Original Article

The effects of acupuncture during labour on nulliparous women: A randomised controlled trial

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Abstract

Background: Acupuncture is as an ancient system of diagnosis and treatment. It is regarded as a complementary tool for pain management.

Aims: To assess the effects of acupuncture on nulliparous women during labour with respect to pain, labour duration and maternal acceptability.

Methods: One hundred and forty-four healthy nulliparous women in active phase were randomised into the study and control group, receiving real and minimal acupuncture, respectively. Visual analogue scale was used to assess pain. Objectives were to evaluate acupuncture effect on pain and labour duration and patients' willingness to receive acupuncture for subsequent pregnancies.

Results: Visual analogue scale pain score in the study group was lower after two hours. Active phase duration and the oxytocin units administered were lower in the study group. Study group patients had greater willingness to receive acupuncture again. No adverse effects were detected.

Conclusions: Acupuncture could reduce pain experience, active phase duration and oxytocin units. Patients were satisfied and no adverse effects were noted.

Key words: active phase, acupuncture, labour pain, oxytocin.

Introduction

It is now maintained by many that acupuncture should be considered as a useful adjunct in the specialty of pain, and that it can be of value in comprehensive pain clinics as well as physical therapy practice. Acupuncture is certainly not a cure-all; however, researchers and clinicians both attest to its benefits.[1] The dominant rationale cited in clinical studies is that acupuncture stimulates the release of neurochemicals.[2] It has been determined that endomorphin-1, beta-endorphin, encephalin, and serotonin levels increase in plasma and brain tissue through acupuncture application. It has been observed that the increases of endomorphin-1, beta-endorphin, encephalin, serotonin, and dopamine cause analgesia, sedation, and recovery in motor functions.[3] More than 70% of acupuncture points coincide with trigger points.[4] Acupuncture point (acupoint) stimulation stimulates small myelinated nerve fibres in muscle, which send impulse to the spinal cord to activate the spinal cord, midbrain, and hypothalamus–pituitary. More detailed rationales for acupuncture have now appeared in textbooks.[5,6]

One of the areas of research has been the evaluation of its application in the treatment of the labour pain.[7–10] To our knowledge, at the time of writing, three small-scale, uncontrolled studies and at least three randomised clinical trials have reported efficacy of acupuncture in reducing labour pain.[11–15] All those three controlled trials were conducted in Scandinavia (Norway and Sweden) and acupuncture treatment was used as an adjunctive therapy. In Iran, there is no routine, uniform protocol for labour analgesia except for specialised protocols in some private centres. Therefore, during the last decade, painless labour has been an important issue at the level of health authorities in Iran. Multiple protocols have been submitted to propose a practical, universal and at the same time safe and inexpensive modality to provide the mothers with acceptable analgesia during labour that could be integrated into a national obstetrics program. The main plans

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are intravenous pethidine, spinal and epidural anaesthesia, and inhalation of N_2O. This article reflects the authors attempt to evaluate possible applicability of acupuncture as an analgesic technique for labour among Iranian nulliparous mothers, mainly with regard to its ability to reduce labour pain and duration, and to determine its acceptability by Iranian patients.

Methods

The study was performed as a single-blind, randomised clinical trial in the delivery ward at a government general hospital near Tehran during an eight-month period between February and September 2005. Ethical approval for the study was obtained from Ethical Committee of the Tehran University of Medical Sciences (TUMS). We did not know the standard deviations of our outcomes, but to detect a difference of one standard deviation among the two arms with a significance level of 0.05, the total number of 145–150 patients would translate into a power of more than 90%.[16]

During the study 150 consecutive women in spontaneous active phase of labour were randomly allocated to one study group and one control group. The onset of active phase was defined as cervical dilatation of 4 cm or more and/or presence of three contractions of longer than 40 s in a period of ten minutes. In the study group, acupuncture was used to control pain. In the control group, minimal acupuncture was offered and performed for the parturient. Minimal acupuncture means insertion of needles in places that are not regarded as acupoints, mainly locations that are familiar injection sites, such as buttocks, thighs, and arms. Randomisation was done using 150 sequentially numbered, opaque, sealed envelopes containing small pieces of paper with either 'Study' or 'Control' words printed on them. The papers were produced using a computer program. Table 1 shows the inclusion and exclusion criteria.

