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**Clinical Study**

# Clinical studies on different acupuncture time for primary dysmenorrhea

## 不同针刺时间治疗原发性痛经的临床研究

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**Abstract**
**Objective:** To seek the optimal acupuncture time for primary dysmenorrhea and provide clinical basis for optimal acupuncture treatment protocol.
**Methods:** A total of 90 eligible cases were randomly allocated into three groups, 30 cases in each group. Points Guanyuan (CV 4), bilateral Zusanli (ST 36) and Sanyinjiao (SP 6) were selected for patients in all three groups, with a different treatment duration: 15 min in group A, 30 min in group B and 45 min in group C. Then the clinical efficacy in each group was evaluated by pain symptom scoring.
**Results:** As for the pain symptom scores, there were statistically significant intra-group differences between before and after treatment in three groups (all $P<0.05$); coupled with statistically significant inter-group differences between group B and the other two groups (both $P<0.05$). As for clinical efficacy, there were statistical differences between group B and the other two groups (both $P<0.05$), indicating that 30 min of acupuncture is the optimal duration in the treatment of dysmenorrhea.
**Conclusion:** With the same needling manipulation, 30 min of acupuncture treatment achieves a better efficacy for primary dysmenorrhea.
**Keywords:** Acupuncture Therapy; Point, Guanyuan (CV 4); Point, Zusanli (ST 36); Point, Sanyinjiao (SP 6); Dysmenorrhea; Needle Retaining

**【摘要】目的：**寻求针刺治疗原发性痛经的最佳针刺时间，为优化针刺治疗原发性痛经方案提供更好的临床依据。**方法：**将 90 例符合纳入标准的患者随机分为 3 组，每组 30 例。3 组均针刺关元及双侧足三里和三阴交，A 组治疗 15 min，B 组治疗 30 min，C 组治疗 45 min。根据治疗后疼痛症状积分的变化评价临床疗效。**结果：**组内比较，3 组治疗前后疼痛症状积分均有统计学差异(均 $P<0.05$)；组间比较，治疗后 B 组疼痛症状积分明显低于 A 组和 C 组，组间差异有统计学意义(均 $P<0.05$)。3 组临床疗效有统计学差异(均 $P<0.05$)。结果提示 30 min 的针刺时间治疗痛经的疗效最佳。**结论：**在针刺手法相同的条件下，30 min 的治疗时间对原发性痛经的临床疗效较好。
**【关键词】**针刺疗法；穴，关元；穴，足三里；穴，三阴交；痛经；留针
**【中图分类号】**R246.3　　**【文献标志码】**A

Primary dysmenorrhea (PD), also known as functional dysmenorrhea, refers to pain during menstruation with an absence of underlying organic problems. The main symptom is cramps concentrated in the lower abdomen or pelvis. It may radiate to the lumbosacral region and medial aspect of the thighs. Symptoms often co-occurring with menstrual pain include nausea and vomiting, diarrhea, dizziness, and fatigue[1]. Dysmenorrhea has a high incidence and greatly affects the patients' life and work.

Acupuncture has been reported to be beneficial to PD[2-3]. Some studies investigated the association between treatment duration/timing and the clinical efficacy[4-5]. We did this clinical trial on the hypothesis that different acupuncture time may influence the efficacy for PD. The results are now summarized as follows.

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## 1 Clinical Materials

### 1.1 Diagnostic criteria

This was based on the diagnosis for PD in the *Obstetrics and Gynecology*[6] and *Guiding Principles for Clinical Study of New Chinese Medicines*[7]: a cold and down-bearing sensation of the lower abdomen before or during the periods (within 1 week), heavy or scanty menstrual volume, dark color coupled with clots, cold limbs, diarrhea, breast distension, dizziness, fatigue, lumbar soreness, a pale face, sweating or even shock (1-2 of the above symptoms); a history of dysmenorrhea;

  

and exclusion of organic conditions by gynecological examination or ultrasonography.

**1.2 Inclusion criteria**

Those who met the above diagnostic criteria; exclusion of organic conditions; having a clear consciousness and stable vital signs; aged between 18 and 26 years; no history of Chinese or Western medical treatment; willing to cooperate in the treatment, examination and efficacy evaluation; and voluntarily signed the informed consent.

