

Acupuncture for cervical ripening and induction of labor at term – a randomized controlled trial

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Akupunktur zur Zervixreifung und Weheninduktion ab dem Geburtstermin – eine randomisierte kontrollierte Studie

Zusammenfassung. Ziel: Ziel der Arbeit war zu untersuchen, ob mittels Akupunktur ab dem Geburtstermin die Zervixreifung beeinflusst, Wehen induziert und dadurch die Zahl der medikamentösen Einleitungen wegen Terminüberschreitung reduziert werden kann.

Methoden: Am Geburtstermin wurden Frauen prospektiv in eine Akupunkturgruppe (AG) oder in eine Kontrollgruppe (KG) randomisiert. Die Daten von 45 Frauen wurden ausgewertet (AG n = 25, KG n = 20). Einschlusskriterien waren ein gesicherter Geburtstermin, ein komplikationsloser Schwangerschaftsverlauf, eine Einlingschwangerschaft in Schädellage. Ausschlusskriterien waren Zervixöffnung von >3 cm, Wehentätigkeit, vorzeitiger Blasensprung, Zustand nach Sectio, mütterliche und kindliche Pathologien. Die Frauen wurden in 2-tägigen Abständen untersucht. Es wurde die Zervixlänge mittels Vaginalsonographie gemessen, ein Zervixabstrich für einen Fibronectintest entnommen und ein Tastbefund nach dem Bishop Score erhoben. In der AG wurden jeden 2. Tag beidseits die Punkte Hegu (Dickdarm 4) und Sanyinjiao (Milz 6) gestochen. Zehn Tage nach dem Geburtstermin wurde die Geburt mittels Prostaglandin Vaginaltableten eingeleitet.

Ergebnisse: Die Zervixlängen waren in der AG am 6. und 8. Tag nach dem errechneten Geburtstermin kürzer als in der KG (jeweils $P = 0,04$). In der AG war die Zeitspanne vom ersten positiven Fibronectintest bis zur Geburt 2,3 Tage, in der KG 4,2 Tage. ($P = 0,08$) Im Mittel lag die Zeitspanne vom Termin zur Geburt in der AG bei 5,0 Tagen in der KG bei 7,9 Tagen. ($P = 0,03$). In der AG wurden 20% (n = 5) der Frauen eingeleitet, in der KG 35% (n = 7) ($P = 0,3$). Gesamtgeburtsdauer, Eröffnungsphase und Austreibungsphase waren in beiden Gruppen nicht unterschiedlich. Bei 56% der akupunktierten Frauen (n = 14) und bei 65% der Kontrollpatienten (n = 13) wurde Oxytocin zur Unterstützung der Wehentätigkeit verwendet. ($P = 0,54$)

Zusammenfassung: Die Akupunktur der Punkte Di 4 und Mi 6 ab dem Geburtstermin unterstützt die Zervixreifung und kann das Intervall Termin-Geburt verkürzen.

Schlüsselwörter: Akupunktur, Zervixreifung, Weheninduktion.

Summary Objective: The aim of this study was to evaluate whether acupuncture at term can influence cervical ripening, induce labor and thus reduce the need for postdates induction.

Methods: On the estimated date of confinement (EDC) women were prospectively randomized to an acupuncture group (AG) or a control group (CG). Data of 45 women were evaluated (AG, n = 25; CG, n = 20). Inclusion criteria were as follows: confirmed EDC, uncomplicated course of pregnancy, singleton pregnancy in cephalic presentation. Exclusion criteria were as follows: cervical dilation > 3 cm, active labor, premature rupture of membranes, previous cesarean section, pathologies in mother or fetus. Women were examined at 2-day intervals. The cervical length was measured with vaginal ultrasonography, cervical mucus was obtained for a fetal Fibronectin test and the cervical status was assessed according to the Bishop score. In the AG, the points Hegu (Large Intestine 4) and Sanyinjiao (Spleen 6) were pierced on both sides every second day. If women were not delivered 10 days after EDC, labor was induced by administering vaginal prostaglandin tablets.