At the time of admission, if the parturient met the inclusion criteria, the ward nurse offered participation in the study and after signing the informed consent, the nurse picked the envelope with the lowest number and allocated her as such. All data including study outcomes except for the points detail were recorded by the responsible midwife who was unaware of the allocation using a standard data form. Patients were not aware of the type of acupuncture. Acupuncture was performed by one of the authors throughout the study who was trained in the TUMS during a course of practical acupuncture. C-type acupuncture needles (Seirin GMBH, Neu-Isenburg, Germany) were used. Points were selected bilaterally according to parturient symptoms, and needles were inserted at 45 degree or perpendicularly with a depth that depended on the thickness of the subcutaneous fat. The selection of points was done according to acupuncture principles of point selection,[6,17] and was subject to variation from patient to patient. For patients of the study group, the needles were manually stimulated until the *de chi* sensation (sensation of warmth, numbness, tingling, or heaviness) was provoked. The needles were not taped and were removed either when delivery occurred or the patient herself asked to do so or when the effect terminated or no effect was made at all. For the patients of the control group, they were not asked about the *de chi* sensation, and the needles were manually stimulated for about 20 min. Needle removal indications for control patients were the same as study patients. Data concerning the dilatation, effacement and station, birthweight, APGAR score for the first minute, and active phase duration were also recorded. Duration of labour was defined as the time interval between onset of the active phase and the delivery of the fetus. All parturients received care from midwifes in the delivery ward in keeping with national health standards. Routine analgesia was not applied to either group. The main study outcomes were pain, duration of active phase, and acceptability. The secondary outcome was the amount of oxytocin used.

During the study the severity of pain or discomfort was measured using visual analogue scale (VAS). To this end, a colour gradient ranging from yellow to red was used. The yellow end indicated no pain or completely relaxed (0) and the red end denoted the most severe pain possible and very tense (100). The parturients were asked to choose a point in the scale at the beginning of the study and then at 30, 60, and 120 min thereafter and then every hour. After delivery, acceptability was assessed by asking mothers about their satisfaction with the treatment and whether they would be willing to receive acupuncture in their subsequent childbirth(s).

Table 1 Inclusion and exclusion criteria of the study

Inclusion criteria	Exclusion criteria
• Singleton, term (> 37 weeks) • Nulliparity • Parturient in spontaneous active phase	• Presence of a medical or surgical disease that can adversely affect pregnancy • An indication for Caesarean section • Presence of pace maker • Presence of emphysema • History of anticoagulant administration • Documented HIV, HCV, or HBV infection • Presence of pregnancy-related complications including chorioamnionitis, placental abruption, placenta previa, and pre-eclampsia/eclampsia. • Cervical dilatation > 6 cm

HBV, hepatitis B virus; HCV, hepatitis C virus.

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Table 2 Characteristics of participants in the study and control groups. Values are given either as number and percentage or as mean and 95% confidence interval for mean

Characteristics	Study group ($n = 70$)	Control group ($n = 74$)	P-value*
Age (years)	26.1 (22.7–29.6)	23.1 (21.3–24.9)	0.311
Weight (kg)	72.6 (66.2–79.1)	71.1 (66.2–75.9)	0.332
Height (cm)	162.9 (158.2–167.6)	159.2 (156.3–162.1)	0.170
Gestational age (weeks)	39.5 (39.0–40.0)	39.2 (38.7–39.6)	0.621
Birthweight (g)	3068 (2909–3226)	3147 (2934–3360)	0.631
APGAR	8.9 (8.8–9.0)	8.8 (8.7–8.9)	0.333
Dilatation			
1–2	6 (8.6%)	3 (4.1%)	0.532
3–4	62 (88.6%)	69 (93.2%)	
> 5	2 (2.9%)	2 (2.7%)	
Effacement			
0	1 (1.4%)	0	0.464
0–30	10 (14.3%)	7 (9.5%)	
40–50	53 (75.7%)	57 (77.0%)	
60–70	6 (8.6%)	10 (13.5%)	

*Significance value is defined at 0.05.

