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ORIGINAL RESEARCH



The Clinical Efficacy of Self-Designed Nuangong Zhitong Ling in Primary Dysmenorrhea of Cold Coagulation Syndrome

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Abstract

Objective: To investigate the clinical efficacy of the self-designed Nuangong Zhitong Ling in primary dysmenorrhea (PD) of cold coagulation syndrome. Methods: Forty patients with PD of cold coagulation syndrome who were treated with the self-designed Nuangong Zhitong Ling in our hospital from January 2023 to December 2024 were included in the study group. Another 40 patients with the same disease who were treated with ibuprofen sustained-release capsules during the same period were included in the control group. The clinical efficacy, pain conditions, temperature changes in the infrared thermal imaging regions of the two groups were compared, and the occurrence of adverse reactions during the treatment period was statistically analyzed. Results: After 3 months of treatment, the total effective rate of the study group was higher than that of the control group (75.00% vs 42.50%; ρ < 0.05). After 1, 2, and 3 months of treatment, the visual analogue scale (VAS) scores of pain in both groups were decreased, and the degree of decrease in the study group was greater than that in the control group (ρ < 0.05). After 3 months of treatment, the temperatures of the Shengue, and lower abdomen in the study group were lower than those in the control group (ρ < 0.05). During the treatment period, no adverse reactions such as nausea, vomiting, or dizziness occurred in either group. Conclusion: The self-designed Nuangong Zhitong Ling has significant application value in PD of cold coagulation syndrome, which can provide clinical efficacy via relieving pain symptoms and improving local tissue temperature changes to remove cold retention and blockage, without serious adverse reactions yet with good safety.



1 Introduction

Primary dysmenorrhea (PD), also known as functional dysmenorrhea, is a common gynecological disease characterized by spasmodic lower abdominal pain and discomfort in the lumbar and sacral regions before or during menstruation [1,2]. A previous report [3] conducted a survey of 807 young women with PD, and found that the incidence rate of PD is high, which seriously affects the quality of life of patients. Medication (nonsteroidal anti-inflammatory drugs) and non-medication (localized heat application and exercise) interventions can alleviate pain, offering potential treatment options for PD that enable patients to perform daily activities and improve their quality of life [4].

In recent years, the advantages of traditional Chinese medicine (TCM) have become increasingly evident, with its definite therapeutic effects and minimal toxic side effects, which have been widely praised by medical staff and patients [5]. According to traditional TCM theory, cold coagulation syndrome is one of the relatively common TCM syndromes of PD [6]. The treatment principle is mainly focused on warming the meridians to dispel cold, transforming stasis, and relieving pain. The syndrome is attributed to internal emotional injuries or invasion of the body surface by wind, cold, summer heat, dampness, dryness, and fire evils. When the body's healthy gi is insufficient and the Wei-defense and exterior are not properly protected, it leads to blood stasis in the Chong and Ren meridians or cold coagulation in the meridians, ultimately causing stagnation of gi and blood or insufficient transformation and generation of qi and blood that triggers pain [7,8]. TCM has a significant alleviating effect on the pain of PD, which is closely related to its anti-inflammatory and analgesic effects [9,10]. TCM

may exert its therapeutic effects on primary dysmenorrhea by acting on key target proteins such as signal transducer and activator of transcription 3 (STAT3) through bioactive components like β -sitosterol, kaempferol, and baicalein [11].

The formula of Nuangong Zhitong Ling, composed of herbs such as Evodia rutaecarpa, multiple Cinnamomum cassia, and Angelica sinensis, has the effects of dispelling cold to relieve pain, tonifying fire to assist yang, and promoting the flow of qi and blood, which coincides with the core pathogenesis of PD. However, we found that this formula has been relatively less developed in clinical practice, and previous studies have mostly used subjective scales for evaluation. Therefore, in addition to evaluating clinical efficacy, this study innovatively introduced infrared thermal imaging region temperature technology to explore the application value of the self-designed Nuangong Zhitong Ling in PD with cold coagulation syndrome.

