Effectiveness of Acupuncture for the Initiation of Labour at Term: A Pilot Randomized Controlled Trial

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Abstract

Objective: This study was designed to determine the effectiveness of acupuncture for the initiation of labour in women at term.

Methods: A prospective pilot randomized control trial was undertaken, in which 16 pregnant women at term were randomly assigned to receive acupuncture either at sites reported to cause onset of labour or at nearby sham sites. The primary outcome assessed was the interval from initial acupuncture treatment to delivery.

Results: There was a difference in intervention to delivery interval of 62 hours in favour of the treatment group. Furthermore, women in this group had shorter labours by a mean of 2 hours and 20 minutes.

Conclusion: The interesting results of this pilot trial warrant further investigation into the use of acupuncture for the initiation of labour in women at term.

Résumé

Objectif : Cette étude a été conçue afin de déterminer l'efficacité de l'acupuncture pour amorcer le travail chez les femmes à terme.

Méthodes : Dans le cadre d'un essai comparatif randomisé pilote prospectif, 16 femmes enceintes à terme ont été affectées, au hasard, à un groupe « acupuncture selon des points reconnus comme permettant d'amorcer le travail » [traitement] ou à un groupe « acupuncture selon des points factices avoisinants » [placebo]. Le critère d'évaluation principal était l'intervalle séparant le traitement d'acupuncture initial et l'accouchement.

Résultats : Nous avons constaté une différence de 62 heures, pour ce qui est de l'intervalle séparant l'intervention et l'accouchement, entre les deux groupes (en faveur du groupe « traitement »). De surcroît, les femmes de ce groupe ont connu des périodes de travail plus courtes (réduction moyenne de la période de travail : 2 heures et 20 minutes).

Conclusion : Les résultats intéressants obtenus dans le cadre de cet essai pilote justifient la tenue d'autres études portant sur l'utilisation de l'acupuncture pour amorcer le travail chez les femmes à terme.

Key Words: Acupuncture, induction of labour, alternative medicine

Competing Interests: None declared.

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INTRODUCTION

Postdates pregnancy is defined as a gestation beyond 294 completed days (42 weeks) from the date of the last menstrual period.[1] Approximately 7% of women deliver at more than 42 weeks' gestation if intervention is not undertaken earlier.[1] It has previously been shown that the incidence of perinatal mortality increases as gestational age increases beyond 41 completed weeks.[1] Complications associated with postdates pregnancy include oligohydramnios and intrauterine growth restriction related to placental insufficiency, increased birth trauma for both mother and infant related to macrosomia, and meconium aspiration syndrome.[1] Current guidelines recommend close observation with antenatal surveillance from 41 to 42 weeks' gestation, and delivery when the cervix is favourable.[2] Therefore, it is generally accepted that medical intervention to accomplish delivery is reasonable once 41 weeks' gestation is reached. Approximately 30% of inductions of labour are performed in women who are postdates.[3] However, induction for postdates pregnancy is associated with an increased risk of Caesarean section.[4] The only intervention that has been shown to decrease the incidence of postdates pregnancy is sweeping of the membranes.[5]

In traditional Eastern medicine, acupuncture has been used to expedite delivery.[6] There is, however, little information available on the effectiveness of acupuncture for the induction of labour. A recent systematic review identified only

one clinical trial comparing acupuncture for third trimester cervical ripening or labour induction with placebo.[6] This trial included 56 women, but data regarding post-randomization exclusions (20% of participants) were not included, and an intent-to-treat analysis could not be undertaken. Thus, the results could not be incorporated into the meta-analysis.[6,7]

Since that meta-analysis was completed, Harper et al. have published a randomized trial of 56 nulliparous women at between 39+4 and 41 weeks' gestation with a singleton pregnancy and an unfavourable cervix (Bishop's score of less than 7).[4] Patients were randomized to receive either usual care or usual care plus three outpatient acupuncture treatments at points reputed to cause onset of labour. They demonstrated a non-significant decrease in mean time to delivery of 21 hours in the acupuncture group. Additionally, 70% of women in the acupuncture group laboured spontaneously, compared with 50% in the control group (P = 0.12), and 39% of patients in the control group delivered by Caesarean section compared with 17% of the treatment group (P = 0.07). In patients who did not undergo induction, those randomized to acupuncture delivered a mean 50 hours earlier than women in the control group. Additionally, at any point after randomization, women who had received acupuncture were more likely to have delivered than women in the control group. Limitations of the study included small sample size and absence of blinding.

