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Acupuncture before planned admission for induction of labor (ACUPUNT study): A randomized controlled trial.

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CONDENSATION

Tweetable Statement: Acupuncture may be useful to increase the rate of spontaneous labor onset before the planned date for induction of labor.

Short title:

AJOG at a glance:

Acupuncture before scheduled induction of labor.

A. Why was this study conducted?

The increase in the number of labor inductions is a worldwide phenomenon. The application of strategies that result in spontaneous onset of labor could potentially reduce scheduled induction of labor rates and increase positive labor experiences. There is increasing interest in acupuncture as a method to achieve spontaneous onset of labor.

B. What are the key findings?

The proportion of spontaneous onset of labor and premature rupture of membranes before the scheduled induction of labor date increased in the group of women following an acupuncture program.

C. What does this study add to what is already known?

. This study describes the routine clinical practice, the context of which is defined by the baseline characteristics of the study population. We assessed maternal and neonatal outcomes not well evaluated in previous studies on acupuncture during pregnancy.

ABSTRACT

BACKGROUND: The increase in the use of induction of labor is a worldwide phenomenon in the current management of labor and delivery in Western societies, with approximately one out of every four pregnancies undergoing this procedure This has led women to seek various methods for stimulation of the onset of labor. Some data suggest that the use of acupuncture for favoring spontaneous labor onset could reduce the number of inductions of labor procedures. However, good quality evidence in this respect is not yet available.

OBJECTIVE: The aim of this study was to evaluate the effectiveness of acupuncture using a filiform needle to induce spontaneous onset of labor in women with a scheduled induction of labor date and assess the safety and satisfaction of women undergoing acupuncture.

STUDY DESIGN: We conducted a multicenter, randomized, controlled, parallel-arm, unmasked trial in three hospitals in Spain. Eligible participants were

women older than 18 years with a singleton pregnancy and a cephalic presentation, scheduled for induction of labor following center-specific protocols. Participants were randomly allocated to one of two groups: the intervention group, which underwent acupuncture sessions for a maximum of four days prior to the scheduled induction of labor, or the control group, which received no specific pre-labor intervention. The primary study outcome was the proportion of women admitted because of spontaneous onset of labor or premature rupture of membranes before or the day of the scheduled induction of labor.

RESULTS:

Between November 2017 and June 2023, 212 women were recruited and included in the analysis (106 in the acupuncture group and 106 in the control group). There were no significant differences between the two groups in the baseline demographic characteristics. Regarding the primary outcome, 65.1% (69/106) of women in the acupuncture group and 39.6% (42/106) in the control group were admitted for spontaneous onset of labor or premature rupture of membranes ($p < 0.001$). Overall, women in the intervention group were admitted 1.25 days before (SD 1.4) their scheduled induction of labor date compared to 0.67 days (SD 1.15) for those in the control group (p=0.001). The median time from recruitment to hospitalization was 4.48 days for the acupuncture group and 5.33 days for the control group (HR 0.52, 95% CI 0.35 – 0.77, p=0.001). There were no significant differences between the two groups regarding the time from admission to delivery or the cesarean delivery rate. Nor were there differences in

the rates of maternal or neonatal outcomes, and no maternal or fetal deaths occurred in either group.

CONCLUSION: Acupuncture with filiform needles, administered 4 days prior to scheduled induction of labor increased admission for spontaneous onset of labor and premature rupture of membranes before the induction of labor date.

Keywords: acupuncture, acupressure, induction of labor, prolonged pregnancy, post-term pregnancy, spontaneous onset of labor, maternal satisfaction.

MAIN TEXT

INTRODUCTION

The increase in the use of induction of labor (IOL) is a worldwide phenomenon in the current management of labor and delivery in Western societies, with approximately one out of four pregnancies undergoing this procedure for a variety of reasons[1].