All data were entered into a dedicated database (Microsoft Access 2000, Microsoft Corp, Redmond, WA, USA) and were analysed using SPSS 12.0 (SPSS Inc., Chicago, IL, USA) for windows. For qualitative variables, χ^2 test was used, and for numerical variables t-test for independent samples was applied.

Results

Of 150 women who entered the study, 70 received the real acupuncture and 74 underwent minimal acupuncture (Fig. 1). No parturient refused participation. Four losses occurred because the patients required Caesarean section for termination of labour. One patient in the study group underwent Caesarean section at 40 min and the other three within the first 30 min. One patient in the study group underwent

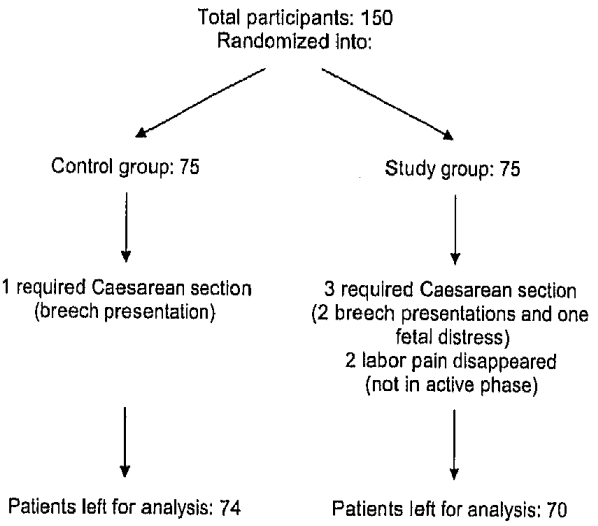

Figure 1 Trial patient allocation.

section because the fetus passed thick meconium and all other Caesarean sections were done because of breech presentation. There was no difference between the groups concerning the percentage of Caesarean sections (P-value = 0.12). In two patients in the study group, the pain and contraction disappeared completely, and they were thought not to be in the true active phase of labour. The distribution of characteristics among the patients of the study and control groups is shown in Table 2. No significant difference could be detected between these two groups.

The points that were utilised during real acupuncture are summarised in Table 3. No parturient in the study had received any kind of acupuncture treatment prior to this study. Before initiation of the intervention, the VAS score of pain was recorded for each parturient. Patients in the control group had a significantly lower VAS score in the very beginning (37.51 (33.57–41.45)) compared to those in the study group (54.16 (50.39–57.92)). Despite this finding, the study group patients showed milder increase in their VAS score during the course of the labour and had comparably lower subsequent scores. This difference became significant only after elapse of two hours and the mean VAS score for

Table 3 Acupuncture points and their indications used in the study group

Point	Indication
Large intestine (LI) 4	Analgesia
Urinary bladder (UB) 32	Back pain
Urinary bladder (UB) 60	Back pain
Spleen (SP) 6	Severe pain during contractions
Stomach (ST) 36	General pain
Liver (LIV) 3	Analgesia
Gall bladder (GB) 34	Cervical rigidity
Heart (HT) 7	Anxiety, nervousness

Table 4 Dependent variables in the study and control groups. Values are given either as number and percentage or as mean and 95% confidence interval for mean