2 Methods and Materials

2.1 Clinical information

A total of 80 patients with PD of cold coagulation syndrome who were admitted to our hospital for treatment from January 2023 to December 2024 were selected and randomly divided into two groups: the control group (n = 40) and the study group (n = 40). This study was approved by the Ethics Committee of our hospital. Written informed consent was obtained from the patients. The two groups were comparable in terms of age, body mass index, average disease duration, age at menarche, Visual Analog Scale (VAS) score at the beginning of the menstrual cycle, and marital status ($\rho > 0.05$, Table 1).

Table 1 Comparison of general information before treatment between the two groups.

Group		Study group	Control group	#Z X²	ρ
Case		40	40		
Age/year		23.08 ± 2.48	23.38 ± 2.32	-0.588	0.578
Body mass inde	ex/(kg/m²)	21.26 ± 1.55	21.09 ± 1.84	0.447	0.656
Disease dura	tion/year	8.00 (8.00, 9.00)	9.00 (8.00, 9.00)	-0.89	0.374
Age at menarche/year		12.00 (12.00, 13.00)	13.00 (12.00, 13.00)	-1.702	0.089
VAS score at the beginning of the menstrual cycle/score		6.00 (6.00, 7.00)	6.00 (5.75, 7.00)	-1.159	0.246
Marital	Married	21 (52.50)	20 (50.00)	0.05	0.022
status/[n(%)]	Unmarried	19 (47.50)	20 (50.00)	0.05	0.823

2.2 Inclusion and exclusion criteria

Inclusion criteria: (1) Meet the diagnostic criteria for PD in "Obstetrics and Gynecology (8th Edition)". (2) Meet the criteria for PD of cold coagulation syndrome in "Traditional Chinese Gynecology (9th Edition)". (3) 18-28 years old. (4) Have not received treatment for PD in the past month. (5) Patients with complete clinical records.

Exclusion criteria: (1) Serious primary diseases such as cardiovascular and cerebrovascular diseases, liver and kidney dysfunction, rheumatism and immunity. (2) Peptic ulcer and malabsorption syndrome. (3) Abnormal consciousness, lack of consciousness or expression disorders, and mental illnesses. (4) Allergic to traditional Chinese medicine or its metabolic components, or allergic constitution. (5) Alcoholics and/or those who abuse or are dependent on psychoactive substances or drugs. (6) Claustrophobic syndrome.

2.3 Treatment methods

Control group: Ibuprofen sustained-release capsules (National medicine permission number (NMPN): H20203355, Nanjing Yiheng Pharmaceutical Co., Ltd., specification: 0.3 g \times 24 capsules/box) was taken. One day before the onset of dysmenorrhea and on the day of dysmenorrhea, take one tablet every 12 hours

orally.

Study group: The self-designed Nuangong Zhitong Ling free from decoction was provided. The formula consists of 6 g Evodia rutaecarpa (Wuzhuyu), 6 g Cinnamomum cassia (Rougui), 12 g Angelica sinensis (Danggui), 10 g Radix Paeoniae Rubra (Chishao), 10 g Rhizoma Chuanxiong (Chuanxiong), 10 g Herba Epimedii (Xianlingpi), 10 g Radix Achyranthis Bidentatae (Niuxi), 15 g fried Radix Codonopsis (Chaodangshen), 12 g fired Rhizoma Atractylodis Macrocephalae (Chaobaizhu), 20 g Rhizoma Corydalis (Yuanhu), 10 g raw Pollen Typhae (Shengpuhuang), and 6 g Glycyrrhiza uralensis (Gancao). These herbals were boiled with strong fire first and then mild fire twice, with the absence of seepage when a drop is placed on paper as the judgement. The formula was orally taken from 7 days before menstruation to 3 days during menstruation, once in the morning and once in the evening, one bag/time, dissolved in boiling water.

Patients in the two groups were treated for 3 months.

2.4 Observational indexes

Clinical efficacy: The menstrual pain, menstrual characteristics (menstrual volume, color, and quality), and tongue coating and pulse (tongue body often pale and dark or bluish purple, tongue coating white and slippery or white and greasy, with a deep and tight or

string-like pulse) were assessed based on TCM syndrome scores for PD. Each symptom is scored from 0 to 4, with 0 indicating disappearance of the symptom and 4 indicating severe symptoms. According to the "Technical Guidelines for Clinical Research of TCM New Drugs of Syndrome Category" [8], the calculation formula is: Total effective rate = (number of cases with clinical control + effective + significantly effective)/total number of cases × 100%. The standards are as follows: Clinical control: ≥ 95% reduction in syndrome score; Significantly effective: 70-95% reduction in syndrome score; Ineffective: < 40-70% reduction in syndrome score; Ineffective: < 40% reduction in syndrome score.