Results: The cervical length in the AG was shorter than that in the CG on day 6 and day 8 after EDC ($P = 0.04$ for both). In the AG the time period from the first positive Fibronectin test to delivery was 2.3 days, while that in the CG was 4.2 days ($P = 0.08$). The time period from EDC to delivery was on average 5.0 days in the AG and 7.9 days in the CG ($P = 0.03$). Labor was induced in 20% of women in the AG (n = 5) and in 35% in the CG (n = 7) ($P = 0.3$). Overall duration of labor, and first and second stage of labor were not different in the two groups. In 56% of women who underwent acupuncture (n = 14) and in 65% of controls (n = 13), Oxytocin was used to augment labor. ($P = 0.54$)

Conclusion: Acupuncture at points LI 4 and SP 6 supports cervical ripening at term and can shorten the time interval between the EDC and the actual time of delivery.

Key words: Acupuncture, cervical ripening, induction of labor, complementary medicine.

Introduction

Acupuncture is an important part of the Traditional Chinese Medicine (TCM). Over the past 2500 years, Chinese physicians of many generations helped develop and

improve the art of acupuncture treatment. TCM itself is about 4000 years old. The earliest gynecological documents go back to the Shang-Dynastie (1500-1000 BC). The first scripts deal with obstetric problems and the treatment of infertility [1].

Nowadays TCM still has an impressive power. Even in the 21st century many medical disorders caused by our lifestyle can be diagnosed and treated by TCM, though we are thousands of years away from the ancient Chinese people, where TCM had its origin.

Starting in the 1970s Acupuncture treatment has become more and more popular in Austria [2, 3] Recently there has been an increasing demand for acupuncture in pregnancy. Because there are no severe side effects, acupuncture is an ideal treatment alternative for pregnancy disorders. Several obstetrical indications, such as correction of breech presentation, induction of labor, pain relief during childbirth, hyperemesis and lactation disorders have been effectively treated with acupuncture (accepted by WHO 1995) [4–7].

However, there is still a lack of controlled clinical trials for acupuncture treatment. Acupuncture is an individual treatment. Different persons with the same problem do not necessarily need the same point combination. Studies that use a fixed acupuncture point combination can provide clear results, but the individual person could have had a more effective treatment according to his/her constitution. In clinical trials the actual effect of acupuncture may be less. Keeping this in mind, there are some interesting clinical trials of acupuncture treatment in obstetrics

Recent studies showed that acupuncture on a weekly basis from 36 weeks onwards can shorten the first stage of labor by 2 hours, and that women require smaller quantities of oxytocin [8, 9]. Acupuncture also showed a significant influence on cervical ripening [10]. During labor, acupuncture can be used to intensify and coordinate labor and thus reduce pain [11, 12]. Dunn et al. used TENS (transcutaneous electrical nerve stimulation) on acupuncture points Sanyinjiao (Spleen 6) and Taichong (Liver 3) in 20 post-date pregnancies and achieved a significant increase in the frequency of contractions in the acupuncture group compared to the placebo group [13].

In pregnancy and during labor point combinations should be used according to the woman's constitution. However there are some frequently used points with proven effects. The acupuncture points Hegu (Large Intestine 4) and Sanyinjiao (Spleen 6) are frequently used in obstetrics and gynecology. Hegu is considered to have a strong energetic and oxytocic effect. Sanyinjiao is believed to improve circulation in the lower abdomen [14].

The aim of the present study was to evaluate whether the fixed point combination Hegu and Sanyinjiao at term influences cervical ripening, induces labor and thus reduces the need for postdates induction.

Patients, materials and methods

During a routine control on their estimated date of confinement (EDC), pregnant women were informed about the possibility to join the study. After written informed consent had been obtained, patients fulfilling the inclusion and exclusion criteria were randomized through random selection (by com-

puter-generated pseudo-random numbers) into one of the two study groups. For this study approval from our institutional review board was obtained.

