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Clinical Study

Therapeutic effect of warm needling plus acupoint sticking therapy on primary dysmenorrhea due to cold-dampness retention

温针加穴位贴敷对寒湿凝滞型原发性痛经的疗效影响

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Abstract

Objective: To observe the clinical efficacy of warm needling plus acupoint sticking therapy for primary dysmenorrhea.

Methods: A total of 60 eligible cases were randomly allocated into a treatment group (n=30) and a control group (n=30) according to their sequence of consultation. Patients in the treatment group were treated with warm needling combined with acupoint sticking therapy, whereas patients in the control group were treated with oral Ibuprofen (Fenbid) capsules. After two menstrual cycles, the visual analogue scale (VAS) score, COX menstrual symptom scale (CMSS) and clinical efficacy were compared between the two groups.

Results: After treatment, the VAS and CMSS scores were significantly reduced in both groups, indicating that both treatment protocols can remarkably alleviate pain. There was a between-group statistical difference in comparing the CMSS score (P<0.05), but no between-group statistical difference in the VAS score (P>0.05). However, the follow-up visit showed between-group statistical differences in comparing VOA and CMSS scores (both P<0.01). The clinical effect, relapse rate and long-term efficacy in the treatment group were better than those in the control group.

Conclusion: Warm needling plus acupoint sticking therapy is a simple but effective therapy for primary dysmenorrhea. In addition, it causes fewer cases with relapse.

Keywords: Warm Needling Therapy; Acupoint Sticking Therapy; Dysmenorrhea; Visual Analog Scale; Pain Measurement

【摘要】目的：观察温针加穴位贴敷治疗原发性痛经的临床疗效。**方法：**将符合条件的60例患者按就诊的先后顺序采用随机数字表分为治疗组和药物组，每组30例，治疗组采用温针加穴位贴敷，对照组口服芬必得胶囊，治疗两个月经周期，然后对比两组患者治疗后视觉模拟量表(visual analogue scale, VAS)评分、COX痛经症状量表(COX menstrual symptom scale, CMSS)评分及临床疗效。**结果：**治疗后，两组患者疼痛VAS评分及CMSS评分均明显降低，说明两种治疗方案均可明显缓解痛经患者的疼痛。治疗后，CMSS评分组间差异有统计学意义(P<0.05)，而疼痛VAS评分差异无统计学意义(P>0.05)。随访时，两组患者疼痛VAS评分及CMSS评分差异均有统计学意义(均 P<0.01)。治疗组临床疗效、复发率和远期疗效均优于药物组。**结论：**温针加穴位贴敷治疗原发性痛经疗效确切，操作简便，见效明显，且复发率低，值得临床推广使用。

【关键词】温针疗法；穴位贴敷法；痛经；视觉模拟量表；疼痛评价
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Primary dysmenorrhea is a common problem treated in acupuncture and gynecology departments. It affects approximately 50% female adolescents[1], and 18% of these women experience severe dysmenorrhea[2], which is a common cause of absenteeism and reduced quality of life in women. We treated this condition (due to cold-dampness retention) with warm needling combined with acupoint sticking therapy between January 2012 and December 2013 and compared with oral Ibuprofen. The results are now summarized as follows.

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1 Clinical Materials

1.1 Diagnostic criteria

This was based on the diagnostic criteria for dysmenorrhea in the *Guiding Principles for Clinical Study of New Chinese Medicines*[3]: periodic lower abdominal pain during, before or after (within 1 week) period coupled with other associated symptoms that may affect the patients' life and work, and exclusion of organic reproductive conditions.

Pattern identification (cold-dampness retention) in Chinese medicine was based on the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*[4]. Major

symptom: cold pain with tenderness in the lower abdomen during, before or after periods that alleviates with warmth. Minor symptoms: scanty or obstructed menstruation with purple blood clots, cold intolerance, cold hands and feet, a bluish pale complexion, nausea and vomiting. The tongue is dark with a white coating. The pulse is deep and tense. A diagnosis can be made with the major symptom coupled with 1 of the item 2 and item 3 minor symptoms or more than 2 minor symptoms as well as the tongue/pulse conditions.

1.2 Inclusion criteria

Those who met the diagnostic criteria for dysmenorrhea; those who met the pattern identification of dysmenorrhea due to cold-dampness retention; young, unmarried women aged between 15 and 30 years old; and those who signed the informed consent.