Pain condition: The VAS was used for pain assessment. A straight line was drawn with 0 on the left end (indicating no pain) and 10 on the right end (indicating unbearable pain). Patients marked their pain perception on the line, and medical staff measured the distance between the mark and the left end. A longer distance denoted a more severe pain level.

Comparison of infrared thermal imaging region temperature: Before treatment and 3 months after treatment, infrared thermal imaging diagnostic testing (ZR-2010A; infrared thermal imaging technology from Beijing Zhongrui Huaxia Medical Technology Co., Ltd.) was conducted. The temperature measurement range is 20-50 °C; temperature accuracy (δ): $\delta = \pm 0.4$ °C under an environment of 25 ± 3 °C; temperature resolution (NETD): ≤ 0.07 °C (70 mk); detector resolution: 384×288; working wavelength band: 8-14 μ m. Referring to "Infrared Thermography Temperature Measurement Technology and Its Applications" [12], the observation room temperature (20-24 °C) and humidity (50-60%) were strictly controlled, with air conditioning vents avoiding the patients and even distribution of heat sources. Patients from both groups were then asked to remove

their clothes for temperature measurement at the Shenque and lower abdomen areas. The Shenque area is defined as a circular region with a diameter of 2 cm centered on the navel. A professional healthcare worker with over 4 years of work experience conducted the operation, who was unaware of the patients' conditions in the two groups.

Incidence of adverse reactions: The occurrence of dizziness, nausea, diarrhea, and rash or itching was statistically recorded during the treatment period.

2.5 Statistical methods

Statistical analysis was performed using SPSS 18.0. The Shapiro-Wilk test was used for normality testing. The infrared thermal imaging region temperatures of the Shenque, and lower abdomen were expressed as (mean ± standard deviation). For intergroup comparisons, the independent samples t-test was used. Quantitative data that did not follow a normal distribution were expressed as [M (P25, P75)] using the quartile method. Mann Whitney U test was used for comparison between two groups, generalized estimation equation was for comparison between two or more time points within a group, and Bonferroni method was for multiple comparison between groups. The total clinical effective rate was expressed as a rate or composition ratio, and compared using the χ^2 test. The comparison between two groups of ranked data was performed using the Mann Whitney U test. The difference was considered statistically significant with ρ < 0.05.

3 Results

3.1 Comparison of clinical efficacy between the two groups

3 months after treatment, there was a significant difference in the overall clinical efficacy rate between the two groups, and the study group had a higher rate (75.00% vs. 42.50%) ($\rho < 0.05$, Table 2).

Table 2 Comparison of clinical efficacy between the two groups [n (%)].

Group	Case	Clinical	Significantly	Effective	Ineffective	Total effective
		control	effective		Therrective	rate
Study group	40	12 (30.00)	10 (25.00)	8 (20.00)	10 (25.00)	30 (75.00)
Control	40	5 (12.50)	6 (15.00)	6 (15.00)	23 (57.50)	17 (42.50)
group		3 (12.30)	0 (13.00)	0 (13.00)		
$Z X^2$						8.717
p						0.003

3.2 Comparison of pain scores between the two groups

Prior to treatment, there was no significant difference in the VAS scores between the two groups ($\rho > 0.05$).

After 1, 2, and 3 months of treatment, the VAS scores in both groups were decreased, and the reduction in the study group was greater than that in the control group (ρ < 0.05, Table 3).

Table 3 Comparison of pain scores between the two groups ([M (P25, P75)], points).

