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A clinical trial of acupuncture about time-varying treatment and points selection in primary dysmenorrhea

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ABSTRACT

Objective: To observe the clinical therapeutic effects of acupuncture at single point Shiqizhui (EX-B8) and multi-points in time-varying treatment for primary dysmenorrhea.
Methods: 600 patients with primary dysmenorrhea were randomly assigned to the single point group ($n=200$) including group A (treating before the menstruation, $n=100$) and group B (immediately treating as soon as pain occurrence, $n=100$), the multi-points group ($n=200$) including group C (treating before the menstruation, $n=100$) and group D (immediately treating as soon as pain occurrence, $n=100$), or the control group, group E ($n=200$, no treatment). The therapeutic effects were analyzed after treatment for three menstrual cycles and interviewed for three follow-up periods.
Results: Acupuncture could effectively relieve menstrual pain for primary dysmenorrhea compared with the control group ($P<0.05$, $P<0.01$). Immediate pain relief occurred following acupuncture within 5 min in group B ($P<0.01$) and group D ($P<0.01$), and the two groups obviously relieved menstrual pain for VAS scores. Both group A and group C obviously relieved menstrual pain ($P<0.01$), and group C was better than group A ($P<0.05$). Compared with group D, Group C was much better for CMSS scores in cycle 1.
Conclusion: Treating before the menstruation is better than immediately treating as soon as pain occurrence at the improvement in symptoms of dysmenorrheal at multi-points. And single point is better than multi-points when immediately treating as soon as pain occurrence. The present trial suggest Shiqizhui (EX-B8) should be chosen as a convenient point.

1. Introduction

Dysmenorrhea is a painful uterine contraction during menstruation and is one of the most common disorders in women (Shah-Hosseini et al., 2005). It affects almost half of them, with symptoms becoming too severe in 10% of the half women to disturb their routine activities (Daniels et al., 2005; Holtzman et al., 2008). Primary dysmenorrhea (PD), which is defined as painful menses in women with normal pelvic anatomy, usually begins during adolescence. Depending on the measurement used, 20% to 90% of young girls report primary dysmenorrheal (Harel, 2006; Latthe et al., 2006; Patel et al., 2006).

Evidence of efficacy supports use of pharmacological agents such as NSAIDs (Wong et al., 2009), and the use of oral contraceptives (Sundell et al., 1990) to alleviate menstrual pain. However, side effects may not be well tolerated or pain relief may be inadequate for some women. Acupuncture has been proven by a great number of randomized controlled trials (RCTs) that it is effective in treatment of chronic low back pain (Witt et al., 2006), knee osteoarthritis (Witt et al., 2005), migraine (Li et al., 2009), chronic neck pain (Willich et al., 2006), and other conditions. Acupuncture has been used to treat dysmenorrhea for over 2000 years in China. Recent developments of acupuncture in Australia indicate that through adequate and appropriate evaluation, it is being integrated into mainstream health care in Australia

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(Changli Xue et al., 2009). A clinical study showed both acupuncture and western medication are effective for primary dysmenorrhea and acupuncture treatment is better than Ibuprofen (Bing and Xiaohua 2011).

Acupuncture on treatment of primary dysmenorrhea is usually started before the menstruation in clinical. Several studies have used different time sequences of acupressure in dysmenorrheal (Wayne et al., 2008; Cho and Hwang, 2010; Lin et al., 2010). There are short of the evidence-based medicine about the point selection and time of intervention in primary dysmenorrhea. The aim of our study was to examine the effectiveness of acupuncture in time-varying treatment with single point and multi-points, and to screen out the best therapeutic regimen for primary dysmenorrhea. The program is registered with its own identifier (ChiCTR-TRC-09000471) by Chinese Clinical Trial Register in China.

2. Methods

2.1. Patients

Women were recruited for the study from five centers: Shandong University of Traditional Chinese Medicine, Affiliated Hospital of Shandong University of Traditional Chinese Medicine, Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine, Zhejiang University of Traditional Chinese Medicine Institute of Acupuncture and Massage, Affiliated Hospital of Shandong Provincial Research Academy of Traditional Chinese Medicine between March 2008 and January 2010. All the volunteers provided informed consent. This study was approved by the Ethics Committee of Shandong University of Traditional Chinese Medicine Affiliated Hospital.