1.3 Exclusion criteria

Dysmenorrhea secondary to uterine fibroids, adenomyosis, endometriosis and pelvic inflammation; having irregular menstruation; those who didn't meet the pattern identification of cold-dampness retention; having complications of severe primary conditions in cardiovascular, liver, kidney and hemopoietic systems or mental disease; having taken oral contraceptives or other hormonal drugs within the last 3 months; and those who experienced bleeding, ulceration or blisters over the area for acupoint sticking therapy.

1.4 Statistical methods

The SPSS 19.0 version software was used for statistical analysis. The measurement data accorded with positive distribution and homogeneity of variances were expressed as mean ± standard deviation ($\bar{x} \pm s$). The *t*-test was used for intra-group comparison before and after treatment; otherwise the Mann-Whitney *U* test was employed. The enumeration data were expressed as rate or proportion. The Wilcoxon rank sum test was used for ranked data. A *P* value of less than 0.05 indicated a statistical significance.

1.5 General data

A total of 60 outpatients from the Gynecology and Acupuncture Departments of our hospital were randomly allocated into a treatment group (n=30) and a control group (n=30) according to their sequence of consultation. The 30 cases in the treatment group were aged between 16 and 30 years and their duration ranged from 1.2 to 12 years. The 30 cases in the control group were aged between 15 and 29 years and their duration ranged from 1 to 12 years. There were no between-group statistical differences in comparing age, duration and pain severity (P>0.05), indicating that the two groups were comparable (Table 1).

Table 1. Between-group comparison of baseline data

Group	*n*	Mean age ($\bar{x} \pm s$, year)	Mean duration ($\bar{x} \pm s$, year)	Pain severity (case)		
				Severe	Moderate	Mild
Treatment	30	21.3±3.2	4.3±0.9	7	15	8
Control	30	20.6±3.4	4.8±0.6	6	13	11

2 Treatment Methods

2.1 Treatment group

2.1.1 Warm needling therapy

Points: Guanyuan (CV 4), Qihai (CV 6), Zhongji (CV 3), Zigong (EX-CA 1) and Sanyinjiao (SP 6).

Method: The above points were punctured 0.8-1.0 cun perpendicularly using filiform needles of 0.30 mm in diameter and 40 mm in length. The needles were retained 30 min upon the arrival of qi. During needle retaining, moxa cone (as the size of a jujube pit) was ignited from the bottom and attached to the needle tails (2 cones). Starting 5 d prior to the period, the treatment was done once a day, for 5 d. A course of treatment covered 2 menstrual cycles. The patients were treated for a course of treatment, coupled with a 3-month follow-up.

2.1.2 Acupoint sticking therapy

Points: Same as the warm needling points.

Method: Herbal pastes were made from *Bai Jie* Powder [included *Bai Jie Zi* (*Semen Sinapis*), *Gan Sui* (*Radix Kansui*), *Xi Xin* (*Radix et Rhizoma Asari*) and *Yan Hu Suo* (*Rhizoma Corydalis*), etc.] and fresh ginger juice. Then herbal cakes of about 3 cm in diameter and 1 cm in thickness were applied to above points and immobilized with special patches of 6 cm in length (manufactured by Zhejiang Hangzhou Qianyuan Medical Equipment Co., Ltd., China) for 1-2 h until a burning and mild painful sensation occurred in the local area. After the herbal cakes were removed, the green transparent (Lincomycin and Lidocaine) gel or moist burn cream was applied to prevent blisters. Depending on the patients' skin conditions, this therapy was conducted once every 7-10 d, for 3-5 times (a course of treatment).

2.2 Control group

Starting 5 d prior to the period, patients in the control group took a Fenbid capsule (300 mg/capsule, manufactured by Sino-American Tianjin Smith Kline & French Laboratories Ltd., China) for each dose, 2 doses a

day, for 6 d. A course of treatment covered 2 menstrual cycles. The patients were treated for a course of treatment, coupled with a 3-month follow-up.

During the treatment, patients in both groups were advised to avoid cold, raw, spicy or pungent food, eat more fruits and vegetables, and stay away from cold.

3 Efficacy Observation

3.1 Observation items

3.1.1 Dysmenorrhea score

This was based on the *Guiding Principles for Clinical Study of New Chinese Medicines* (Table 2)[3]. The pain severity was then graded according to the scores: mild (5-7 points), moderate (8-12 points) and severe (13-15 points).

