effect of improving pain symptoms in the traditional Chinese medicine group was better than that in the western medicine group.

To summarize, the addition of blood circulation and menstruation regulating the soup can effectively improve the symptoms of dysmenorrhea, which is safe and feasible, and is a good prescription for the treatment of primary dysmenorrhea.

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