

Clinical efficacy observation on treatment of primary dysmenorrhea with ginger-partitioned moxibustion at Zigong (EX-CA 1)

隔姜灸子宫穴治疗原发性痛经的临床疗效观察

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Abstract

Objective: To investigate the clinical effect of ginger-partitioned moxibustion at Zigong (EX-CA 1) for primary dysmenorrhea.

Methods: A total of 112 patients with primary dysmenorrhea were randomized into an observation group and a control group according to their visiting sequence, 56 cases in each group. Patients in the observation group received ginger-partitioned moxibustion at Zigong (EX-CA 1), while patients in the control group received oral intake of analgesic. For both groups, treatment started 1 week before menstruation and lasted for 3 menstrual cycles, continued by a 3-month follow-up visit, then the clinical efficacy was evaluated.

Results: By the end of treatment, symptom score in the observation group was lower than that in the control group, showing a statistical significance ($P < 0.05$). After 3 months of treatment, the value of prostaglandin F_{2a} (PGF_{2a}), systolic-to-diastolic peak velocity ratio (S/D), resistance index (RI) and pulsatility index (PI) in the observation group were significantly higher than those in the control group, showing statistical significances (all $P < 0.01$). The recovery rate in the observation group was higher than that in the control group, showing a statistical significance ($P < 0.05$).

Conclusion: Ginger-partitioned moxibustion at Zigong (EX-CA 1) for primary dysmenorrhea is a combination of the merits of warming function of moxibustion, dissipating function of ginger and stimulation of acupoint, and is better than oral intake of analgesic.

Keywords: Acupuncture-moxibustion Therapy; Moxibustion Therapy; Indirect Moxibustion; Ginger-partitioned Moxibustion; Point, Zigong (EX-CA 1); Dysmenorrhea

【摘要】目的: 观察隔姜灸子宫穴对原发性痛经的止痛效果。**方法:** 将符合纳入标准的 112 例原发性痛经患者按照入院的先后顺序随机分成观察组和对照组, 每组 56 例。观察组接受隔姜灸子宫穴, 对照组口服常规止痛药, 两组均在经前 1 星期开始干预, 共治疗 3 个月经周期, 并随访 3 个月, 比较两组患者的临床疗效。**结果:** 治疗结束时, 观察组患者症状积分低于对照组, 组间差异有统计学意义($P < 0.05$)。治疗 3 月后, 观察组患者的前列腺素 F_{2a} (PGF_{2a}) 水平及子宫动脉血流的收缩期峰流速与舒张期峰流速比(S/D)、阻力指数(RI)及搏动指数(PI)的值均优于对照组, 组间差异均有统计学意义(均 $P < 0.01$)。观察组治愈率高于对照组, 组间差异有统计学意义($P < 0.05$)。**结论:** 隔姜灸子宫穴治疗原发性痛经, 发挥了艾灸的温通、生姜的温散、腧穴的刺激等综合作用, 疗效优于口服止痛药物。

【关键词】 针灸疗法; 灸法; 间接灸; 隔姜灸; 穴, 子宫; 痛经

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Primary dysmenorrhea (PD) is a common gynecological disease. It may cause low back soreness, lower abdominal distending pain without genital organic changes by gynecological examination and occurs with the menstrual cycles. Typically, it starts within 2-3 years after the first menstrual period and affects women of adolescent and reproductive age. Research has shown

that the occurrence rate of PD is 33.1% in China, including 53.2% of primary condition^[1]. At present, Western medicine treatment for PD is mainly focused on oral medicine, which is hard to sustain a good clinical effect. Acupuncture has been proven to be effective in treating PD with fewer adverse effects. We have treated PD with ginger-partitioned moxibustion at Zigong (EX-CA 1) and compared it with Western medicine to investigate the short-term and long-term effect of this method. Now, the report is given as follows.