Inclusion criteria were an EDC confirmed by ultrasound fetometry before the 20th week of gestation, an uncomplicated course of pregnancy and a singleton pregnancy in cephalic presentation. Exclusion criteria were a cervical dilatation of more than 3 cm, active labor, confirmed premature rupture of membranes, previous cesarean section, maternal pathologies (preeclampsia, gestational diabetes) or fetal growth retardation or malformation.

Women were examined on EDC and at 2-day intervals thereafter. Fetal heart rate was monitored, the cervical length was measured by vaginal ultrasound, cervical mucus was obtained for a fetal Fibronectin test with a cotton swab and the cervical status was assessed by the Bishop score [15, 16]. After the examination the points Hegu (Large Intestine 4) and Sanyinjiao (Spleen 6) were pierced on both sides in patients from the acupuncture group (AC). A neutral needle technique was used and a De Qi feeling was produced. The needles were left in position for 20 minutes. If women were not delivered 10 days after EDC, labor was induced by administering vaginal prostaglandin tablets.

The following parameters were obtained: the change of cervical length over the course of time, the time period from the first positive Fibronectin test to delivery, the time period from EDC to the actual time of delivery, the number of post-date inductions, the duration of the first stage of labor (defined as the period from active labor with 3cm cervical dilatation to full dilatation), the second stage of labor (defined as the period from full cervical dilation to delivery) and the overall duration of labor. Furthermore, the proportion of patients who received oxytocin to augment labor and the mode of delivery were compared.

Data were analyzed by Chi square test, Fisher's exact test, t-Test and Wilcoxon's test. A *P*-value of less than 0.05 was considered to indicate statistical significance.

Results

Initially 56 pregnant women were included in the study. In the acupuncture group (AG), labor was induced in one woman because of an abnormal fetal heart rate monitoring and in two women because of premature rupture of membranes. In the control group, two women asked for elective induction of labor before completing the study protocol. In three further patients labor was induced, because of premature rupture of membranes and in an additional three, because of an abnormal fetal heart rate pattern (Fig. 1).

The data of 25 women from the AG and of 20 women from the control group (CG) were evaluated. There were no differences in terms of age, parity, Bishop score and cervical length on the first day of examination between the two groups (Table 1).

In the AG, the cervical length shortened at a faster rate. On day 6 and 8 after EDC, a significant difference was noticed ($P = 0.04$ in both, Wilcoxon's test) (Fig. 2). However, no difference was found in the Bishop scores. The time period from the first positive fibronectin test until delivery was 2.3 days ($n = 18$) in the acupuncture group and 4.2 days ($n = 13$) in the control group ($P = 0.08$, t-Test). In 7 acupuncture patients and 7 control patients, the fetal Fibronectin test was never found to be positive.

