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CLINICAL CASE REPORT

Effects of LI-4 and SP-6 Acupuncture on Labor Pain, Cortisol Level and Duration of Labor

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Abstract
Nowadays, acupuncture is widely used to manage pain, and childbirth is a condition requiring appropriate pain management interventions. The efficacy of acupuncture in the management of labor pain has recently been studied, but the results are not

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satisfactory and conflicts exist. In this study, we investigated the effects of acupuncture on labor pain, serum cortisol level, and duration of labor. We conducted a randomized, single-blind, controlled trial that included 63 nulliparous women: 32 in the study group and 31 in the control group. Acupuncture was performed at the SP-6 and the LI-4 points in the study group, and sham acupuncture was performed at the same points in the control group. Pain scores and serum cortisol levels were measured before and after the intervention. Changes in these measures and in the duration of labor were compared between the groups. No significant variations in pain scores or serum cortisol levels were observed between the two control groups. However, the duration of labor was significantly lower ($p < 0.001$) in the group receiving real acupuncture. Our results show that acupuncture is significantly associated with a decreased duration of labor, even though it was no better than a placebo for the treatment of labor pain.

1. Introduction

The process of childbirth is a physiologic event accompanied by severe pain. This pain adversely affects uterine oxygen consumption as well as uterine contractility, and it increases peripheral resistance, cardiac output and blood pressure [1]. Pain, anxiety, and stress during delivery can cause increased release of catecholamines and cortisol into the circulation. Elevated cortisol levels can lead to decreased uterine blood flow and delayed contractions [2–4]. Increasing need for pain management and patient satisfaction strategies in addition to the above mentioned facts have led to a large number of studies for management of pain and distress during labor.

Acupuncture is a complementary medical modality that has been widely investigated for the management of painful conditions such as shoulder pain, osteoarthritis, headache, musculoskeletal pain, and low back pain since 1970 [5,6]. Acupuncture involves stimulation and manipulation of specific body points by fine needles. Various types of stimulation by acupuncture have been developed, such as electroacupuncture, which accompanies electrical stimulation with needle manipulations, and laser acupuncture, which uses laser instead of needles for stimulation [6]. Utilization of acupuncture as a supplementary modality for pain management during labor has been recently brought under investigation. In 2011, Smith et al [7] reviewed the effects of acupuncture in labor. They stated that when compared to placebo or routine care, acupuncture reduced patient anxiety, pain intensity, length of labor, requirement for analgesics, and rate of instrumental vaginal or cesarean deliveries [7]. By contrast, Cho et al [8] reported no superiority of acupuncture-accompanied management to routine care in labor.

Due to this existing controversy and lack of studies to verify the efficacy of SP6/LI4 acupuncture on pain and length of labor and serum cortisol levels during labor, we conducted the present study to shed light on this issue. Our hypothesis was that SP6/LI4 acupuncture would decrease the intensity of labor pain and the length of labor.

2. Materials and methods

2.1. Study population

A single-blind randomized controlled trial was conducted on 63 pregnant mothers between October 2011 and October 2012. We choose Hafez and Hazrat-e-Zeinab hospitals, affiliated to Shiraz University of Medical Sciences for the study, as they are considered to be main childbirth centers in Shiraz, Iran. This study was a parallel randomized controlled trial with allocation ratio 1:1. Additionally, the Board Committee of Human Research of Shiraz University of Medical Sciences approved the study protocol ethically. Informed consent was obtained from all participants.

We recruited any Farsi-speaking nulliparous singleton woman with a healthy fetus that displayed no intrauterine growth restriction or anomaly, who was referred in active phase of labor at term (37–42 weeks gestational age) with cephalic fatal presentation. Additionally, we chose our study group from women who refused epidural analgesia during labor. Women with any underlying disease (such as diabetes mellitus, gestational diabetes mellitus, and pre-eclampsia), which could complicate the labor, and those who had previously received analgesics, were excluded.