Eligible participants met the following inclusion criteria: (1) the diagnostic criteria of primary dysmenorrhea in the Primary Dysmenorrhea Consensus Guideline (Lefebvre et al., 2005); (2) aged from 16 to 35 years old without history of delivery; (3) with normal menstrual cycle (28 ± 7 days); (4) course of dysmenorrhea varying from 6 months to 15 years; (5) menstrual pain scoring more than 40 mm on a 100 mm VAS during the baseline menstrual period (one period prior to present menstrual period with treatment) according to the patient-kept dairy; (6) no oral administration of any analgesic nor acceptance of other therapies 2 weeks before the trial; and (7) the syndrome of qi stagnation and blood stasis or the syndrome of blood stasis due to cold on blood. The following main criteria for exclusion were applied: women with secondary dysmenorrhea caused by endometriosis, uterine myoma, endometrial polyps, pelvic inflammatory disease, and other gynecological problems; women allergic to aspirin; considering that some Chinese people may have a basic knowledge of points and acupuncture, participants with history of acupuncture treatment and knowledge of the effects of points.

2.2. Randomization and allocation

The study was a multicenter randomized controlled trial. Allocation was conducted by another administrator with the usage of center-randomization system (commission to China Academy of Chinese Medical Science). Random numbers of participants were administered by a research coordinator who from an independent institution not involved in this study by means of a computer-generated. Participants were randomly assigned to one of three groups (the single point group, the multi-points group or the control group), blocked random-allocation sequence with a block size of 6. The single point group and the multi-points group were

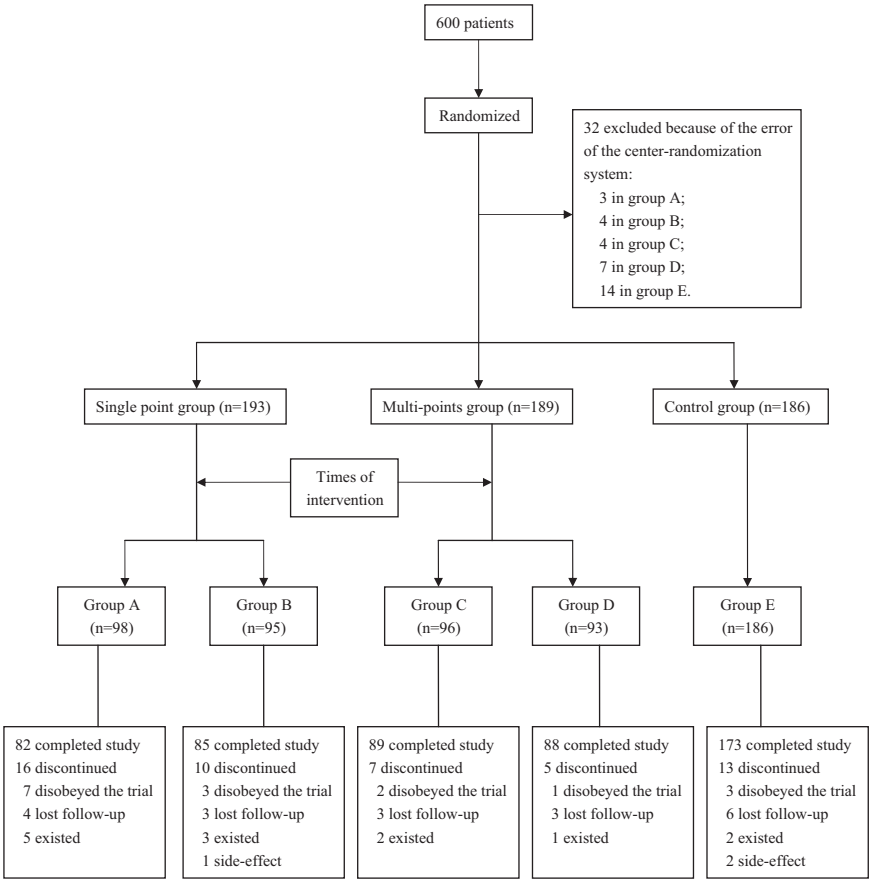

Fig. 1. Flow chart of the trial. Group A and Group C: Treating before the menstruation; Group B and Group D: Treating as soon as pain occurrence;Group E: No treatments.