**1.3 Exclusion criteria**

Those who didn't meet the diagnostic and inclusion criteria; an absence of a clear consciousness or stable vital signs; having complications of severe cardio-cerebrovascular diseases, diabetes, infection, heart disease, malignant hypertension, liver or kidney insufficiency, hemopoietic system disorder, mental problems, and infection conditions such as HIV/AIDs, hepatitis and tuberculosis (TB); having complications contraindicated to this clinical trial; unwilling to participate in this trial or dropped out during the trial; having deteriorated condition or severe complications; and those who were unwilling to cooperate or participating in other clinical trials.

**1.4 Rejection criteria**

The efficacy and safety were unable to be evaluated in those who have taken both Chinese and Western medicine or those with incomplete clinical data.

**1.5 Drop-out criteria**

Those who dropped out because of unsatisfactory efficacy or those who did not have time to finish the treatment.

All subjects were free to withdraw from the study.

**1.6 Statistical method**

The SPSS 16.0 version software was used for statistical management. The Chi-square test was used for enumeration data. Tests for normality and homogeneity of variances were used for measurement data. Normally-distributed and homogeneous data were expressed in the form of mean ± standard deviation ($\bar{x} \pm s$). The *t*-test was used for intra-group comparison before and after treatment and one-way analysis of variance for inter-group comparison. The Wilcoxon rank-sum test was used for abnormally-distributed and inhomogeneous data and ranked data. A *P* value of less than 0.05 indicated a statistical significance.

**1.7 General data**

A total of 90 cases treated in the First Hospital affiliated to the University of South China between September of 2013 and September of 2015 were recruited in this trial. These cases were randomly allocated into 3 groups, 30 cases in each group. There were no inter-group statistical differences in baseline data, indicating that the three groups were comparable (Table 1).

**Table 1. Inter-group comparison in baseline data**

| Group | *n* | Mean age ($\bar{x} \pm s$, year) | Mean duration ($\bar{x} \pm s$, year) |
|---|---|---|---|
| A | 30 | 20.2±1.3 | 4.7±1.8 |
| B | 30 | 20.7±1.3 | 5.4±2.2 |
| C | 30 | 20.2±1.2 | 5.0±2.2 |

## 2 Treatment Methods

Points: Guanyuan (CV 4), bilateral Zusanli (ST 36) and Sanyinjiao (SP 6).

Method: The patient was asked to take a supine lying position. After routine sterilization, the above points were punctured by 0.8-1.5 cun using disposable filiform needles of 0.30 mm in diameter and 40 mm in length, followed by 30 s of even reinforcing-reducing manipulation upon arrival of qi. The needles were retained 15 min in group A, 30 min in group B, and 45 min in group C.

The treatment started 5-7 d before the periods (once a day) until the menstruation began. One menstrual cycle made up a treatment course. The clinical efficacy was evaluated after 3 courses.

## 3 Efficacy Observation

**3.1 Efficacy criteria**

This was based on the pain symptom scoring in the *Gynecology and Obstetrics* (Table 2)[6].

**Table 2. Symptom scoring of dysmenorrhea**

| Item | Scoring (point) |
|---|---|
| General pain relief methods | Unable to relieve: 1; temporarily relieved: 0.5 |
| Shock | 2 |
| Restlessness | 1 |
| A pale face | 0.5 |
| Cold sweats | 1 |
| Cold limbs | 1 |
| Bed rest required | 1 |
| Disturbed work and life | 1 |
| Lumbar soreness/pain | 0.5 |
| Nausea/vomiting | 0.5 |
| A down-bearing sensation of the anus | 0.5 |
| Pain within a day | 0.5 |
| Pain in each additional day | + 0.5 |

The efficacy evaluation was based on the *Guiding Principles for Clinical Study of New Chinese Medicines*[7].

Recovery: The symptom score was 0 coupled with an absence of abdominal pain and associated symptoms.

Marked efficacy: The symptom score decreased to 1/2 of the pre-treatment score, coupled with significantly relieved abdominal pain and improvement of associated symptoms. The patient could stay at work.

Improvement: The symptom score decreased to 1/2-3/4 of the pre-treatment score, coupled with relieved abdominal pain and improvement of associated symptoms. The patient could stay at work.