Considering the average intensity of labor pain reported in a previous study [9], we calculated $\alpha = 0.05$ and $\beta = 0.2$, which yielded a sample size of 63. As shown in the flow diagram (Fig. 1), 94 pregnant women were selected through convenience sampling, and 71 were randomly assigned to an experimental acupuncture group and a control group by simple randomization using their hospital admission code. Ultimately, we had 32 patients in the experimental group and 31 patients in the control group. Generating the random allocation sequence, enrolling the participants and assigning the participants to interventions were performed by the coauthors.

As we were able to recruit 63 patients for analysis, the power of our study remained 80%.

In both groups, Fentanyl 50 μg intravenous was given as routine care for labor [10].

2.2. Study protocol

At initiation of the active phase, defined by cervical dilatation of $\geq$ 4 cm and three or more contractions lasting $>$ 40 seconds within 10 minutes, acupuncture for the study group and sham acupuncture for the control group were performed. One of the investigators (M.H.) trained the acupuncturist in the study to perform procedures to increase her comfort with delivering treatment and monitored compliance with the protocol throughout the study. We based the acupuncture point selections on Western

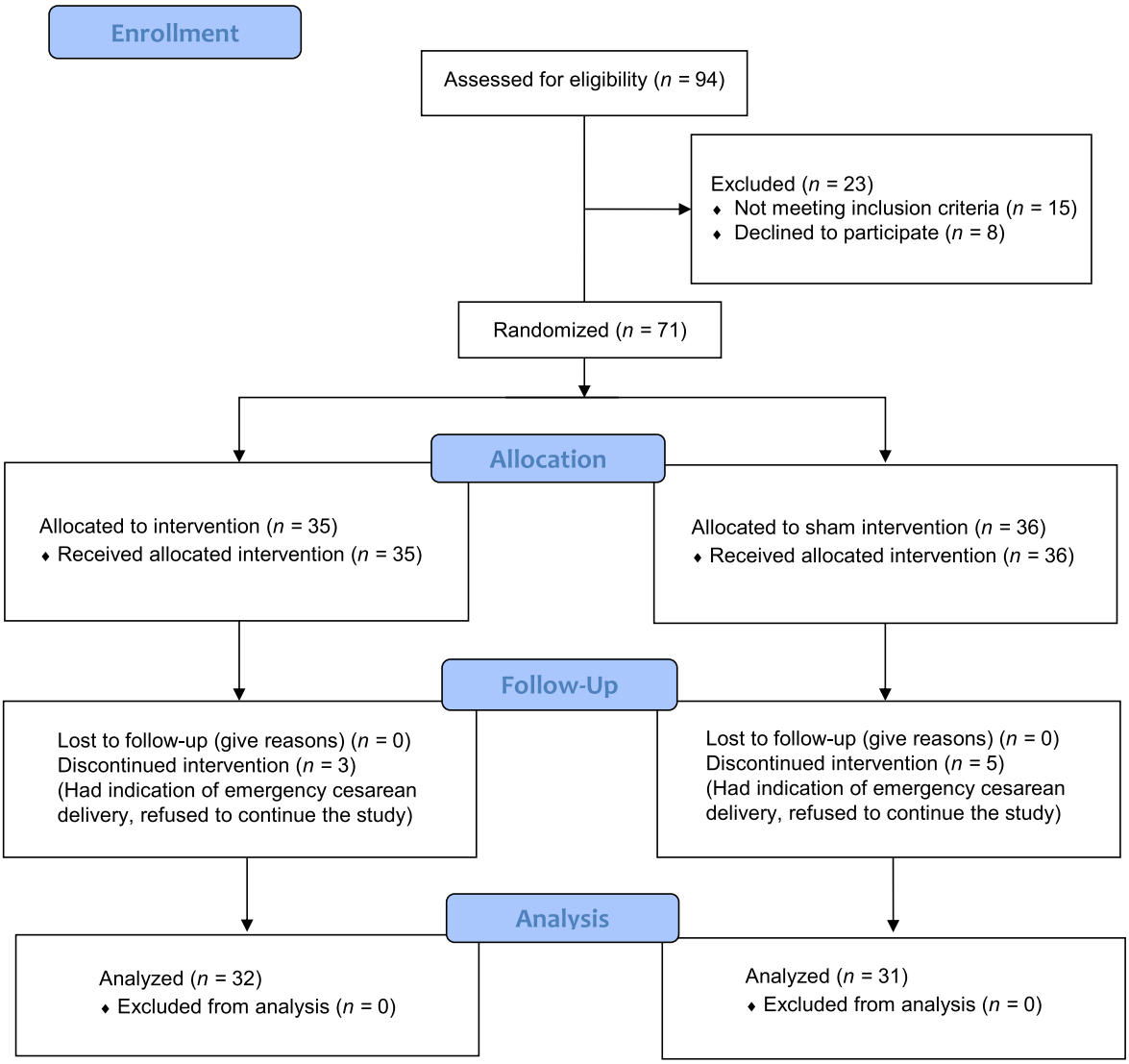

Figure 1 Flow diagram.

medical acupuncture. We used only acupuncture, and no other interventions were administered. The intervention group received acupuncture with a 0.25 mm × 40 mm stainless steel C-type needle (Seirin GmbH, Neu-Isenburg, Germany) at LI-4 and SP-6 for 20 minutes. The SP-6 point is located at a width of four fingers above the medial malleolus on the posterior border of the tibia (Fig. 2). The LI-4 point is located on the dorsum of the hand, between the first and second metacarpal bones, in the middle of the second metacarpal bone on the radial side (Fig. 3). Manipulation was performed until the patient reported De-Qi sensation described mostly by