respectively randomly assigned two groups once again with a block size of 4 (Fig. 1). Due to the unique nature of acupuncture operations, the double-blind cannot be adopted between subjects and physicians. However, to ensure the integrity of the trial, the researchers could not assess the efficacy of treatment to avoid misleading the patients, and the potential impact on the compliance and outcome measurement was induced by it. And we are sure that the acupuncturists, the valuators of therapeutic effect, the valuators of data management and the statistical data would not be the same person.

2.3. Intervention

Participants received the treatment for three consecutive menstrual cycles and three months of follow-up. Sterile disposable acupuncture needles (Hwato 0.25×40 mm, made in Suzhou) were used.

2.4. Single point groups (group A and group B)

Shiqizhui (EX-B8) was selected. The treatment took palace with patients in a pronated position. Needle sites was disinfected, and disposable needle was inserted into the selected point and retained to a depth of 0.5–1 cm for 30 min. Basic needling techniques of lifting-thrusting and twirling were applied for about 30 s every 10 min.

2.5. Multi-points groups (group C and group D)

Sanyinjiao (SP6), Diji (SP8), Ciliao (BL32) and Shiqizhui (EX-B8) were selected. The treatment took palace with patients in either a supine or pronated position. Needle sites were disinfected, and disposable needles were inserted into the points and retained to a depth of 1–1.5 cm for 30 min. Basic needling techniques of lifting-thrusting and twirling were used for about 30 s every 10 min.

2.6. Control group (group E)

These patients received no treatments.

2.7. Times of intervention

Group A was treated before the menstruation at single point (Shiqizhui EX-B8); group B was immediately treated as soon as pain occurrence at single point (Shiqizhui EX-B8); group C was treated before the menstruation at multi-points (Sanyinjiao SP6, Diji SP8, Ciliao BL32 and Shiqizhui EX-B8 , Figs. 2 and 3); group D was immediately treated as soon as pain occurrence at multi-points (Sanyinjiao SP6, Diji SP8, Ciliao BL32 and Shiqizhui EX-B8). Group A and C were treated once a day about 3 to 7 days (we usually chose 5 days) before the menstruation until the menstrual onset. Group B and D were treated as soon as pain occurrence once a day, continuing 3 days. And the treatments were lasted for three consecutive menstrual cycles.

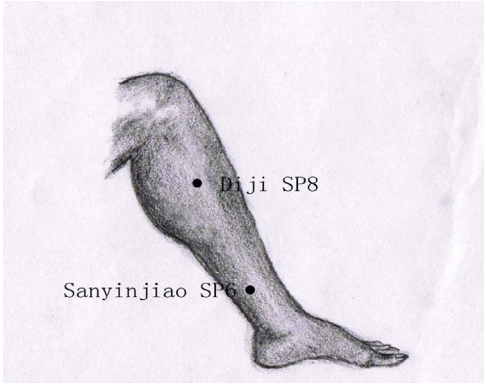

Fig. 2. The VAS value in Group B at different acupuncture time. −10 min means before acupuncture; 5 min, 10 min , 20 min, and 30 min mean upon acupuncture; > 30 min, > 60 min, and > 120 min mean after needle withdrawal.

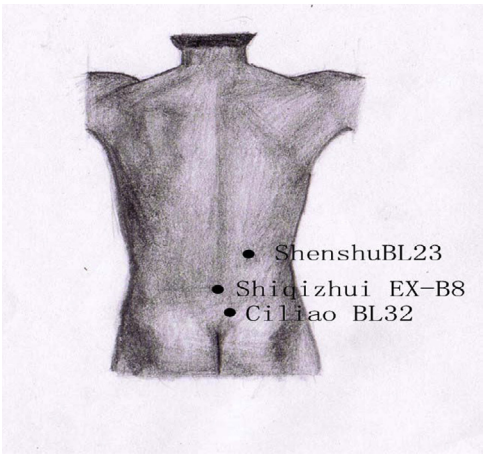

Fig. 3. The VAS value in Group D at different acupuncture time. −10 min means before acupuncture; 5 min, 10 min , 20 min, and 30 min mean upon acupuncture; > 30 min, > 60 min, and > 120 min mean after needle withdrawal.

