

Acupuncture to Induce Labor: A Randomized Controlled Trial

Conclusions: The evidence from the Cochrane systematic review suggests that acupuncture may reduce the need for induction methods; however, there is a need for well-designed trials in this area.

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Approximately 5-10% of pregnancies are prolonged beyond 42 weeks.¹ As a pregnancy continues beyond term, the risks of an adverse event including neonatal and postneonatal death increase. A policy of induction of labor after 41 weeks is recommended to reduce perinatal mortality.

For some women with a postterm pregnancy, an induction of labor may lead them to explore less invasive methods of intervention before being medically or surgically induced. The theory of traditional Chinese medicine would expect labor to commence when the energy or qi flows correctly and the blood circulates well.³ Research has been undertaken to examine the use of acupuncture to stimulate the onset of labor.⁴⁻⁶ Evidence of the effectiveness and safety of acupuncture to stimulate the onset of labor is described in a Cochrane systematic review.⁷ Fourteen trials were identified in the search, and three trials of 203 women were included in the review. The need for induction methods was reduced among women receiving acupuncture compared with standard care (147 women, relative risk [RR] 1.45, 95% confidence interval [CI] 1.08-1.95).

There were no differences between acupuncture and control for any other outcomes reported. These trials were of moderate methodological quality and, when combined, were of a relatively small size. The mechanism underlying acupuncture to induce labor may involve stimulation of the uterus by hormonal changes or by the nervous system. Stimulation of acupuncture points is known to increase the discharge of thalamic nuclei and the hypothalamic anterior pituitary system.⁸ It is hypothesized that acupuncture neuronal stimulation may increase uterine contractility either by central oxytocin release or by parasympathetic stimulation of the uterus⁹ without influencing locally active factors such as interleukin-8 and prostaglandin F₂

The evidence from the Cochrane systematic review suggests that acupuncture may reduce the need for induction methods; however, there is a need for well-designed trials in this area. We tested the hypothesis that a 2-day intervention of acupuncture administered to women with a postterm pregnancy would be effective at reducing the need for induction methods and would reduce the time from acupuncture to delivery compared with women given sham acupuncture.

MATERIALS AND METHODS

We recruited women to this trial from the antenatal clinic at the Women's and Children's Hospital, Adelaide, South Australia, between May 1998 and February 2005. The ethics committee of the Women's and Children's Hospital approved the research. Women older than 16 years with a singleton pregnancy and cephalic presentation who were scheduled for a postterm induction were eligible for the study, and were identified by the researchers, midwives, or obstetricians. Women were excluded if they were in active labor (cervix fully effaced, 3 cm dilated or more) with regular uterine contractions, if there were any contraindications to induction of labor or vaginal birth, or if they presented with spontaneous prelabor rupture of membranes.

After obtaining written consent from participants and collecting baseline data, women were randomized to acupuncture or sham acupuncture. A central telephone randomization service was available 7 days a week at the recruiting hospital. A computer-generated randomization schedule was created by an independent statistician and incorporated into a telephone randomization service so that the clinicians were blinded to future allocations. The randomization schedule was of variable block size and stratified by parity (nulliparous and multiparous). The number of cases in each

randomization block was not revealed to the acupuncturist.

Three acupuncturists registered with the Australian Acupuncture and Chinese Medicine Association administered the acupuncture during the study period. The majority of women saw the same acupuncturist for both treatments, except for some sessions administered over the weekend. All women were allocated two 45-minute sessions over a 2-day period before the planned medical/pharmacological induction. The decision to administer acupuncture over 2 days was pragmatic, with acupuncture performed 2 to 3 days before the hospital's induction policy performed 10 days postterm.