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1 Clinical Materials

1.1 Diagnostic criteria

The diagnostic criteria were stipulated in accordance with the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*^[2]: distending pain in the lower abdomen during menstruation, radiating to lumber lordosis, or even faint, with periodical attack; mostly in girls during adolescence or young women before marriage; without any obvious organic change of the genital organs.

1.2 Inclusion criteria

Aged between 14 and 30 years old; women before childbirth; informed consent.

1.3 Exclusion criteria

Irregular menstrual periods or menstrual period longer than 60 d; with severe diseases in the cardiovascular, hepatic, renal or hematopoietic system; with mental disorders; taking contraceptive medicine or using intrauterine device; unable to follow the treatment protocol, cannot evaluate the therapeutic effect, or cannot judge the clinical effect or safety due to lack of materials; allergic to the medicine or moxibustion; scar diathesis.

1.4 Statistical methods

All data were processed by the SPSS 19.0 version software. Measurement data were tested by SW for normal distribution, in which age and duration were of normal distribution and described by mean $\pm$ standard deviation ($\bar{x} \pm s$) and analyzed by *t*-test; symptoms score, prostaglandin $F_{2\alpha}$ (PGF_{2 α}), systolic-to-diastolic peak velocity ratio (S/D), resistance index (RI), pulsatility index (PI) were not of normal distribution and analyzed by rank-sum test. The enumeration data were described by frequency or ratio and analyzed by using Chi-square test. $P < 0.05$ indicated a statistical significance.

1.5 General data

A total of 112 patients conforming to inclusion criteria of PD were enrolled between January 2015 and September 2016. By their visiting order, the patients were randomly divided into an observation group or a control group, 56 cases in each group. Patients in both groups finished the whole treatment procedure without drop-out or severe adverse event. In comparison of the average age and duration before the treatment, the differences were not statistically significant (all $P > 0.05$), (Table 1).

Table 1. Baseline comparison ($\bar{x} \pm s$)

Group	<i>n</i>	Average age (year)	Average duration (year)
Observation	56	23.6 $\pm$ 4.2	4.3 $\pm$ 3.1
Control	56	22.9 $\pm$ 4.5	4.7 $\pm$ 3.4

2 Therapeutic Methods

2.1 observation group

Points: Bilateral Zigong (EX-CA 1).

Methods: A fresh ginger was sliced into pieces of 0.5 mm in height and 2 cm in diameter and pricked with needles to make several holes before placed on Zigong (EX-CA 1). Put a moxa cone (1.5 cm in diameter, 2 cm in height and 2 g in weight) at the center of ginger slice and ignited. Lifted the slice for a moment if patients felt burning pain, then put down once again until local skin turned red and moist. Burnt 5-7 cones at each point every time. The treatment started 7 d before the menstruation, once a day until menstruation, and lasted for 3 menstrual cycles.

2.2 Control group

Patients in the control group received oral administration of *Tong Jing Bao* powder (SFDA approval number: Z41021972), 10 g each time, twice a day. Took the medicine 1 week prior to the period and lasted until the third day of the period, and continuously for 3 menstrual cycles.

3 Therapeutic Effects

3.1 Observed items

3.1.1 Symptom score

This was based on the symptoms evaluation criteria in *Guiding Principle for Clinical Study on Treatment of Dysmenorrhea by Chinese Medicine*^[3], and the pain scores were evaluated before, after and 3 months after treatment (Table 2).

3.1.2 Laboratory items

Level of PGF_{2 α} , S/D, RI and PI (artery blood flow status detected by Color Doppler) were measured before and after the treatment.

3.2 Criteria for therapeutic effect

This was based on the therapeutic effects on dysmenorrhea in the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*^[4].

Cure: Clinical symptoms disappeared, no recurrence in 3 menstrual cycles after the treatment was stopped, symptoms score was 0.

Marked effect: Obvious alleviation of abdominal pain, improvement in other symptoms, at least 1/2 decrease of symptom scores.

Effective: Alleviation of abdominal pain, improvement in other symptoms, symptoms score declined to 1/4-1/2 of that before treatment.

Failure: No relief of pain and other symptoms after treatment.