2.8. Outcome measures

The primary outcome measure was the Cox Menstrual Symptom Scale (CMSS) formulated by Cox DJ (Cox and Meyer 1987). The CMSS, as a tool for evaluating patients' symptom integrally, is important for this kind of trial. We adopted the CMSS after we obtained permit from Professor Daniel J. Cox. The scale constituted of 17 items of symptom. In severity evaluation, each symptom is scored in five levels: 0 score denote not noticeable; 1 score denote slightly bothersome; 2 scores denote moderate bothersome; 3 scores denote severely bothersome; and 4 scores denote very severely bothersome. In the duration of the evaluation, each variable is scored in five grades by the retained time of symptom: 0 score denote did not occur; 1 score denote lasted less than 3 h; 2 scores denote lasted 3 to 7 h; 3 scores denote lasted an entire day; and 4 scores denote lasted several days. The scores of clinical symptoms of all the patients were recorded before trial (as baseline) and at the end of each in the three-cycle treatment period. Moreover, a three-cycle follow-up study was performed on Group A, Group B, Group C and Group D, and the respective scores were recorded also. And the CMSS scores of patients in control group were not recorded in follow-up.

Secondary outcome measures included the Visual Analogue Scale (VAS) and side effects. The VAS is composed of a 100 mm horizontal line with the words “no pain” on the left and “pain as bad as it could be” on the right. The pain scales were completed immediately in the baseline and recorded immediately at 10 min before acupuncture, upon insertion at 5 min, 10 min, 20 min and 30 min, as well as 30 min, 60 min and 2 h after needle withdrawal in each of treatment in group B and group D. The side effects included fainting during acupuncture, hematoma, needling sensation after acupuncture and other abnormalities such as menstrual period, menstrual volume and menstrual cycle.

2.9. Statistical analysis

Mean and standard error (SE) were determined for all data. Rank sum test was used to analyze the data of between-group

Table 1
Comparison of the severities of Menstrual abdominal pain in CMSS scores ($M \pm SE$) .

		Group A	Group B	Group C	Group D	Group E
	Baseline	2.58 ± 0.08	2.72 ± 0.07	2.72 ± 0.07	2.57 ± 0.07	2.66 ± 0.06
Treatment period	Cycle 1	$2.14 \pm 0.09^{**}$	$2.14 \pm 0.09^{**}$	$1.78 \pm 0.08^{**}$	$2.05 \pm 0.07^{**}$	2.49 ± 0.06
	Cycle 2	$1.77 \pm 0.07^{**}$	$1.79 \pm 0.08^{**\#\#}$	$1.56 \pm 0.10^{**\#\#}$	$1.74 \pm 0.09^{**\#\#}$	$2.41 \pm 0.06^{*}$
	Cycle 3	$1.62 \pm 0.08^{**\#}$	$1.64 \pm 0.10^{**\#\#}$	$1.43 \pm 0.09^{**}$	$1.55 \pm 0.10^{**\#\#\triangle}$	$2.40 \pm 0.06^{*}$
Follow-up period	Cycle 4	$1.63 \pm 0.09^{**\#}$	$1.50 \pm 0.09^{**\#\#}$	$1.34 \pm 0.09^{**\#\#}$	$1.50 \pm 0.10^{\#\#\triangle\triangle}$	
	Cycle 5	$1.65 \pm 0.10^{**\#\#}$	$1.54 \pm 0.09^{**\#\#}$	$1.48 \pm 0.10^{**\#\#}$	$1.37 \pm 0.11^{\#\#\triangle\triangle}$	
	Cycle 6	$1.51 \pm 0.10^{**\#\#\triangle}$	$1.62 \pm 0.10^{**\#\#\triangle\triangle}$	$1.35 \pm 0.10^{**\#\#\triangle}$	$1.41 \pm 0.09^{\#\#\triangle\triangle}$	

Notes: Compared with screen cycle, $^{*}P < 0.05$, $^{**}P < 0.01$.
Compared with 1st cycle, $^{\#}P < 0.05$, $^{\#\#}P < 0.01$.
Compared with 2nd cycle , $^{\triangle}P < 0.05$, $^{\triangle\triangle}P < 0.01$.