Variable	Study group ($n = 70$)	Control group ($n = 74$)	P-value*
Active phase duration (h)	3.41 (3.06–3.77)	4.45 (4.06–4.83)	< 0.001
Augmentation			
Yes	67 (95.7%)	72 (97.3%)	0.514
No	3 (4.3%)	2 (2.7%)	
Oxytocin units	5.63 (4.69–6.57)	7.81 (6.84–8.78)	0.001
VAS† in the beginning	54.16 (50.39–57.92)	37.51 (33.57–41.45)	< 0.001
VAS† at 30 min	48.67 (44.97–52.36)	47.00 (43.09–50.91)	0.268
VAS† at 60 min	51.25 (48.05–54.44)	57.38 (53.38–61.37)	0.099
VAS† at 120 min	56.51 (52.63–60.39)	69.91 (65.99–73.84)	< 0.001
Average VAS† for the first two hours	52.64 (49.74–55.54)	52.94 (49.19–56.69)	0.693
Patients' rating			
Very good	38 (54.3%)	5 (6.8%)	< 0.001
Good	26 (37.1%)	24 (32.4%)	
Mediocre	6 (8.6%)	30 (40.5%)	
Weak	0	15 (20.3%)	
Willingness			
Yes	67 (97.1%)	53 (73.6%)	< 0.001
No	2 (2.9%)	19 (26.4%)	

*Significance value is defined at 0.05.
†0 was defined as no pain and 100 as the most severe pain imaginable. VAS, visual analogue scale.

the first two hours of the study remained similar between the two groups (Table 4). Similar proportion of the patients among the two groups required augmentation with oxytocin. But the number of administered units oxytocin was significantly lower for the patients in the study group (5.63 (4.69–6.57) units compared to 7.81 (6.84–8.78) units). The duration of the active phase was also significantly lower among study group patients (Table 4). During the course of the study no adverse effect of the acupuncture could be found. No patient requested removal of the needles during the study in either group. There was no difference between APGAR score of the babies born in either groups (Table 2) Satisfaction between study and control groups was also different. More patients in study group rated acupuncture effectiveness as very good. More than 95% of the study group patients were willing to receive acupuncture treatment for their subsequent gestation. This willingness in the control group amounted to 73.6% (Table 4).

Discussion

The main finding of this study was that acupuncture can reduce the duration of the labour active phase and decrease the amount of oxytocin needed for augmentation. Our findings with respect to pain experience shows that acupuncture can reduce labour pain although this pain reduction was not as obvious as our other findings. Despite our effort for conduction of randomisation using opaque envelopes, patients in the control group had lower VAS scores of pain in the beginning of the study before implementation of any intervention. Although patients in the control group had less pain complaint, during the two hours of intervention, patients in the study group showed less intense pain. This probably demonstrates the effect of acupuncture because after two hours the patients in the study group had lower VAS pain scores. Authors cannot exclude the effect of suboptimal randomisation leading to patients with different pain tolerance in the control group, but if patients in the control group could tolerate pain better than their study group counterparts, they would not be expected to have higher VAS scores anywhere along the course of the study. In any case, the mean VAS pain scores of the two groups were similar after two hours which may show the cancelling effect of the initial lower scores for the control group on pain-reducing effect of the acupuncture. The higher proportion of willingness to receive acupuncture in subsequent pregnancies among study group patients may indicated subjective satisfaction of these patients and is consistent with acupuncture having pain-reducing effects.

There are a number of shortcomings inherent to this study. First of all we could not blind any group other than patients and data collectors. The physician performing the acupuncture could not be made blind. Another limitation of the study is lack of objective measurement of pain. Although VAS score is a subjective tool, it is widely applied and is a valid instrument for assessment of pain.[18] Acupuncture point selection is another subject of discussion. In this study, the practising physician chose the points according to patients' symptoms. Nearly all patients received stimulation at point LI 4 but other points were not used as universally during the study. Our findings were consistent with those in previous randomised trials. Skilnand *et al.* showed that acupuncture can reduce pain and make the duration of the labour shorter. Their study included both nulliparous and non-nulliparous

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women. Ramnero *et al.* also reported that acupuncture can lessen the labour pain experience. Their study groups also included both nulliparous and non-nulliparous women and similar results could be obtained. In our study, only nulliparous parturients were included. Inclusion of nulliparous patients led to cervical dilatation and effacement matching between groups and better evaluation of acupuncture effect on labour duration. In the end, we concluded that acupuncture is a safe and acceptable technique that is capable of reducing labour pain and duration of the labour active phase. It also reduces the number of oxytocin units used. These issues may characterise acupuncture as an appropriate method of labour analgesia.

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