Despite IOL having recently been demonstrated as a safe option with equal or better results than expectant management in terms of perinatal results,[2] some studies have reported that spontaneous onset of labor (SOL) minimizes interventions and medicalization of the physiological process and provides a more positive birth experience.[3] On the other hand, several studies have described some bad experiences of women after undergoing IOL.[4] These studies reported an increase in the pain experienced,[4] longer IOL processes, a greater need for pain relief, longer hospital stay, lack of information, autonomy, and support, as well as active participation of the mother in the decision-making process.[5-6] This has led women to seek other less medicalized methods for stimulation of the onset of labor.

Several studies have suggested that the use of acupuncture for favoring SOL could reduce the number of planned inductions. The studies available demonstrate that acupuncture is a relatively safe treatment with minor or limited adverse events, such as pain, inflammation, hematoma, or bleeding at the insertion site. In this context, acupuncture has gained increasingly more interest in obstetrics and gynecology, although the results are controversial.[4]

The mechanism underlying IOL by acupuncture involves stimulation of the uterus by hormonal changes or the nervous system. Stimulation of acupuncture points is known to increase the discharge of thalamic nuclei and the hypothalamic anterior pituitary system[7]. Acupuncture may increase uterine contractility by the release of central oxytocin or parasympathetic stimulation of the uterus without influencing locally active factors such as interleukin-8 and prostaglandin F2.[7]

This study aimed to evaluate the effectiveness of acupuncture using a filiform needle to induce SOL in women with a scheduled IOL date and assess the safety and satisfaction of women undergoing acupuncture.

MATERIALS AND METHODS:

Study design.

We conducted a multicenter, randomized, controlled, parallel-arm, unmasked study across three hospitals: the Maternal-Fetal departments of the *Hospital Clínic de Barcelona* (HCB), *Hospital de la Santa Creu i Sant Pau of Barcelona* (HSCSP), and the *Hospital Universitario Hospiten Sur* on Tenerife Island. The Spanish Agency of Medicines and Medical Products and the Ethics Committees of the participating hospitals approved the research protocol in July 2017. The study was registered in the EU Clinical Trials Register (EudraCT 2017-000145-40) and adhered to the CONSORT guidelines[8]. All study participants provided written informed consent.

Screening and recruitment

Eligible participants were women older than 18 years with a singleton pregnancy and a live fetus in cephalic presentation, scheduled for IOL following

center-specific protocols, with low- or middle-risk pregnancies (as defined by national guidelines), (Supplementary material A1) reaching week 41, or at 40 weeks in the case of advanced maternal age (≥40 years) or a pregestational body mass index (BMI) ≥30 kg/m^2. The decision to induce was made by the attending physician or midwife, who were not part of the research team and IOL was scheduled by an administrative staff member not involved in the study.

The exclusion criteria included women in the first stage of labor (cervix fully effaced, dilation of 3 cm or more, and regular uterine contractions) or premature rupture of membrane (PROM), women planning to deliver outside the participating hospitals, or those with language barriers impairing understanding of the study.

Upon scheduling the induction, a midwife involved in the study explained the study to the woman and obtained informed consent. Randomization was performed using a computer-generated random number list (created by the University of Barcelona) in a 1:1 ratio, concealed in sealed and opaque envelopes. Women were included in the study only after providing signed informed consent.

Intervention

Participants were randomly allocated to the intervention group, which received acupuncture treatments for up to four days prior to the scheduled IOL date, or the control group, which did not receive any specific pre-labor interventions. To maintain consistency, neither group was offered amniotic membrane stripping (Hamilton maneuver) to preclude any actions potentially initiating labor.

The intervention group underwent acupuncture treatment consisting in one session daily for 4 days before the scheduled IOL date [9]. The acupuncture protocol was based on classical acupuncture and bibliography available up to 2017 (Supplementary material 2) and the same acupuncture points were treated by a certified acupuncturist midwives in all the participants. Each acupuncture session included cardiotocography (CTG) before and after treatment to monitor fetal well-being and uterine activity.