Table 2
Comparison of the whole time of Menstrual abdominal pain in CMSS scores ($M \pm SE$) .

		Group A	Group B	Group C	Group D	Group E
	Baseline	2.77 ± 0.11	2.88 ± 0.09	2.73 ± 0.08	2.79 ± 0.11	2.69 ± 0.07
Treatment period	Cycle 1	$2.16 \pm 0.11^{**}$	$2.48 \pm 0.11^{**}$	$2.01 \pm 0.10^{**}$	$2.40 \pm 0.09^{**}$	$2.58 \pm 0.07^{**}$
	Cycle 2	$2.10 \pm 0.11^{**}$	$2.42 \pm 0.11^{**}$	$1.80 \pm 0.11^{**}$	$1.99 \pm 0.11^{**\#}$	$2.48 \pm 0.07^{**}$
	Cycle 3	$2.06 \pm 0.11^{**}$	$2.21 \pm 0.13^{**\#}$	$1.62 \pm 0.11^{**\#}$	$1.83 \pm 0.10^{**\#}$	$2.49 \pm 0.08^{**}$
Follow-up period	Cycle 4	$1.87 \pm 0.11^{**\#\diamond}$	$1.96 \pm 0.12^{**\#\triangle\diamond}$	$1.65 \pm 0.12^{**\#\triangle}$	$1.70 \pm 0.12^{**\#}$	
	Cycle 5	$1.85 \pm 0.11^{**\#\triangle\diamond}$	$1.99 \pm 0.12^{**\#\triangle\diamond}$	$1.88 \pm 0.12^{**\triangle}$	$1.51 \pm 0.12^{**\#\triangle}$	
	Cycle 6	$1.86 \pm 0.11^{**\#\triangle\diamond}$	$1.97 \pm 0.13^{**\triangle\diamond}$	$1.66 \pm 0.11^{**\#\triangle}$	$1.70 \pm 0.12^{**\#}$	

Notes: Compared with screen cycle, $^{*}P < 0.05$, $^{**}P < 0.01$.
Compared with 1st cycle, $^{\#}P < 0.05$, $^{\#\#}P < 0.01$.
Compared with 2nd cycle , $^{\triangle}P < 0.05$, $^{\triangle\triangle}P < 0.01$.
Compared with 3rd cycle, $^{\diamond}P < 0.05$, $^{\diamond\diamond}P < 0.01$.

Table 3
Comparison of CMSS scores for the severities of primary dysmenorrhea ($M \pm SE$) .

		Group A	Group B	Group C	Group D	Group E
	Baseline	14.41 ± 0.79	15.07 ± 0.90	12.93 ± 0.74	13.31 ± 0.55	14.90 ± 0.54
Treatment period	Cycle 1	$9.12 \pm 0.66^{**}$	$10.01 \pm 0.70^{**}$	$7.83 \pm 0.55^{**\diamond\diamond}$	$9.56 \pm 0.55^{**}$	13.20 ± 0.50
	Cycle 2	$7.35 \pm 0.53^{**}$	$8.68 \pm 0.75^{**}$	$6.80 \pm 0.58^{**}$	$7.58 \pm 0.62^{**}$	12.58 ± 0.551
	Cycle 3	$7.11 \pm 0.57^{**}$	$8.89 \pm 0.80^{**}$	$6.07 \pm 0.61^{**}$	$6.72 \pm 0.64^{***\triangle}$	12.60 ± 0.53
Follow-up period	Cycle 4	7.00 ± 0.67	6.96 ± 0.68	$5.00 \pm 0.48^{\#\#}$	6.62 ± 0.63	
	Cycle 5	6.70 ± 0.57	7.12 ± 0.78	5.78 ± 0.56	5.42 ± 0.54	
	Cycle 6	6.43 ± 0.58	7.13 ± 0.66	$4.97 \pm 0.55^{\#}$	5.72 ± 0.55	