Table 2. Symptoms evaluation 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 (+0.5 for each additional day)

3.3 Results

3.3.1 Comparison of symptom scores

Before treatment, symptom scores in both groups showed no statistical significance ($P>0.05$). At the end of and 3 months after treatment, symptom scores in both groups dropped significantly, and intra-group comparison showed statistical significances (both $P<0.01$). There was no statistical significances in comparing the symptom scores at the end of and 3

months after treatment in the observation group ($P>0.05$). The differences of symptom scores at the end of and 3 months after treatment in the control group showed statistical significances ($P<0.05$). Inter-group comparisons at the end of and 3 months after treatment showed statistical significances in double time spot respectively (all $P<0.05$), (Table 3).

Table 3. Comparison of symptom scores (case)

Group	<i>n</i>	Before treatment	After treatment	3-month after treatment
Observation	56	11.64±2.67	2.10±3.21 ¹⁾²⁾	2.35±3.42 ¹⁾²⁾
Control	56	11.83±2.49	3.49±3.58 ¹⁾	6.64±4.02 ¹⁾

Note: Intra-group comparison, 1) $P<0.01$; inter-group comparison, 2) $P<0.05$

3.3.2 Comparison of PGF_{2α}, S/D, RI and PI

Before treatment, PGF_{2α}, S/D, RI and PI showed no statistical differences between the two groups (all $P>0.05$). After treatment, the differences within the groups in PGF_{2α}, S/D, RI and PI showed statistical significances (all $P<0.01$). The differences between groups in PGF_{2α}, S/D, RI and PI were statistically significant (all $P<0.01$), (Table 4).

3.3.3 Comparison of clinical efficacy

After treatment, the cure rate in the observation group was 51.8%, versus 30.4% in the control group, showing a statistical significance ($P<0.05$), indicating a better effect in the observation group. The total effective rate was 98.2% in the observation group, versus 87.5% in the control group, between-group comparison showed a statistical significance ($P<0.05$), (Table 5).

Table 4. Comparison of PGF_{2α}, S/D, RI and PI before and after treatment ($\bar{x} \pm s$)

Group	<i>n</i>	Time	PGF _{2α} (ng/mL)	S/D	RI	PI
Observation	56	Before treatment	347.46±54.33	6.38±1.68	3.28±1.16	0.98±0.22
		After treatment	133.88±19.15 ¹⁾²⁾	4.28±0.81 ¹⁾²⁾	1.91±0.81 ¹⁾²⁾	0.48±0.21 ¹⁾²⁾
Control	56	Before treatment	342.13±58.29	6.43±1.79	3.41±1.22	0.96±0.19
		After treatment	169.22±43.41 ¹⁾	5.06±1.13 ¹⁾	1.41±0.72 ¹⁾	0.68±0.28 ¹⁾

Note: Intra-group comparison, 1) $P<0.01$; inter-group comparison, 2) $P<0.05$

Table 5. Comparison of clinical efficacy (case)

Group	<i>n</i>	Cure	Marked effect	Effective	Failure	Cure rate (%)	Total effective rate (%)
Observation	56	29	20	6	1	51.8 ¹⁾	98.2 ¹⁾
Control	56	17	16	16	7	30.4	87.5

Note: Inter-group comparison, 1) $P<0.05$

4 Discussion

PD falls under the category of abdominal pain during

menstruation in Chinese medicine. Chinese medicine holds that, due to growth and development, adolescent girls may experience kidney qi deficiency, insufficient

essence and blood and insufficiency in the Thoroughfare and Conception Vessels. In terms of etiology and pathogenesis, PD can be diagnosed into excess or deficiency. The 'excess' here refers to emotional injuries, cold dampness affecting the Thoroughfare and Conception vessels, or cold retention in meridians obstructing the flow of qi and blood. As a result, the obstruction causes pain. The 'deficiency' here refers to malnourishment of the uterus and Thoroughfare and Conception vessels. As a result, malnourishment causes pain. PD is located in the uterus and closely associated with qi and blood. Blood stasis and qi deficiency can both be the cause and effect. Stagnation of qi and blood may cause malnourishment of the uterus and Thoroughfare and Conception vessels, while qi deficiency may aggravate blood stagnation. Consequently, the treatment strategies are to circulate qi, move and nourish blood, and alleviate pain. In modern medicine, PD is associated with endocrine disorder and incomplete development of reproductive organs^[5].