There has been a rapid increase in the use of complementary and alternative medicine over the last several decades.[6] Some obstetrical patients request information about the use of acupuncture as a method of labour induction. While anecdotal evidence exists on the usefulness of this technique,[8] there has been little research-based evidence to support this practice. Evidence from well-designed randomized control trials will enable women to make educated decisions about methods of labour induction.

The acupuncture site most commonly used for induction of labour is referred to as "spleen 6," or SP6, located just above the medial malleolus.[8] The risks of acupuncture are minimal: injury to underlying structures is rare, and infection is seldom seen when sterile needles are used. Occasionally a very small amount of bleeding is encountered from the skin site; this is easily controlled with minimal pressure on the site. Acupressure is a technique that is often used as an adjunct to acupuncture; it involves the application of pressure (with the thumbs or fingertips) to the same discrete points on the body that are stimulated in acupuncture.

The goal of this pilot study was to gain an appreciation for the magnitude of the effect of using acupuncture for the initiation of labour, thereby allowing a sample size calculation for a future trial. In addition, this pilot study was intended to provide data on feasibility from a cost and time perspective and to ensure that patients will accept and comply with the intervention and the randomization.

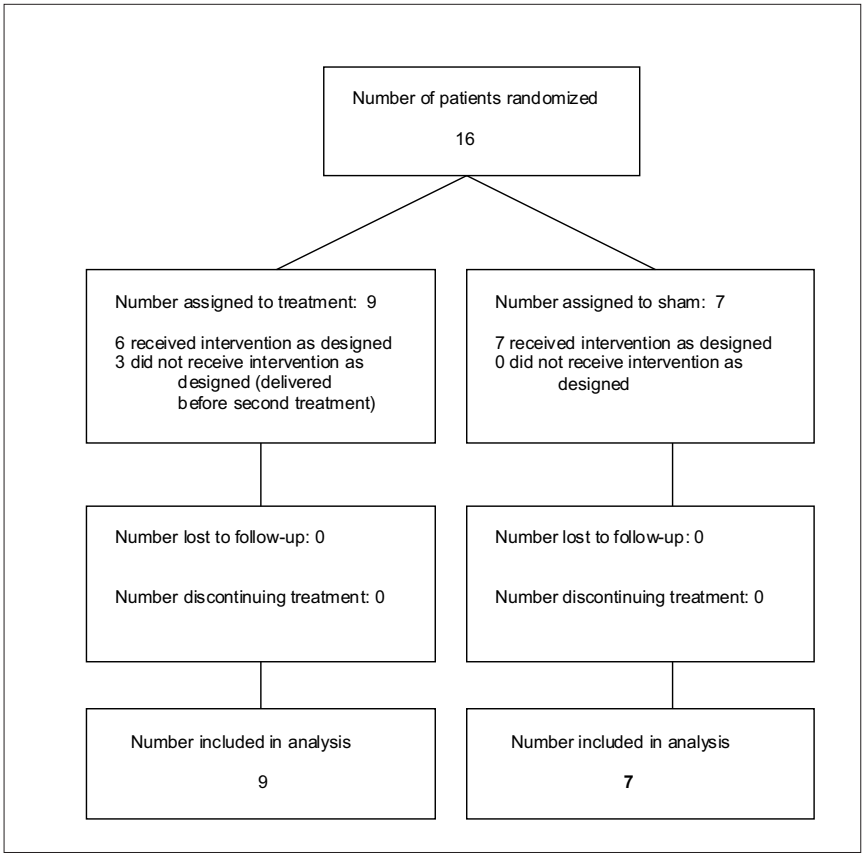
MATERIALS AND METHODS

The protocol for the acupuncture treatments was designed by a certified acupuncturist (R.D.) in consultation with the President of the Canadian Medical Acupuncture Society (S.A.). We compared the effectiveness of traditional acupuncture sites with nearby sham sites that are not known to be useful in initiating labour. Sixteen patients were randomized in a double-blind fashion to receive acupuncture at either the treatment or the control site. The primary outcome was time from first acupuncture treatment to delivery. Secondary outcomes included the need for standard methods for induction of labour, duration of active labour, the need for standard pain relief, and the incidence of non-reassuring fetal heart rate in labour. Approval was obtained from Queen's University Research Ethics Board.

A research nurse approached patients in the obstetrical clinics who were between 39+0 weeks and 40+3 weeks' gestation regarding participation in the study. Inclusion criteria included nulliparity, an uncomplicated singleton gestation, provision of informed consent, a Bishop's score of < 7 prior to randomization, and reassuring fetal status. All interested patients underwent a digital cervical examination by the research nurse prior