Notes: Compared with screen cycle, $^{*}P < 0.05$, $^{**}P < 0.01$.
Group A compared with group C, $^{\#}P < 0.05$, $^{\#\#}P < 0.01$.
Group B compared with group D, $^{\triangle}P < 0.05$, $^{\triangle\triangle}P < 0.01$.
Group A compared with group B, $^{\triangledown}P < 0.05$, $^{\triangledown\triangledown}P < 0.01$.
Group C compared with group D, $^{\diamond}P < 0.05$, $^{\diamond\diamond}P < 0.01$.

comparisons. Wilcoxon signed-rank test was used to analyze the data within-group comparison.

In this trial, the statistical analysis was performed by a statistician blinded to allocation, using the SAS version 8.1 (SAS Institute, Cary, NC). The level of significance was established as $P < 0.05$. The data analysis was based on the intention-to-treat (ITT) population and per-protocol (PP) population. The results of PP and ITT showed no difference. And we choose per-protocol population as a supportive analysis.

2.10. Sample size

The sample size was calculated based on an effective power of 95% in acupuncture for PD (we referred to the pertinent literatures about acupuncture for PD by VIP database from 1989 to 2006). It was calculated that 480 subjects (160 in each group of the study) were needed to detect a difference among the three groups with a power of 80% at the 5% level of statistical significance. The sample size was increased to 600 subjects to allow for just over 20% drop out rate.

3. Result

3.1. Menstrual abdominal pain in the CMSS scores

The severities of menstrual abdominal pain and the whole time of menstrual pain shown by CMSS scores in different groups were listed in Tables 1 and 2. Compared with Group E, the significant relief was found in all acupuncture groups after the three cycles of treatment and three months of follow-up ($P < 0.01$). Compared with the first cycle of treatment, it showed that the significant relief in Group A from the second cycle of treatment till follow-up ($P < 0.01$). Group B, Group C and Group D also showed the similar tendency. And it also showed all acupuncture groups had cumulative effect in Tables 1 and 2.

3.2. The CMSS scores in the same time of intervention with different points

The severities and the whole time of primary dysmenorrhea in the CMSS scores were listed in Tables 3 and 4. There were

Table 4
Comparison of CMSS scores for the whole time of primary dysmenorrhea (M ± SE) .

		Group A	Group B	Group C	Group D	Group E
	Baseline	20.51 ± 1.06	21.57 ± 1.08	19.02 ± 0.91	20.67 ± 0.96	20.56 ± 0.71
Treatment period	Cycle 1	13.57 ± 1.05**	16.79 ± 1.09*▽	11.21 ± 0.74**◇◇	15.24 ± 1.07**	19.22 ± 0.70
	Cycle 2	12.06 ± 0.94**	14.58 ± 1.16**	9.55 ± 0.70**	11.66 ± 1.02**	18.65 ± 0.72
	Cycle 3	11.28 ± 0.96**	14.05 ± 1.17**	8.52 ± 0.74**#	10.15 ± 1.02**△	18.38 ± 0.73
Follow-up period	Cycle 4	10.31 ± 0.95	11.32 ± 1.03	7.38 ± 0.68#	10.15 ± 1.05	
	Cycle 5	10.19 ± 0.92	11.37 ± 1.08	8.62 ± 0.77	8.90 ± 1.05	
	Cycle 6	9.64 ± 0.90	11.27 ± 1.04	7.17 ± 0.72#	8.95 ± 0.10	

Notes: Compared with screen cycle, $^{*}P<0.05$, $^{**}P<0.01$.
Group A compared with group C, $^{\#}P<0.05$, $^{\#\#}P<0.01$.
Group B compared with group D, $^{\triangle}P<0.05$, $^{\triangle\triangle}P<0.01$.
Group A compared with group B, $^{\triangledown}P<0.05$, $^{\triangledown\triangledown}P<0.01$.
Group C compared with group D, $^{\diamond}P<0.05$, $^{\diamond\diamond}P<0.01$.