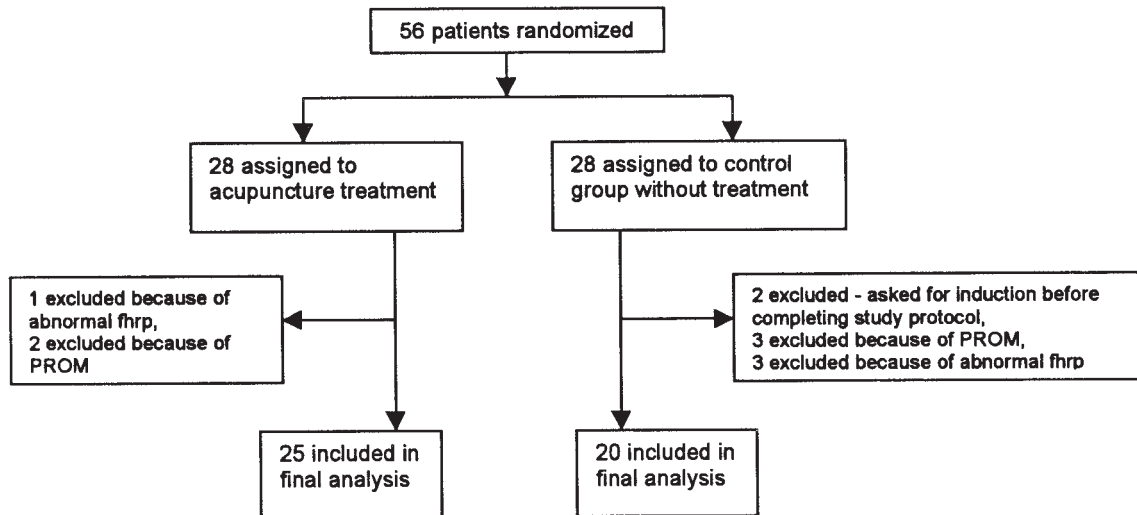


Fig. 1. Trial profile, PROM (premature rupture of membranes), fhrp (fetal heart rate pattern)

None of the women in the AG went into labor immediately after acupuncture or up to one hour after acupuncture. However, four patients were delivered within 24 hours after the first acupuncture treatment. In contrast, no patient in the control group was delivered within 24 hours after the first exam. On average, the time period from the EDC to actual delivery was 5.0 days in the AG and 7.9 days in the CG ($P = 0.03$, t-Test). The proportion of women who were delivered during the period from their EDC until 10 days thereafter is shown in Fig. 3. Women who underwent acupuncture were delivered earlier than the control group ($P = 0.07$, Wilcoxon’s test).

Labor was induced 10 days after the EDC in 20% of women in the acupuncture group ($n = 5$), and in 35% of the control group ($n = 7$) ($P = 0.25$, Chi square test). First stage of labor, second stage of labor and the overall duration of labor were not different in the two groups. (Table 2). 56% ($n = 14$) of women who underwent acupuncture and 65% ($n = 13$) of control patients were given oxytocin to augment labor). ($P = 0.54$, Chi square test).

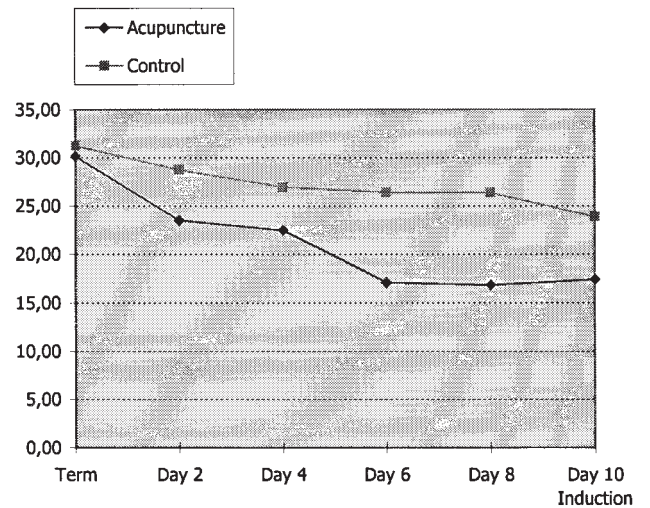


Fig. 2. Change of cervical length (mm)

Table 1. Demographic data

	Acupuncture group	Control group	P-value
Age mean value (± SD)	29,8 (± 4,2)	28,0 (± 6,0)	0,26*
Parity			
Primiparous	n = 23	n = 17	0,35+
Multiparous	n = 2	n = 3	
Bishop-Score / first examination n mean value (± SD)	4,5 (± 2,0)	4,4 (± 2,0)	1,0*
Cervical length / First examination mean value (± SD)	30,0 (± 7,1)	31,2 (± 7,1)	0,48*