to randomization in order to determine the Bishop's score. If the Bishop's score was < 7, patients underwent an ultrasound to complete a biophysical profile and an amniotic fluid index. Patients were randomized if they had a biophysical profile score of 8/8 and a normal amniotic fluid index. Two appointments for acupuncture sessions were arranged, the first within two to three days, and the second within one week, with an accredited physiotherapist acupuncturist; the acupuncturists were informed of the outcome of randomization for the patient but were blinded to obstetrical parameters (e.g., cervical assessment) and outcomes.

Four acupuncturists were involved in the trial, and they were instructed to follow the same protocol. Patients were given three options for positioning during the treatments: side-lying on the treatment bed with pillows under the abdomen and between the legs, sitting with legs extended and pillows under the knees, or seated prone in a supported massage chair with feet resting on the floor. The sites for the treatment and the control groups were selected by pairing adjacent sites known and not known to have an effect on the initiation of labour. The points are carefully landmarked by acupuncturists, and they can be standardized between patients despite individual differences.

Flow diagram of eligible patients



In the treatment group, the points used were always inserted in the same order: Sp6, then St43 and Bl60 with manual stimulation of Li4. Sites are named for the acupuncture meridian on which they fall, followed by a number that indicates a set point along the meridian: Sp represents spleen, St the stomach, Bl the bladder, Li the liver and Gb the gallbladder. The sites were Sp6: above the medial malleolus, Li4: at the highest point of adductor pollicis with the thumb adducted, St43: in the depression distal to the base of the second and third metatarsal bones, and Bl60: at the midpoint between the lateral malleolus and the Achilles tendon. If one of these sites was unavailable for use (e.g., the patient was unable to tolerate insertion at a given site) an alternate site (Gb36 located on the anterior border of the fibula) was used. All patients received four point acu-stimulation at 1–2 Hz for approximately 30 to 45 minutes. The electrical stimulation was provided by an electronic device specific to acupuncture. Leads were attached to the acupuncture needle, and electrical current amplitude was adjusted until the patient began to feel tingling or buzzing in waves or pulses, or until the acupuncturist observed slight movement of the soft tissues at the needle site. A 2 Hz electrical pulse at the specific acupuncture sites chosen is thought to be most effective for initiating cervical dilatation and uterine contractions[8] and was used in this study for both case and control groups.