There was little research evidence to guide the design of the acupuncture intervention, and the acupuncture points were based on one expert opinion.¹⁰ The acupuncture protocol was based on classical acupuncture, and acupuncture points were selected on the basis of traditional Chinese medicine meridian theory, which includes local and distal acupuncture points to induce labor. All women allocated to the acupuncture treatment group received acupuncture points Hegu LI4, Sanyinjiao Sp6, sacral points Shangliao UB31 and Ciliao UB32, Zhusanli ST 36, Taichong Liv 3. Any underlying pathology from a traditional Chinese medicine framework, eg, deficiency of Blood or Qi or stagnation of Qi and Blood was examined and treated, if appropriate, with additional acupuncture points, eg, Fuliu KI 7, Pishu BL 20, Weishu BI 21, Taichong LIV 3. The needles were administered for a maximum of 30-40 minutes with strong needle stimulation. The needle depth varied depending on the point being stimulated; Seirin 1-2 inch needles were used with a 32 gauge (0.25 mm) diameter and inserted using a guide tube. All participants received the de qi sensation, which is the needling sensation of soreness, numbness, or heaviness.

The sham acupuncture group received the same treatment procedure in terms of the timing and duration. Sham acupuncture points (points that are not acupuncture points and inserted away from classical acupuncture points and meridians with minimal insertion and stimulation) were selected on the sacral area, hand, foot, a point below the knee, and lower leg. These included points located on the foot anterior to the junction of the third and fourth metatarsals, 4 cun (anatomical units) below and two fingerbreadths lateral to the knee, 2 cun above Kidney 3 between the Spleen and Kidney meridians, 2 cun above the wrist crease between the Lung and Pericardium meridians, and 1 cun lateral away from the sacral points Shangliao UB31 and Ciliao UB32.

The hospital guideline for induction of labor for postterm pregnancies is applied 10 days postterm.² All women proceeded to a pharmacological or surgical induction if they had not been admitted to the labor ward in spontaneous induction by their scheduled date for induction. During the course of their care, all women were offered pain relief by their primary caregiver-usually their midwife but also by medical staff.

Caregivers were blind to the women's study group. The treatment allocation was known only to the acupuncturist administering the study intervention. Data were collected by a researcher not involved with the administration of the trial intervention. The analyst was blind to women's study group. The primary outcome measures specified a priori were the need for induction, a reduction in the need for prostaglandins, oxytocin, and artificial rupture of membranes for induction of labor, change in Bishop score, time of intervention to time of delivery, and length of active labor. Secondary outcomes were methods of pain relief, mode of birth, Apgar scores less than 7 at 5 minutes, and admission of the mother and neonate from the labor room to postnatal ward together. Subsidiary endpoints were meconium-stained amniotic fluid, incidence of nonreassuring fetal heart rate tracing, neonatal jaundice requiring phototherapy, neonatal seizures, and acceptability of treatment intervention to the woman. Measurement of the Bishop scores was estimated by the midwife or medical staff. Baseline scores were measured on the day women were scheduled for induction of labor, and the second measurement was performed before induction or after admission to hospital in spontaneous labor.

Qualitative research has reported on positive psychosocial outcomes after acupuncture treatment.¹¹ These outcomes have included improved sense of balance, centeredness, and perceived relaxation. To estimate whether acupuncture changed women's sense of control during labor, the labor agency scale of control in childbirth was used.¹² Women were asked to complete this self-complete questionnaire within 24 hours after birth and again at 6 weeks postpartum. The labor agency scale

is a validated and reliable questionnaire that consists of 29 negative and positive statements listed in a random sequence. Women were asked to mark a point along a seven-point scale that described their childbirth experience, ranging from almost always to rarely. At the same time that the labor agency scale was administered, women were asked about their likes and dislikes regarding participation in the trial and which study group they thought they were allocated to. To examine blinding and assess the credibility of acupuncture and the control group, women completed a short questionnaire, developed by Vincent,¹³ after the first treatment and at 6 weeks postpartum.

The analysis was carried out by an independent statistician (N.B.) using the SAS 9.1.3 program (SAS Institute, Cary, NC). The analysis used an intention-to-treat approach. The primary study outcome measures were compared between the two groups using analysis of variance, χ^2 tests, and log-binomial regression to estimate adjusted RRs and 95% CIs. We aimed to report in RRs, and, therefore, a log-binomial regression analysis was undertaken.¹⁴ Levels of significance were reported at $P < .05$.