If SOL or PROM occurred before the scheduled IOL date, the patient was admitted as per routine, discontinuing further acupuncture treatments.

If SOL or PROM did not initiate by the scheduled IOL date, all participants were admitted for IOL as planned. Induction methods included mechanical (double-ballon catheter- Cook ballon (CRB®) - OR single-ballon with Foley catheter) and pharmacological (endocervical prostaglandins -PGE2-Dinoprostona-Propess® 10 mgrs.- or oral prostaglandins - PGE1-Misoprostol-Cytotec®, Misofar® 50mcg/4h) approaches for cervical ripening, with direct oxytocin use in cases with favorable obstetric conditions (Bishop score ≥6)[10].

Study outcomes and data collection.

The primary outcome of our study was the number of women admitted for SOL (defined as cervix fully effaced, dilation of 3 cm or more, and regular uterine contractions) or PROM before or the day of the scheduled IOL. Secondary outcomes were the Bishop score at admission, the time from admission to delivery, the reasons for admission (including PROM, SOL, IOL, among others), the need and type of cervical ripening methods employed, the use of oxytocin,

the need for an epidural, and the mode of delivery. We also recorded the number of doses of acupuncture administered in the intervention group.

CTG was defined as normal, intermediary or abnormal[11]. Maternal satisfaction scores were assessed at hospital discharge using 3 questions from the validated SAT-Q questionnaire[12] on satisfaction with the treatment received, the overall effectiveness of the treatment, and obtention of expected benefits (Supplementary material 3). To minimize recall bias, all questionnaires were administered before discharge. Maternal morbidity was assessed by several criteria: the occurrence of postpartum hemorrhage, quantified as a blood loss >500cc for vaginal delivery and 1000cc for cesarean births, manual removal of the placenta, maternal fever (temperature >100.4F), shoulder dystocia, uterine rupture, third- or fourth-degree perineal tear, and admission to the intensive care unit (ICU). Neonatal outcomes of interest included the 5-minute Apgar score, umbilical pH, and neonatal intensive care unit (NICU) hospitalization. A composite outcome was also evaluated for both, maternal and neonatal results.

Sample size and statistical analysis.

Considering previously collected local data, the rate of SOL among pregnant women with the above-mentioned characteristics scheduled for IOL is 30% (unpublished data), with previous studies showing that acupuncture may increase this rate to 50%. Assuming a power of 85%, we estimated that a total of 106 pregnant women should be included in each group to detect this difference with a two-sided type I error of 5%. Data were entered in a database designed for the study by an investigator not involved in intervention administration. An independent statistician conducted the analysis using PASW statistics 25.0 (IBM,

Armonk, NY). Continuous variables were presented as means and standard deviations (SD) and were analyzed using the Student *t* or the Mann-Whitney U-test, as appropriate. Categorical variables are shown as total counts and percentages and compared using the chi-square or Fisher's exact test, as appropriate.

We performed a survival analysis to compare the incidence of admission before IOL by the study groups. An event was defined as a woman admitted before the scheduled induction date, from enrollment to admission. These data were plotted using the Kaplan-Meier method and analyzed with the log-rank test. Furthermore, we compared admission time to delivery, applying censoring at the time of cesarean delivery since it reduces the duration of labor. We also quantified the days gained due to the SOL compared to the planned induction date.

All statistical tests were 2-tailed, with statistical significance set at a p-value <0.05.

RESULTS

Between November 2017 and June 2023, 212 women were eligible to participate and provided signed consent. Consequently, 212 women were included in the analysis: 106 in the acupuncture group and 106 in the control group (Figure 1).

Table 1 shows the baseline demographic characteristics of the participants. There were no significant differences in these variables between the two groups. Women allocated to the acupuncture group underwent a mean of 2.92 (SD 1.25) sessions.