Zigong (EX-CA 1) first appeared in *Qian Jin Yi Fang* (Supplement to the Essential Prescriptions Worth a Thousand Gold). Physicians in history found that acupuncture or moxibustion at Zigong (EX-CA 1) can treat lower abdominal pain and stasis, like prolapse of uterus, irregular menstruation, PD or infertility with a quick effect. Modern anatomy finds the existence of lateral cutaneous branch of iliohypogastric nerve and superficial epigastric artery on the superficial layer of Zigong (EX-CA 1), and branches of iliohypogastric nerve, inferior epigastric artery and vein in deep layer of Zigong (EX-CA 1). The above nerves are mainly connected to T₁₂-L₁, and the nerves radiating uterus are mainly connected to T₁₁-L₂ and S₂-S₄^[6]. It's thus clear that nearly the same nerve segments are located on Zigong (EX-CA 1) and uterus, and some parts of the afferent nerve are coincided. This might be the morphological basis of the theoretical correlation between acupoints and Zang-fu organs which can explain the radiation pain in gynecological diseases, and the morphological basis for the therapeutic function of Zigong (EX-CA 1) in the treatment of gynecological diseases.

The main materials for ginger-partitioned moxibustion are moxa and ginger slice. As recorded in *Ben Cao Gang Mu* (Compendium of Materia Medica), moxa is mild in nature, bitter in taste without toxin, and has the function of restoring yang, regulating qi and blood, dispersing damp cold, eliminating phlegm, warming uterus, stopping bleeding and preventing abortion. Fresh ginger has the function of warming the middle and dissipating cold, which will facilitate with fresh ginger in the functions of warming vessels,

tonifying qi, dissipating stasis and stopping pain. By working together, it can produce hemostatic and analgesic function. Researches have shown that infrared radiation during moxibustion has a good penetrating capability^[7-8], which is also easily accepted by human body. Moreover, a burning moxa has the dual therapeutic functions of medicine and warming stimulation. Through acting on pelvic region, it has the warming effect and thus improve local micro-circulation, and inhibit contraction of uterus smooth muscle for the relief of PD. Constituents in moxa, including eucalyptol, camphor and borneol, have the function of anti-inflammation and analgesic^[9-11]. Other research showed that partitioned moxibustion for the treatment of PD is by reducing the level of PGF_{2α}^[12-15]. Scholars have also found that partitioned moxibustion can increase β-EP in serum, which is a neurohormone linked with pain^[16]. This has provided solid proof for the relief of pain in PD treatment.

We have observed the therapeutic efficacy of ginger-partitioned moxibustion for PD and compared it with oral intake of medical powder. After 3 menstrual cycles of treatment, both methods had a good clinical effect; the symptom scores in the observation group were lower than those in the control group, and between-group comparison showed statistical significances ($P < 0.05$); PGF_{2α}, S/D, RI and PI were superior to those in the control group, and between-group comparison showed statistical significances (all $P < 0.01$). The cure rate in the observation group was higher than that in the control group, between-group comparison showed a statistical significance ($P < 0.05$). Such result showed that both methods have a valid effect for PD, while ginger-partitioned moxibustion has a better and more stable therapeutic effect than oral intake of the medical powder.

Above all, ginger-partitioned moxibustion at Zigong (EX-CA 1) in treating PD can take full advantage of the warming effect of moxibustion, the diffusing effect of ginger and stimulation of acupoint, which can substantially improve the therapeutic effect. However, the mechanism of this method requires a further investigation.

Conflict of Interest

The author declared that there was no potential 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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