The sample size was based on assessing the effect of acupuncture on stimulating the onset of labor. A trial of 360 women would have an 80% power to detect a 20% relative reduction in the number of women with a postterm pregnancy who required one or more methods of induction (vaginal prostaglandins, artificial rupture of membranes, syntocin infusion) from 70% to 56% with a two-sided significance level of 5%. An estimate of 10% loss to follow-up or withdrawal from the trial was made, requiring 396 women.

RESULTS

Screening women scheduled for induction identified 814 women who were approached to participate in the trial between May 1998 and February 2005 (Fig. 1). Four hundred fifty (46%) women refused to participate, citing reasons such as not being interested in acupuncture (33%), fear of needles (22%), unable to make arrangements to attend the trial treatment (19%), and other reasons such as having a first baby and feeling anxious, deciding to use a private acupuncturist, not wanting to be randomized, and already participating in other trials. Twenty-six women did not receive two study sessions. The reasons included problems with child care, feeling too tired, and lack of transportation to the study. Fifty women received one acupuncture session because of spontaneous onset of labor. Given that the number of women lost to follow-up was less than 10%, a decision was made to stop recruitment when 364 women had been randomized to the trial. An intention-to-treat analysis was performed.

The randomized groups were comparable on most baseline maternal characteristics at trial entry. There was a greater than 5% difference in maternal age and categorization of the Bishop score. More women in the acupuncture group scored in the lower category of the Bishop score. Primary outcomes were adjusted for maternal age and the raw Bishop score.

Data on primary outcomes were available for all 364 women (Table 2); adjusted and unadjusted analyses are reported. The number of women requiring prostaglandin induction was borderline significant (RR 1.25, 95% CI 0.98-1.59, $P = .07$); this effect was reduced after adjustment (RR 1.20, 95% CI 0.96-1.51, number needed to treat [NNT] 11, $P = .11$). There were no significant differences between the two treatment groups for any adjusted primary outcomes (Bishop score: RR 1.08, 95% CI 0.92-1.26, $P = .34$; spontaneous labor: RR 0.97, 95% CI 0.71-1.32, $P = .8$; artificial rupture of membranes only: RR 0.93, 95% CI 0.72-1.20, NNT 30, $P = .57$; oxytocin only: RR 0.89, 95% CI 0.60-1.32, NNT 40, $P = .55$; artificial rupture of membranes plus oxytocin: RR 0.87, 95% CI 0.57, 1.33, NNT 19, $P = .52$; prostaglandins, artificial rupture of membranes, and oxytocin: RR 0.84, 95% CI 0.37, 1.91, NNT 80, $P = .68$; augmentation of labor with oxytocin: RR 0.98, 95% CI 0.74-1.29, NNT 42, $P = .88$); median time from acupuncture intervention to birth was 68.6 hours (interquartile range 53.9-79.5) for women in the acupuncture group compared with 65 hours (interquartile range 49.3-76.3) in the control group ($P = .23$), and the length of labor (excluding women who had caesarean deliveries) was 5.9 hours (interquartile range 4.10-9.25) for women in the acupuncture group compared with 6.5 hours (interquartile range 4.08-9.7) for women in the control group ($P = .5$).

There were no significant differences between the two groups for any secondary study outcomes

(Table 3). All neonates were born alive. The number of neonatal complications was low, and there were no differences in admission of the infant to the neonatal intensive care unit or in the occurrence of neonatal seizures between groups. The response rate to the labor agency scale questionnaire administered to women within 24 hours after birth was 90.3%, and 85% at 6 weeks. Women reported moderate levels of control, but there were no differences between groups in women's sense of control immediately after labor and at 6 weeks postpartum (Table 3).