Table 2. Pain scoring criteria (point)

Symptoms/signs	Score
Lower abdominal pain during, before or after periods	5
Unbearable pain	1
Significant abdominal pain	0.5
Restlessness	1
Shock	2
A pale complexion	0.5
Cold sweats	1
Cold limbs	1
Pain that requires bed rest	1
Pain that affects life and work	1
Pain that cannot be alleviated by analgesic methods	1
Pain that can be alleviated by analgesic methods	0.5
Associated low back pain	0.5
Associated nausea/vomiting	0.5
Associated bearing-down sensation of the anus	0.5
Pain within a day	0.5 (plus 0.5 for each additional day)

3.1.2 VAS score

Absence of pain: 0 point; mild but tolerable pain: ＜3 points; sleep-disturbed but tolerable pain: 4-6 points; and progressively intense and unbearable pain that affects appetite and sleep: 7-10 points.

3.1.3 COX menstrual symptom scale (CMSS) score

This included the evaluation on general frequency of menstrual symptoms and average severity. The CMSS consists of 18 items and each item has 5 grades according to symptom severity and duration.

Severity: 0 point for absence of discomfort; 1 point for mild discomfort; 2 points for moderate discomfort; 3 points for severe discomfort; and 4 points for extremely severe.

Duration: 0 point for absence of symptoms; 1 point for symptoms lasting ＜3 h; 2 points for symptoms lasting 3-7 h; 3 points for symptoms lasting 7-24 h; and 4 points for symptoms lasting ＞24 h.

3.2 Efficacy criteria

The dysmenorrhea scores were graded according to the pain scoring criteria in table 2. The Nimodipine method was used to calculate efficacy index, which was in turn employed for efficacy assessment.

Efficacy index ＝ (Pre-treatment score — Post-treatment score) ÷ Pre-treatment score × 100%.

Recovery: Absence of abdominal pain or associated symptoms, no relapse after 3 months, the efficacy index reached 100%.

Marked efficacy: Significant alleviation of abdominal pain and associated symptoms, able to work without taking medicine, and the efficacy index was ＞50% but ＜100%.

Improvement: Alleviation of abdominal pain and associated symptoms, able to work with medicine, and the efficacy index was ＞25% and ≤50%.

Failure: Abdominal pain and associated symptoms remain unchanged; the efficacy index was ≤25%.

3.3 Treatment results

3.3.1 Intra-group and between-group comparison in VAS and CMSS scores

After treatment, the VAS and CMSS scores were significantly decreased in both groups, showing intra-group statistical significances (both $P < 0.05$); there was no between-group statistical difference in comparing the VAS score ($P > 0.05$); however, there was a between-group statistical difference in comparing the CMSS score ($P < 0.05$). The follow-up after 3 months showed between-group statistical differences in comparing the VAS and CMSS scores (both $P < 0.01$). This indicated that both treatment protocols could significantly alleviate menstrual pain; however, warm needling combined with acupoint sticking had better and more stable efficacy than oral Fenbid capsules (Table 3).

3.3.2 Between-group comparison in clinical efficacy

After treatment, there was a between-group statistical difference in comparing clinical efficacy ($P < 0.05$), showing a better efficacy in the treatment group than that in the control group (Table 4).

Table 3. Between-group comparison in VAS and CMSS scores before and after treatment ($\bar{x}$ ±*s*, point)

Group	*n*	VAS			CMSS		
		Before treatment	After treatment	Follow-up	Before treatment	After treatment	Follow-up
Treatment	30	6.37±1.29	2.73±1.57[1)]	2.50±1.43[3)]	9.33±3.26	4.30±2.33[1)2)]	4.03±2.05[3)]
Control	30	6.43±1.43	3.80±2.09[1)]	3.90±1.93	9.37±2.89	5.80±2.72[1)]	5.63±2.51

Note: The intra-group comparison before and after treatment, 1) $P<0.05$; the period over period between-group comparison, 2) $P<0.05$; the corresponding period between-group comparison, 3) $P<0.01$

Table 4. Between-group comparison in clinical efficacy (case)