Failure: Abdominal pain and associated symptoms remained unchanged.

### 3.2 Results

#### 3.2.1 Clinical efficacy

The Wilcoxon rank-sum test showed statistically significant inter-group differences in clinical efficacy ($P<0.05$). The Mann-Whitney U rank-sum test showed significantly better efficacies in group B and C than in group A (both $P<0.05$) and a significantly better efficacy in group B than in group C ($P<0.05$). This indicated that a needle retaining of 30 min could achieve the optimal efficacy for PD (Table 3).

**Table 3. Inter-group comparison in clinical efficacy (case)**

| Group | *n* | Recovery | Marked efficacy | Improvement | Failure | Total effective rate (%) |
|---|---|---|---|---|---|---|
| A | 30 | 4 | 12 | 10 | 4 | 86.7 |
| B | 30 | 20 | 4 | 6 | 0 | 100 |
| C | 30 | 8 | 4 | 16 | 2 | 93.3 |

#### 3.2.2 Symptoms scores

Before the treatment, there were no statistically significant inter-group differences in symptom scores (all $P>0.05$), indicating that the three groups were comparable. After the treatment, the symptom scores were significantly decreased in all three groups and there were intra-group statistical differences ($P<0.05$), indicating that needle retaining of 3 time durations all can alleviate PD. In addition, the symptom scores in group B and group C were significantly lower than that in group A (both $P<0.05$) and the symptom score in group B was significantly lower than that in group C ($P<0.05$), indicating that needle retaining of 30 min could achieve the optimal efficacy for PD (Table 4).

**Table 4. Inter-group comparison in symptom scores before and after treatment ($\bar{x}\pm s$, score)**

| Group | *n* | Before treatment | After treatment |
|---|---|---|---|
| A | 30 | 12.21±2.33 | 5.34±2.49 |
| B | 30 | 12.52±2.37 | 3.42±2.56[1)2)] |
| C | 30 | 12.13±2.12 | 4.50±3.05[1)] |

Note: Compared with group A, 1) $P<0.05$; compared with group C, 2) $P<0.05$

## 4 Discussion

In Chinese medicine, PD is closely associated with the uterus, the Thoroughfare Vessel and the Conception Vessel, and the menstrual pain occurs as a result of obstruction or malnourishment[8]. As a result, the treatment strategies are to tonify qi and blood, regulate the Thoroughfare Vessel and Conception Vessel, unblock meridians and alleviate pain[9]. Normal menstruation depends on abundant kidney qi, functioning of the spleen and stomach and free flow of liver qi. It is closely associated with the three yin meridians of foot, the Thoroughfare Vessel and the Conception Vessel. As for the points, Sanyinjiao (SP 6) is a crossing point of the Liver, the Spleen and the Kidney Meridians (the three meridians are connected with the Conception Vessel), and acts to harmonize qi and blood and benefit the uterus. Guanyuan (CV 4) is located near the uterus. It is the Front-Mu point of the small intestine and a crossing point between the Conception Vessel and three yin meridians of foot, and acts to warm Yuan-Primordial yang and the uterus. Zusanli (ST 36) is the He-Sea point of the Stomach Meridian and acts to reinforce stomach qi to increase the generation of qi and blood to fill up the uterus, the Thoroughfare Vessel and the Conception Vessel.

Ancient doctors have long realized the importance of time factor in acupuncture treatment. To date, some studies have been done on the association between efficacy and intervention timing, duration of needle retaining, duration of manipulation and duration of acupuncture treatment[10-15]. Since most acupuncturists choose their own needling time, there is no standard optimal time protocol. However, it's necessary to determine reasonable acupuncture time and intervals between treatment sessions in order to achieve the optimal efficacy and at the same time prevent needling tolerance.

This study investigated the efficacy of different acupuncture time for PD. The results have suggested that acupuncture has positive effect on PD and needle retaining of 30 min can achieve the optimal efficacy.

Additionally, there are fewer substantive studies regarding the stimulation and efficacy, since it's hard to quantify the needling manipulation, intensity and stimulation duration. Further study in this regard is needed to come up with a standard and effective acupuncture treatment protocol for PD.

 

**Conflict of Interest**

The authors 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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