Group	Case	Before treatment	1 month after treatment	2 months after treatment	3 months after treatment
Study group	40	6.00 (6.00, 7.00)	4.00 (4.00, 4.00) *	3.00 (3.00, 3.00) *	3.00 (2.00, 3.00) *
Control group	40	6.00 (6.00, 7.00)	5.00 (4.75, 5.00) *	5.00 (4.00, 5.00) *	4.00 (4.00, 4.00) *
Wald χ^2		0.290	40.223	237.384	151.261
P		0.590	< 0.001	< 0.001	< 0.001

Note: Compared with before treatment: *p < 0.05.

3.3 Comparison of infrared thermal imaging region temperature between the two groups

Due to treatment, the temperatures at the Shenque

and lower abdomen areas in the study group were lower than those in the control group (ρ < 0.05, Table 4).

Table 4 Comparison of infrared thermal imaging region temperature between the two groups (mean \pm standard deviation, $^{\circ}$ C).

Group	Case	Lower abdomen	Shenque
Study group	40	32.18 ± 0.82	32.05 ± 0.78
Control group	40	33.81 ± 0.78	33.45 ± 1.29
t/Z		-9.088	-5.881
p		< 0.001	< 0.001

3.4 Comparison of adverse reactions between the two groups

During the treatment period, no adverse reactions such as dizziness, nausea, diarrhea, or rash and

itching were observed in either group.

4 Discussion

To improve the clinical efficacy of PD in patients, this study investigated the effect of self-designed Exploration and Verfication Publishing

Nuangong Zhitong Ling in treating PD patients. The results showed that self-designed Nuangong Zhitong Ling may have good clinical value in treating PD patients.

In the self-designed Nuangong Zhitong Ling formula, Evodia rutaecarpa and Cinnamomum cassia are warm and hot in nature and serve as the principal herbs. *The* Grand Compendium of Materia Medica records that Evodia rutaecarpa is used for its effects of dispelling cold, warming the interior, drying dampness, and resolving depression. Evodia rutaecarpa can dispel cold and relieve pain. Its pungent and aromatic nature allows it to penetrate the three yin meridians, removing cold coagulation in the uterus [13]. Yaoxing Lun (Treatise on the Nature of Medicinal Substances) states that *Cinnamomum cassia* promotes blood circulation, regulates deficiency in the meridians, and enhances the efficacy of other medicines without contraindications. This reveals that *Cinnamomum* cassia has the functions of tonifying fire and assisting yang, as well as warming and unblocking the meridians, which combined with Evodia rutaecarpa can warm blood, activate blood flows, warm yang, dispelling cold, and promote the free flow of gi and blood [14]. Among adjuvant drugs, Angelica sinensis, Rhizoma Chuanxiong, Radix Paeoniae Rubra, Herba Epimedii, Radix Achyranthis Bidentatae, Rhizoma Corydalisu and raw Pollen Typhae play a specific role and work synergistically. Angelica sinensis can nourish blood, blood activate circulation, regulate menstruation, and relieve pain [15]. Rhizoma Chuanxiong promotes blood circulation and regulates qi, acting as a qi-regulating herb in the blood [16]. Raw Pollen Typhae removes blood stasis. Radix Paeoniae Rubra can disperse blood stasis, relieve pain, and unblock the uterine meridians [17]. These four herbs together achieves the dual regulation of gi and blood, resolve blood stasis and unblock the meridians. Herba Epimedii and Radix Achyranthis Bidentatae both can warm the kidneys and assist yang [18]. Herba

Epimedii enters the liver and kidney meridians and can nourish essence and marrow. Radix Achyranthis Bidentatae has the function of removing blood stasis, unblocking the meridians, and guiding blood downward. Rhizoma Corydalis can regulate qi and relieve pain, assisting the principal herbs to enhance the pain-relieving effects. As the adjuvant herbs, fried Radix Codonopsis can tonify the spleen and stomach, and promote the transformation and absorption of food essence, while fired Rhizoma Atractylodis Macrocephalae can strengthen the spleen, invigorate qi, dry dampness, and promote diuresis. Besides, Glycyrrhiza uralensis harmonizes all the herbs in the formula, balancing their properties with its sweet and neutral nature. Together, they achieve the effects of warming yang, dispelling cold, nourishing blood, and relieving pain. Therefore, the self-designed Nuangong Zhitong Ling can improve clinical efficacy and alleviate pain symptoms in PD patients.