Group	*n*	Recovery	Marked effect	Improvement	Failure	*Z* value	*P* value
Treatment	30	2	17	8	3	−1.992	0.046
Control	30	2	6	13	9		

4 Discussion

Primary dysmenorrhea is common menstrual cramps that are not due to other organic reproductive conditions. In Chinese medicine, it falls under the category of 'periodic abdominal pain during period' and often affects female adolescents. Through years of clinical observation, we've found that the most common pattern is cold-dampness retention. Contributing factors include constitutional yang deficiency and external contraction of cold (such as overeating cold, raw food or being caught in the rain, etc.). Today, many women are not careful about staying warm or avoiding cold food during periods. As a result, cold dampness may affect the uterus and bind with blood, leading to obstruction of the qi and blood in the Thoroughfare Vessel and the Conception Vessel and subsequently, menstrual cramps[5]. This condition is located in the Thoroughfare and Conception Vessels and the uterus, associated with qi and blood and manifested as pain.

The efficacy mechanism of moxibustion lies in its warm-heat effect[6]. By combining the warming and unblocking actions of moxibustion and stimulation of needles, warm needling acts to improve microcirculation, inhibit uterine smooth muscle contraction and thus alleviate pain. Consequently, this study employed warm needling for dysmenorrhea due to cold-dampness retention.

Studies have suggested that needling prior to menstrual period can obtain optimal effect in regulating the deficiency and excess of yin and yang and alleviating pain[7]. Guanyuan (CV 4), a crossing point of the Conception Vessel and three yin meridians of foot, acts to regulate the Thoroughfare and Conception Vessels and reinforce the kidney. Qihai (CV 6) and Zhongji (CV 3) benefit the uterus, dissipate cold and circulate qi. Zigong (EX-CA 1) acts to regulate menstruation, stop leucorrhea, and harmonize qi and blood. Sanyinjiao (SP 6) is the crossing point of the three yin meridians of foot and closely associated with the Thoroughfare and Conception Vessels and the lower abdomen. It acts to regulate qi and blood of the three yin meridians of foot and benefit the uterus. Combining warm needling and acupoint sticking at the above points can regulate, warm and unblock the Thoroughfare and Conception Vessels, circulate qi and blood, dissipate cold and stop pain[8-11].

Currently, oral contraceptives or prostaglandin (PG) synthetase inhibitors are the most recent, frequent and effective treatment approach for dysmenorrhea; however, they may cause adverse side effects. Warm needling has a beneficial effect on primary dysmenorrhea due to cold-dampness retention. Studies have indicated that warm needling can regulate excessive uterine smooth muscle contraction resulting from abnormal levels of $PGF_{2\alpha}$ and PGE_2, increase blood flow, improve local hypoxia and ischemia, and thus alleviate pain[12]. This study employed warming needling combined with acupoint sticking therapy for dysmenorrhea due to cold-dampness retention. With comprehensive effect of moxibustion, acupuncture, herbal medicine and point stimulation, this therapy obtained better efficacy than oral Fenbid capsules. In-depth mechanism study is further needed[13-16].

The modified formula of *Bai Jie* Powder in this study was originally from the *Zhang Shi Yi Tong* (*Comprehensive Medicine According to Doctor Zhang*). Major ingredients include *Bai Jie Zi* (*Semen Sinapis*), *Xi Xin* (*Radix et Rhizoma Asari*), *Gan Sui* (*Radix Kansui*) and *Yan Hu Suo* (*Rhizoma Corydalis*). These herbs act to stimulate the skin and cause local congestion coupled with a burning sensation. Wu Shi-ji in the Qing Dynasty (1644-1911) described complicated external application methods for internal, external and gynecological conditions in the *Li Yue Pian Wen* (*Rhymed Discourse on External Remedies*). Huang JW, *et al* treated primary dysmenorrhea with self-made formula for acupoint sticking therapy and obtained marked pain-relief effect[17]. We used fewer herbs, simplified the

preparation but maintained the similar efficacy. *Bai Jie* Powder was used in this study because of its warm-heat stimulation[18]. The past decade has witnessed its good effects for neck pain, rheumatic arthritis, frostbite and other cold-related conditions.

The findings of this study has suggested that warm needling combined acupoint sticking therapy is a safe, simple and effective therapy for primary dysmenorrhea due to cold-dampness retention.

Conflict of Interest

The authors declared that there was no conflict of interest in this article.

Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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