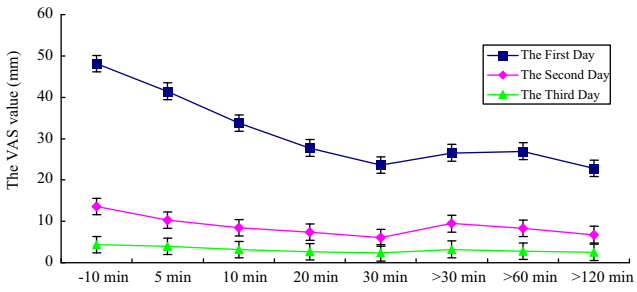

Fig. 4. The VAS value in Group B at different acupuncture time. −10 min means before acupuncture; 5 min, 10 min, 20 min, and 30 min mean upon acupuncture; > 30 min, > 60 min, and > 120 min mean after needle withdrawal.

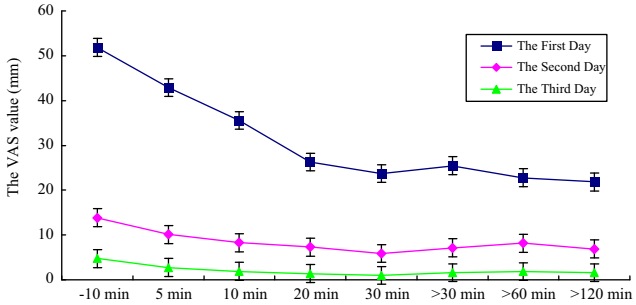

Fig. 5. The VAS value in Group D at different acupuncture time. −10 min means before acupuncture; 5 min, 10 min, 20 min, and 30 min mean upon acupuncture; > 30 min, > 60 min, and > 120 min mean after needle withdrawal.

significant relief in acupuncture groups (Groups A–D) compared with group E ($P<0.01$). However, no difference was found in the three months of treatment period among the four acupuncture groups. Furthermore, the significant relief were found in treating before the menstruation with multi-points compared with single point in the severities and the whole time of primary dysmeorrhea in follow-up ($P<0.05$). We also could find significant differences in treating as soon as pain occurrence with multi-points compared with single point in cycle 3 ($P<0.05$).

3.3. The CMSS scores in different times of intervention with the same point

Tables 3 and 4 showed there was no difference in different times of intervention with single point about the severities of PD. However, the significant difference was found in cycle 1 about the whole time of PD ($P<0.05$) in group B compared with group A. Moreover, the CMSS scores of PD in group C significantly decreased compared with group D in cycle 1 ($P<0.01$).

3.4. Immediate pain relief (group B and group D)

The VAS value in Group B at different acupuncture time for statistical analysis (Fig. 4) showed immediate pain relief occurred within 5 min following first acupuncture by single point Shiqizhui (EX-B8) ($P<0.01$), and lasted for the whole acupuncture process even 2 h after needle withdrawal. The VAS value declined to a minimum at 30 min. The VAS value in Group D at different acupuncture time for statistical analysis (Fig. 5) showed the similar results. There was significant difference between the first day and the second day both in group B and group D.

4. Discussion

Acupuncture is now considered by the general public as one of the most popular treatments of complementary and alternative medicine (CAM) (Xue et al., 2007). The studies are usually about the efficacy and safety of acupuncture or others, such as points using in primary dysmenorrheal (Kashefi et al., 2010; Neda Mirbagher-Ajorpaz, 2011; Smith et al., 2011).

In our trial, patients with primary dysmenorrhea were treated before the menstruation or as soon as pain occurrence by different points. We found that compared with treating as soon as pain occurrence, treating before the menstruation by multi-points was better on decreasing the severities of menstrual abdominal pain and the whole time of menstrual pain. However, compared with multi-points, single point was better on alleviating pain for PD when treating as soon as pain occurrence.