tingling, numbness, or warmth and then rotated clockwise every 5 minutes. In the control group, sham acupuncture was performed by superficial contact of needles in the same site points other than correct technical points of acupuncture. A plaster on LI-4 and SP-6 points fixed the needles for 20 minutes, and the needles were shaken every 5 minutes by the acupuncturist. Patients were not aware of the type of acupuncture that they were experiencing.

Figure 2 SP-6 acupuncture point.

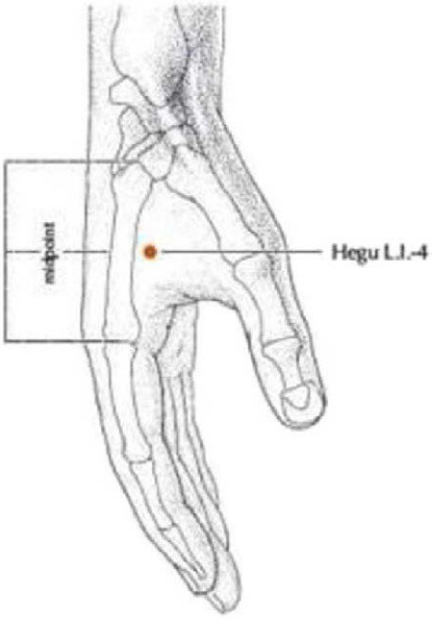

Figure 3 LI-4 acupuncture point.

2.3. Primary outcomes and measurements

The primary outcome measures for this study were pain intensity and duration of labor. The intensity of labor pain was assessed by a linear visual analog pain scale [11]. The duration of labor was considered to be the time between cervical dilatation of 4 cm and complete delivery of the newborn and was assessed in minutes. The secondary outcome of this study was changing in serum cortisol level, before and immediately after intervention.

The pain score of each patient was assessed and recorded initially before starting the procedure during the active phase and immediately after the termination of acupuncture. Severity of pain was scored from 0 (no pain) to 10 (worst imaginable pain) by participants using linear visual analog pain scale. Change in pain score of each patient was calculated and used as the *gain score*. Blood samples were obtained before intervention and 1 hour after intervention by venipuncture and transferred to the laboratory in plastic tubes for measurement of serum cortisol levels. Centrifugation was performed at 3500 rpm for 10 minutes. Serum level of cortisol was measured by radioimmunoassay (DSL-2100 ACTİVE; Diagnostic Systems Laboratories, Webster, TX, USA). Sampling time of cortisol was between 6 PM and 10 PM due to diurnal change of serum cortisol level. To be more precise, cortisol levels normally increase during the early morning; however, if the body encounters a stress such as labor pain, cortisol may be produced at a later point in the day [12].