In the control group, sham acupuncture sites adjacent to the acupuncture sites were selected. These were not located on actual acupuncture meridians and are not known to have an effect on initiation of labour. Sham acupuncture was done in an attempt to blind patients to the treatment that they received. The sites used were Sp6+, Li4+, St43+, Bl60+ and Gb36+. The locations were Sp6+: above the anterior ankle joint line slightly lateral to the border of the tibia, Li4+: in the centre of the anatomical snuff box (located between the 1st and 2nd metacarpal bones), St43+: at the joint line of the ankle superior to the web space of the 3rd and 4th metatarsal bones, Bl60+: inferior and posterior to the fibula head, and Gb36+: also inferior and posterior to the fibula head. Sham sites were stimulated in the same order as the true acupuncture sites. Acu-stimulation was applied as in the treatment group.

Both patient groups were instructed in the use of acupressure at the sites used for the initial acupuncture. They were encouraged to provide acupressure every few hours for

approximately three to five minutes, and they were told that the most important sites were Li4 and Sp6 (or the corresponding sham sites). Patients in both groups were offered medical induction as usual by their obstetrical care provider after 41 weeks. Patients, their obstetrical care providers, and trial researchers were blinded to the patients' study group; the acupuncturists were blinded to all obstetrical parameters. No side effects were identified that would allow patients to determine whether they were receiving treatment or sham acupuncture.

Randomization was performed using a table of random numbers. Patients were then assigned to the treatment or the control group in order of recruitment. In this small pilot study, stratification for gestational age and Bishop's score was not completed.

The primary outcome measure of time from randomization to delivery was analyzed using a 2-tailed *t* test. Secondary outcomes measures were analyzed using Fisher exact tests.

RESULTS

A total of 16 patients were randomized between February 2004 and October 2005, with nine having true acupuncture and seven having sham acupuncture. The randomization of patients and their outcomes are shown in the Figure. There was excellent compliance with the acupuncture protocol. All patients completed at least one acupuncture session, and the 13 undelivered patients all completed the second session. The three patients who delivered prior to the second acupuncture session were all in the treatment group, resulting in an apparent imbalance that was not due to compliance. Because of the small number of patients in this pilot study, we are unable to comment on the implications of this difference with respect to effectiveness of the treatment.

The groups were similar with respect to demographic information, gestational age and Bishop's score at the time of recruitment, and gestational age at first treatment (Table 1).

Table 1. Patient characteristics

	Acupuncture Group (n = 9)	Control Group (n = 7)
Age (years)	26.9	24.4
Nulliparity	100%	100%
Mean gestational age at randomization in days (standard deviation)	280 (2.57)	279 (1.97)
Mean gestational age at first treatment in days (standard deviation)	282 (1.94)	281 (1.60)
Mean Bishop's score at recruitment (standard deviation)	6 (2.9)	5 (2.5)

The mean interval from intervention to delivery in the acupuncture group was 146 hours (range 56–292 hours) while the mean interval in the control group was 208 hours (range 108–264 hours) (Table 2). Of the eight patients who laboured spontaneously, women who had acupuncture at sites reported to cause labour (n = 5) delivered 94 hours sooner than those who had sham acupuncture (n = 3). These values demonstrate a trend to decrease in length of labour, but they do not reach statistical significance.

Four of nine women in the treatment group (44%) required medical induction of labour for postdates, compared with four of seven in the control group (57%). Of the patients requiring further cervical ripening, patients having acupuncture at traditional sites had a mean improvement in Bishop's score of 6 points compared with no change in the control group. All patients presenting for induction of labour underwent cervical ripening with prostaglandin E_2, although two of the patients in the acupuncture group had a Bishop's score of > 7.

Despite a larger mean infant weight in the acupuncture group (a difference of 213 g), women in this group had shorter labours by a mean of 2 hours and 20 minutes.

There was no difference in rate of Caesarean section between the groups. Neonatal outcomes following treatment and sham acupuncture were compared by Apgar scores and frequency of admission to the neonatal intensive care unit (NICU). Three infants required admission to the NICU: two with known congenital heart disease (ventricular septal defect and transposition of the great arteries) and one large-for-gestational age infant with hypoglycemia. We concluded that these admissions were unrelated to the treatment groups; we therefore did not identify any concerns regarding safety of acupuncture for mothers or infants.