When PD occurs, histamine and prostaglandin E2 are released in large quantities, and cell mitochondrial metabolism in local tissues accelerates. Substantial chemical energy is converted into heat energy and released, ultimately leading to an increase of temperature in the painful area. Infrared thermal imaging technology is a novel medical imaging technique developed from the application of infrared technology in the medical field. Infrared thermal imaging technology works by collecting the infrared radiation energy emitted by the human body, converting it into electrical signals, and then these sianals through processing relevant transformations. With software analysis, the temperature distribution across the body is displayed in the form of a color-coded image, ultimately generating a "human pain map." This allows for a visual and more intuitive analysis to identify affected areas, determine the extent of abnormalities, and assess temperature variations [19]. Previous study showed that the detection rate of infrared thermal

imaging for low back and leg pain is comparable to that of CT examination results. Infrared thermal imaging has a higher diagnostic and early warning value in pain diseases and is worthy of promotion and application in hospitals at all levels [20]. This study innovatively introduces infrared thermal imaging technology, which captures the thermal radiation on the surface of the human body and converts it into intuitive images to reveal temperature changes in painful or abnormal areas, providing a new path to improve the accuracy of PD diagnosis. This study found that after treatment, the temperatures at the Shenque and lower abdomen areas in the study group were lower than those in the control group, indicating that the self-designed Nuangong Zhitong Ling can promote the normal circulation of qi and blood in the cold-congealed areas of the body. Nuangong Zhitong Ling contained multiple components such as Evodia rutaecarpa, Angelica sinensis, and Radix Achyranthis Bidentatae. In modern pharmacology, the alkaloids in Evodia rutaecarpa can directly act on the membranes of uterine cells by reducing the influx of calcium ions to inhibit the excessive release of excitatory neurotransmitters such as glutamate (Glu), and weakening the transmission of pain signals to the central nervous system, which is of great significance for pain relief [21]. Ferulic acid, one of the active components in Angelica sinensis, has antithrombotic effects, which can prevent platelet aggregation and fibrinogen (FIB) polymerization reaction, avoid aggravating dysmenorrhea due to blood stasis obstruction, and ensure smooth discharge of menstrual blood [22]. Radix Achyranthis Bidentatae can act on endothelial cells of blood vessels, directly releasing nitric oxide (NO) [23]. As a vasodilator, NO can recognize and activate the heme group of guanylate cyclase (GC), catalyze guanosine triphosphate (GTP), increase the level of cyclic guanosine monophosphate (cGMP), activate protein kinase G, and relax the smooth muscle of the blood

vessel wall, exerting a vasodilatory effect and indirectly affecting the contraction activity of uterine smooth muscle, which is of great significance for improving symptoms.

This study revealed that during the treatment period, there were no adverse reactions in both groups, implying that the self-designed Nuangong Zhitong Ling had good safety. Furthermore, reviewing previous clinical efficacy assessments of PD, which relied heavily on subjective scales, inevitably led to results influenced by various factors. Therefore, the innovation of this article lied in the use of infrared thermal imaging technology for evaluation, which accurately captured the distribution of natural thermal radiation emitted from the human body surface, ensuring the objectivity of research results to a greater extent. However, due to the small sample size and lack of long-term follow-up in this study, it is difficult to ensure the long-term effects of Nuangong Zhitong Ling, which weakens the universality of the study results. Future research is required to address these limitations.

In conclusion, the self-designed Nuangong Zhitong Ling has significant application value in the treatment of PD, which can provide clinical efficacy via relieving pain symptoms and improving temperature changes in local tissues to remove cold coagulation and stagnation, and has good safety. It is worth further promotion in clinical practice.

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Not applicable.

Conflicts of Interest

The author(s) declare(s) no conflicts of interest.

Author Contributions

Substantial contributions to conception and design: Q.Z. Data acquisition, data analysis and interpretation: J.L. Drafting the article or critically revising it for important intellectual content: S.L. and J.C. Final approval of the version to be published: All authors. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of the work are appropriately investigated and resolved: All authors.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of our hospital. Written informed consent was obtained from the patients.

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Availability of Data and Materials

The data presented in this study are available on request from the corresponding author.

Supplementary

Not applicable.

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