Length of active phase of labor (Stage 1) was measured as the duration between cervical dilatation of 4 cm and full dilatation of cervix. Stage 2 was considered as the duration between complete dilatation of cervix and complete delivery of the newborn. Overall duration of labor was considered as the summation of these two stages.

2.4. Statistical analysis

An independent sample *t*-test was used for comparison of patients' age, labor pain scores, duration of labor pain, and cortisol levels among the study and control group.

Confidence interval was considered as 95% and significance as determined at $p < 0.05$. All statistical analyses were performed using the SPSS version 18.0 (SPSS Inc., Chicago, IL, USA).

3. Results

Sixty-three nulliparous women entered the study with a mean age of 26.1 years [standard deviation (SD) = 4]. Patients were allocated randomly into case and control groups with mean ages of 25.3 (SD = 3.5) years and 26.8 (SD = 4.4) years, respectively. Comparison of patient age between groups did not reveal a statistically significant variance of means ($p = 0.152$).

Initial pain scores for the study and control groups were 7.6 [95% confidence interval (CI) = 7.0–8.2] and 7.3 (95% CI = 6.6–7.9), which decreased to 5.1 (95% CI = 4.4–5.8) and 4.9 (95% CI = 4–5.8), respectively. There was no significant variation of initial pain scores between two groups ($p = 0.470$). The decrease in pain score in the acupuncture group was slightly greater than the controls (2.5 *vs.* 2.38), but this did not reach statistically significant variation. These results are summarized in Table 1.

Mean serum cortisol level in the study group was 426 nM (95% CI = 395–456), which increased to 452 nM (95% CI = 411–495). In the control group, initial cortisol level of 385 nM (95% CI = 346–424) increased to 414 nM (95% CI = 343–486) after sham acupuncture. The changes in serum cortisol level did not vary significantly between groups (Table 2).

Overall duration of total labor was significantly lower in study group than in the controls ($p < 0.001$). Mean duration of labor was 162 (95% CI = 146–177) minutes in acupuncture group and 280 (95% CI = 257–304) minutes in the control group. The same results were seen for Stage 2 labor, which was significantly shorter in the intervention group ($p < 0.001$). Details are shown in Table 3.

4. Discussion

Acupuncture has been reported to be effective in improvement of certain painful conditions such as labor

Table 1 Description of pain scores and their changes in study and control groups.

Group	Initial pain score (95% CI)	Postintervention pain score (95% CI)	Changes of pain score (95% CI)
Acupuncture	7.6 (7–8.2)	5.1 (4.4–5.8)	2.38 (1.4–3.5)
Control	7.3 (6.6–7.9)	4.9 (4.1–5.9)	2.50 (2–3.1)
p	0.495	0.697	0.850

CI = confidence interval.

Table 2 Description of serum cortisol levels and their changes within groups.

Group	Initial cortisol level (nmol/L) (95% CI)	Post-intervention cortisol level (nmol/L) (95% CI)	Changes of cortisol level (95% CI)
Acupuncture	426 (395–456)	452 (411–493)	26 (−21, 73)
Control	385 (346–424)	414 (343–486)	29 (−42, 101)
p	0.099	0.359	0.939

CI = confidence interval.