Image Tools Indicators of women's satisfaction with their experience in the trial suggest that, regardless of study group, women liked being in the trial (Table 4). There were no differences between groups; in particular women liked helping with research and liked the extra attention from being in the study. The trial was acceptable to women, with both groups reporting they would agree to take part in the trial if they had to do it all over again

To assess the effectiveness of masking participants, we asked women in both groups which treatment they thought they were receiving after the first treatment and after the birth of their baby. After the first treatment, most women in both groups were unsure of their group allocation (79% acupuncture group compared with 84% sham acupuncture); 18% in the acupuncture group and 2% in the sham group thought they were receiving acupuncture ($P=.16$). After birth, 43% of women in the real acupuncture group and 44% of women in the sham group thought they were receiving acupuncture, and 11% and 12% of women in both groups were unsure of their group allocation ($P=.7$). These results suggest the acupuncture sham group was a credible control. Women rated the credibility of the acupuncture and control highly, and scores were similar with no differences between groups.

DISCUSSION

Use of acupuncture compared with sham acupuncture before a planned induction of labor did not increase the number of women who labored spontaneously or reduce the need for other induction methods. There were no differences in any other primary or secondary outcomes. There was also no evidence of any adverse effects on the mother or neonate after the use of acupuncture. Women's sense of control did not differ between groups, and women were satisfied with the experience of participating in the study.

Preliminary analyses suggested that women in the acupuncture group had a lower Bishop score compared with women in the control group. Although there was a greater proportion of women with a Bishop score of 0 to 3 in the intervention group on trial entry, adjusting for raw Bishop score did not affect the outcome.

This trial has several strengths compared with previous research in this area. Previous trials have been on smaller sample sizes; our study has a much larger sample size. Other advantages of the trial include central randomization, blinded evaluation of outcome assessment, credibility assessment, and high compliance with the study protocol. The credibility of acupuncture and sham acupuncture was rated similarly between women; we successfully blinded women to their group allocation and reduced the potential for bias and increased the validity of the results.

The efficacy of acupuncture reported in the Cochrane systematic review⁷ included three randomized trials of 203 women. Results from the review provide evidence from two trials^{5,6} that women receiving acupuncture required less use of other induction methods compared with women receiving standard care alone (RR 1.45, 95% CI 1.08-1.95, $P=.01$). These two studies were small, involving 147 women, and women were not blind to their group allocation. The findings from these two trials may be due to placebo effects or expectation effects because of the small treatment effect reported in the Cochrane review.

The absence of a treatment effect in our study does not provide evidence that acupuncture does not stimulate the onset of labor or reduce the need for induction methods. Our findings using manual acupuncture, a standardized selection of acupuncture points, administered twice, and commencing a short period before induction may have been inadequate in terms of treatment frequency, intensity, and the onset of treatment. In practice, acupuncturists might consider commencing treatment at term or earlier. In a randomized controlled trial of 329 primiparas, acupuncture was administered

from 36 weeks of gestation and given weekly until birth.¹⁵ This trial reported that women receiving acupuncture demonstrated morphologic change in the cervix, and women experienced shorter length of labor.¹⁵ We cannot rule out that a different treatment approach adopted in future research may give rise to different results. Other forms of acupuncture stimulation such as electrostimulation also should be considered. The design of future research trials of acupuncture to induce labor would benefit from greater consultation with experts.

There is no evidence of harm from the administration of acupuncture in the postterm period to the mother or fetus, and women may still seek out the use of acupuncture to prepare for labor. There is currently insufficient evidence to support the routine use of acupuncture in clinical practice, and further research is required. Further research could examine the use of different protocols from the one used in our trial. It is also important to address and control for the nonspecific effects of acupuncture. The sham acupuncture group was designed to control for placebo effects and to reduce physiological effects from insertion of the needle to a deeper level and by minimal stimulation. Physiological effects such as neurochemical responses cannot be excluded, and future trials might consider use of the placebo needle.¹⁶ We did not compare our results with women receiving no acupuncture, and it would be advantageous for future studies to include a group receiving no acupuncture. Acupuncture requires trained personnel, and future trials should consider assessing the cost-effectiveness.

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