*t-Test, +Fisher’s Exact test

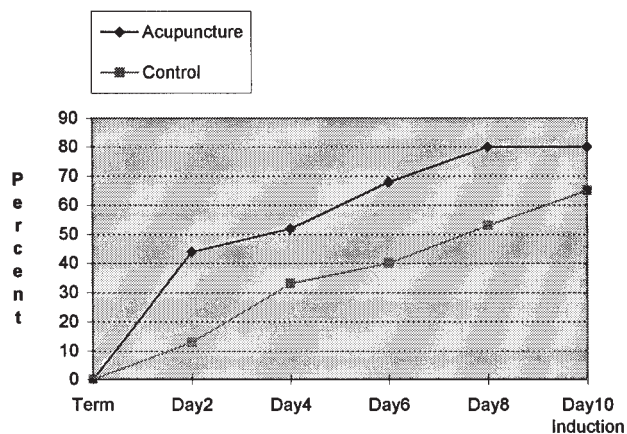


Fig. 3. Percentage of deliveries over time

Table 2. Time of delivery

	Acupuncture mean value (\pm SD)	Control mean value (\pm SD)	<i>P</i> -value*
Total duration of labor	528 (\pm 210)	558 (\pm 194)	0,58
First stage	474 (\pm 211)	516 (\pm 180)	0,41
Second stage	54 (\pm 31)	42 (\pm 26)	0,43

Figures indicate the number of minutes. * t-Test

No differences were seen with respect to the mode of delivery. In each group, three women were delivered by vacuum extraction and two women underwent cesarean section. In the AG, the indication for all operative deliveries were severe abnormal fetal heart rate patterns. In the CG, two cesarean sections and one vacuum delivery were performed because of severe abnormal fetal heart rate patterns, two vacuum deliveries were carried out, because of prolonged second stage of labor.

Discussion

Administration of prostaglandins or oxytocin are effective and established methods of labor induction after the estimated date of confinement (EDC). However, sometimes these agents cause excessive pain, hyperstimulation and abnormal fetal heart rate patterns. Numerous pregnant women are skeptical about drug induction of labor. As acupuncture has been proven effective in shortening the first stage of labor [8, 9], in a pilot study we tried to evaluate the role of acupuncture in supporting the process of cervical ripening and subsequent induction of labor.

To evaluate the efficacy of acupuncture treatment in a randomized controlled study, it is necessary to have a clearly defined treatment program. So we chose Hegu and Sanyinjiao for all women in the treatment group. However, we believe that individual therapy according to each woman's constitution could improve acupuncture's effectiveness. There was no control intervention in the control group. A genuine acupuncture placebo is as unthinkable as placebo-surgery [17]. Other control interventions, such

as pseudo-laser acupuncture, are not adequate, because women would notice that they are being randomized to the control group. Non-specific effects contributing to the effectiveness of acupuncture treatment cannot be excluded in our study. Therefore, we carefully formulated our conclusions.

We were able to show that acupuncture on the points Hegu (Large Intestine 4) and Sanyinjiao (Spleen 6) shortens the interval from EDC to the actual delivery and leads to faster shortening of the cervix. The hypothesis of cervical ripening being induced by acupuncture, which was expressed in a previous study, is supported by the present findings. Prostaglandins play an important role in the process of cervical ripening. In a recent study, a significant association was shown between increased serum prostaglandin E2 levels and the effect of acupuncture [18]. It is possible that the combination of Hegu and Sanyinjiao also influences cervical ripening through this hormonal mechanism.

Immediate induction of labor could not be achieved. Nevertheless, we were able to accelerate cervical ripening and thus indirectly induce labor by acupuncture. There were fewer labor inductions with prostaglandin in the acupuncture group, but this did not achieve significance in our small number of cases. First and second stage of labor as well as mode of delivery were not different in the two groups. In order to actually induce labor by acupuncture the acupuncture sessions may need to be performed more frequently. Electro-acupuncture or other point combinations may need to be applied.

Based on our results we conclude that the acupuncture points Hegu (Large Intestine 4) and Sanyinjiao (Spleen 6) may be helpful in supporting cervical ripening at term and in shortening the time interval between the EDC and the actual time of delivery.

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