DISCUSSION

This pilot study supports previous scientifically unproven statements on the effectiveness of acupuncture for the induction of labour. Our findings suggesting a trend towards a decrease in mean interval from randomization to delivery agree with the findings of previous studies.[4,7] We believe that our study adds further information because of the use of sham acupuncture. This provides evidence that it is not simply the process of acupuncture that stimulates labour; stimulation must be at specific points. Further, by using sham procedures at sites very near those used in traditional acupuncture, we found that it is feasible to blind both patients and care providers to the nature of treatment.

This pilot project has provided a basis for future studies. Our study protocol was successful in patient randomization

Table 2. Results

	Acupuncture group (n = 9)	Control group (n = 7)
Primary Outcomes		
Mean time from 1st acupuncture to delivery in hours (standard deviation)	146 (91.6)	208 (61.0)
Mean length of labour–3cm to delivery in hours (standard deviation)	9.42 (4.0)	11.78 (4.1)
Secondary Maternal Outcomes		
Use of other induction methods	4/9 (44%)	4/7 (57%)
Oxytocin augmentation	6/9 (66%)	5/7 (71%)
Instrumental delivery	2/9 (22%)	2/7 (30%)
Caesarean section	2/9 (22%)	2/7 (30%)
Side effects	0/9 (0%)	0/7 (0%)
Narcotic analgesia	5/9 (56%)	4/7(57%)
Epidural analgesia	8/9 (88%)	7/7 (100%)
Secondary Neonatal Outcomes		
NICU admission	3/9 (33%)*	0/7 (0%)
Apgar < 7 at 5 minutes	1/9 (11%)†	0/7 (0%)
Infant birthweight in grams (standard deviation)	3837 (376)	3624 (467)

*Reasons for NICU admission: one infant had transposition of the great arteries, one had a ventricular septal defect, and one had hypoglycemia.

†This infant had a ventricular septal defect.

and acceptance. Our acupuncture colleagues did not identify any concerns with the sites used for active or sham treatment. It would be important in future studies to gather subjective information from patients about their experience during the protocol. Our patients reported that the experience of undergoing acupuncture provided them with a sense of control over the outcome of their pregnancy and that they enjoyed the interaction with the acupuncturists.

On the basis of this pilot project, a sample size estimate was performed. Practising obstetricians in the research centre were surveyed in order to determine the minimally clinically significant difference between the two groups. They felt that a difference between treatment groups of three days or more from treatment to delivery would be significant. To achieve a power of 80% with an alpha of 0.05, a sample size of 38 patients would be required to detect a difference of three days. For project personnel reasons we were unable to continue the study to recruit this number of patients.

There have been few reports on the use of acupuncture for induction of labour,[6] but some general principles of treatment should be considered. In this study, the number and frequency of treatments was set at two visits in one week for reasons of feasibility; it was difficult to have patients attend for treatment more often than this in the final week of their pregnancy. Most treatment courses using acupuncture for other problems consist of three to five visits before efficacy is determined.[8] More frequent visits may, therefore, have resulted in a higher success rate.

One of the advantages of acupuncture is the ability to individualize therapy. Typically, optimal sites for acupuncture are made after an evaluation and assessment of the individual, as in many other aspects of medicine. In order to perform comparisons in the setting of a clinical trial, all patients received acupuncture at the four predetermined sites. It is important to recognize that, in the clinical setting, treatment could be further tailored to optimize outcomes for patients.

CONCLUSION

On the basis of this pilot project, we were unable to prove or disprove the hypothesis that acupuncture is effective for the initiation of labour in pregnancies at term. However, this study proved that it is feasible to undertake a larger trial, because recruitment and blinding were successful. In this setting we found that acupuncture was safe and well tolerated by patients, as evidenced by the high return rate for the second session. A clinical trial of acupuncture in which the patient and the obstetrical care provider are blinded is feasible and could help to answer the larger question of effectiveness of acupuncture for the initiation of labour at term. Further research is needed in this intriguing area.

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