pain. Recent studies support the efficacy of acupuncture and acupressure in decreasing labor pain and duration, although debate continues [13]. Conflicts may rise from variations among studies regarding acupuncture or acupressure techniques, e.g., using electroacupuncture, as well as choice of control populations. There are specific body points that are related to obstetrics and gynecology. The most common of these points are LI-4 and SP-6, which constitute forbidden points in pregnancy, as they can induce and promote labor and abortion [14]. In the present study, we investigated the efficacy of LI-4 and SP-6 acupuncture technique in improvement of labor pain, decreasing the duration of labor and serum cortisol level in a single-blind sham-controlled randomized clinical trial. Our results revealed that there was no significant difference between case and control groups with respect to labor pain and serum cortisol level. Given the effect of cortisol on pain relief, our hypothesis is that lack of increasing cortisol is the main contributing factor related to lack of pain reduction. Interestingly, a significant decrease in duration of labor was noted in acupuncture group. The decrease was noted specifically in duration of the active phase of labor. Different mechanisms were hypothesized to explain the effect of acupuncture on initiation of labor, one of which is increasing oxytocin secretion from anterior pituitary gland and thalamic nuclei. In support of this view, Gaudernack et al [15,16] suggested that acupuncture decreases the oxytocin requirement to induce labor. Notably, shortening the active phase of labor can decrease fatal complications such as low Apgar score, nerve injury, infections, and maternal complications including puerperal infection and *postpartum* hemorrhage [17]. A small number of controlled randomized studies have been performed to investigate the efficacy of acupuncture on serum cortisol level, labor duration, and labor pain since 2002 [18]. In 2002, Ramnero et al [19] published a randomized controlled study on 46 parturients, which revealed a decreased need for epidural analgesia and higher relaxation in women who received acupuncture compared to controls. In 2002, another study conducted as a randomized single blind sham controlled trial with 210 women showed that acupuncture significantly decreased pain during labor [20]. Hantoushzadeh et al [21] and Ziaei and Hajipour [22] obtained similar results in 2007 and 2006, respectively, showing decreased visual analog pain scale score in women receiving acupuncture during labor. In the most recent study, the authors detected no statistically significant decrease in pain or duration of labor, although mean pain score and labor duration were lower in the acupuncture group [23].

Table 3 Comparison of duration of labor stages between groups.

Group	Duration of Stage 2 (min) (95% CI)	Duration of Stage 3 (min) (95% CI)	Total labor length (min) (95% CI)
Acupuncture	130 (116–145)	36 (32–40)	162 (146–177)
Control	250 (228–270)	35 (30–40)	280 (257–304)
p	0.000	0.739	0.000

CI = confidence interval.

Serum cortisol level rises significantly during the stressful condition of labor. This parameter can be relied on as a measurable value that can estimate the effect of acupuncture on pain and emotional stress during labor [24,25]. The results of our study showed similar changes in serum cortisol levels between groups. Evidence is lacking regarding the effect of acupuncture on serum cortisol during labor. We found one study that investigated the role of electroacupuncture on cortisol level in labor. The authors reported that there was lower adrenocortical hormone and cortisol levels in the electroacupuncture group, although the difference did not reach a statistically significant level [26].

In 2011, Smith et al [7] published the most recent review regarding the efficacy of acupuncture in improvement of labor pain. By balancing the results with study protocols and possible biases, they evaluated the existing data and found support for limited benefits of acupuncture in decreasing pain and requirement of analgesics during labor. The authors suggested that more investigations were required to make definitive decisions on using acupuncture as a complementary modality in management of pain and distress during labor [7].

Our study had certain limitations. The first one was the small study population. We enrolled only nulliparous women to minimize the bias made by a possibility of less pain in multiparous women. Furthermore, we enrolled only those patients who entered the active phase of labor between 6 PM and 10 PM to eliminate the effect of diurnal pattern of variation of serum cortisol levels. Additionally, we did not analyses fetal data such as head circumference and birth weight. Finally, due to the design of our study (randomized control trial), its external validity is not high.

Our study revealed that acupuncture could significantly reduce the duration of labor. However, no efficacy was found in using acupuncture in management of labor pain. Furthermore, acupuncture had no superiority on decreasing serum cortisol levels compared with the sham intervention. We also suggest randomized controlled trials to be performed with larger study populations to clarify efficacy of acupuncture in improvement of the delivery experience for women. Additionally, we highly suggest the utilization of other techniques applied to different points of body to decrease the intensity of labor pain.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jams.2015.08.003

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