In Chinese Medicine, dysmenorrhea is mainly divided into two patterns: excess patterns and deficient patterns. And we mainly study the excess patterns of dysmenorrhea. It is mainly due to stagnation of the liver-qi caused by emotional factors, which impedes blood circulation in the uterus. The contraction of external cold; or drinking cold beverages during the menstrual periods; or exposuring to rains or wading in cold water also can cause dysmenorrhea. As well as we know, Sanyinjiao (SP6) is the junction point of spleen, liver and kidney meridians, and is said to promote the flow of qi and blood in the meridians, improve the nourishment of thoroughfare vessel, conception vessel and uterus, and to relieve menstrual pain (Chen and Chen, 2004; Wang et al., 2004; Zhao et al., 2009). Many records of using SP6 for treatment of dysmenorrhea can be found in TCM classical books. Diji (SP8), the Xi-cleft Point of the spleen channel, can regulate the channel-qi of the spleen and relieve pain. Ciliao (BL32) and Shiqizhui (EX-B8) are selected with clinical experience for treating dysmenorrhea.

The point stimulation could cause the activation of an endogenous opioid system and facilitates the release of specific neuropeptide, in the central nervous system, achieving pain relief (Han, 2004). Some researches declared that the effects of preconditioning acupuncture (PA) were related with neuro-endocrine-immune network regulation, blood circulatory system improvement, microelements metabolism adjustment, and anti free radical injury (Huang and Gao, 1995; Xie and Liu, 2000; Chen et al., 2002). And these ideas are likely the acting mechanism of acupuncture in primary dysmenorrhea.

In terms of anatomy, the saphenous nerve derives from the L2-L4 nerves while the tibial nerve derives from the L4-S3 nerves by SP6. The saphenous nerve derives of femoral nerve form the L2-L4 nerves while the tibial nerve derives from L4-S2 nerves by SP8. The posterior ramus of sacral nerve derives from S2 nerve by BL32. The cutaneous branch of posterior ramus of lumbar nerve derives from L5 in superficial, and muscular branch of the posterior ramus of lumbar nerve derives from L5 deeper by EX-B8. In an animal model stimulation of acupuncture points CV4, SP6, SP8 could regulate neuro-endocrine activities including follicle-stimulating hormone, luteinizing hormone, estradiol and progesterone (Liu et al., 2009).

It was interesting to observe the optimal effects of acupuncture 3 months after the study intervention ceased. The observation that all acupuncture groups experienced significant improvements over time lends further support to the overall therapeutic effect. A recent observational study found a substantial reduction in pain and the use of NSAIDs by 87% of women, and concluded acupuncture may have a role with the management of dysmenorrhea for women for whom oral contraceptives or NSAIDs are contraindicated (Iorno et al., 2008). There will be further study of clinical acupuncture trials with the points, such as the rule of mutual action between points in treating primary dysmenorrhea.

However, there were several potential limitations in this trial: (a) the pain tolerance among people is different, related to some factors such as gender, attention, emotional components, physical sensations, action programs, etc. (Adams and McGuire 1986; McCaul et al., 1992; de Wied and Verbaten, 2001; Pool et al., 2007). Distracting attention away form pain can diminish the subjective experience of it (Eccleston and Crombez, 1999). And it is well known that positive emotions, such as humour, or positive memories may decrease pain-sensitivity (Adams and McGuire, 1986). In this trial, we didn't evaluate the pain threshold of patients before they were acupunctured, maybe it would affect the outcome; (b) in this study, the treatment began in 5 days before the menstruation or as soon as pain occurrence, and acupuncture may interfere the menstrual period, maybe it onset before or late 1 or 2 days. Therefore, it is difficult to control an exactly time for the patients, and maybe this affect the therapeutic effect; (c) because the patients couldn't come to be acupunctured as soon as pain occurrence for some reasons, for example, they were far away from the acupuncturist, so it maybe affect the rigor of the trial; (d) in this trial, we could not ensure all the patients were treated by the same acupuncturist.

5. Conclusion

This trial shows that acupuncture after three months treatment relieved menstrual pain for women with primary dysmenorrhea lasting the follow-up, and it proves acupuncture have recent and long-term effect for primary dysmenorrhea. Immediate pain relief is showed after acupuncture in 5 min for primary dysmenorrhea by single point Shiqizhui (EX-B8). And we can choose Shiqizhui (EX-B8) as a simple, convenient, effective therapy, such as a preferential therapeutic regimen. Acupuncture before the menstruation is better than immediately treating as soon as pain occurrence in relieving the severities and adjusting the whole time of menstrual abdominal pain with multi-points.

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