Table 2 presents the main study findings. Regarding the primary outcome, 65.1% (69/106) of women in the acupuncture group were admitted for SOL or PROM, compared to 39.6% (42/106) in the control group (p<0.001). Assessment of CTGs before and after the acupuncture sessions showed that 1.9% (2/106) of women had a CTG classified as intermediary after the acupuncture session (p=1.00) leading to admission before the scheduled IOL (described in table 2 as ‘’others’’ reason for admission).

Overall, women in the intervention group were admitted 1.25 days earlier (SD 1.4) than their scheduled IOL date compared to 0.67 (SD 1.15) days for those in the control group (p=0.002).

The median time from recruitment to hospitalization was 4.48 versus 5.33 days for the acupuncture and control group, respectively (hazard ratio [HR] 0.52, 95% confidence interval [CI] 0.35–0.77, p=0.001). Figure 2 shows the survival curves for each group. There were no significant differences between groups in the time from admission to delivery, with a median time of 16.5 hours (95%CI 12.67–19.23) and 21.9 hours (95%CI 17.48–25.97) for the intervention versus the control group, respectively (p=0.58).

Among the women requiring IOL, there were no differences in the type of cervical ripening method used, or in the proportion of deliveries requiring oxytocin. Cesarean delivery rates were similar in the two groups, even after stratification by the mode of labor onset. Furthermore, there were no differences in maternal or neonatal outcome rates, and there were no maternal or fetal deaths in either group.

In the acupuncture group, 104/106 (98.1%) participants responded to the satisfaction surveys compared to 66/106 (62.3%) in the control group. The questionnaires to assess participant satisfaction revealed that women undergoing acupuncture treatment were more satisfied than those in the control group. However, on stratification by group or admission time, this improvement was primarily observed among participants receiving acupuncture who spontaneously initiated labor (Figure 3).

COMMENTS

The main finding of this study is that the number of women admitted for SOL or PROM before the scheduled IOL date was higher in the acupuncture compared to the control group. Indeed, the level of satisfaction of women in the acupuncture group was higher regardless of whether admission was or was not on the scheduled date.

There was no difference in the cesarean delivery rate or the time between admission to delivery between the two groups and there were no significant maternal safety concerns or increase in adverse neonatal outcomes in the acupuncture group.

Results of the study in the context of other observations.

A few studies have suggested that acupuncture may be of potential benefit for inducing labor and it was deemed safe in the 2017 Cochrane systematic review[1,13]. Although a meta-analysis showed a statistically significant increase in the rate of SOL in favor of acupuncture (relative risk: 1.12; 95%CI: 1.03, 1.23; I2= 25%)[1], the specific timing and the optimal number of treatments remain

unclear[13]. However, when compared to sham acupuncture, this increase was not evident[7,14-17] The low number of participants included in some studies, the heterogeneity of the acupoints chosen, the use or not of placebo, the use of manual or electroacupuncture stimulation[18,19], the variation in the gestational week at recruitment and the indication for IOL, make comparisons among studies difficult[9]. We attempted to perform a study with an adequate sample size within the context of routine clinic practice.

Overall, few studies have assessed the use of acupuncture before IOL[9,19-20], with most evaluating acupuncture versus prostaglandins[18], or versus usual care near the estimated delivery date (EDD)[15,21], while in our study acupuncture was performed during the 4 days before the scheduled IOL date. This is more representative of the real clinical situation of a large number of women with a low- or medium-risk pregnancy with no urgent need for induction who, after a shared decision process involving information of management options and risks, choose expectant management.

Also, in some studies, the criteria for IOL were not clear. The reason for IOL and gestational age at the beginning of treatment could potentially produce different results. In our study, the reasons for IOL included prolonged pregnancy, BMI ≥30 kg/m2, and maternal age ≥40 years without additional pregnancy risks. The trend towards earlier inductions is shifting, especially in older age groups and higher BMI categories[2]. Therefore, our approach closely aligns with current obstetric practices, emphasizing the significance of individualized care and shared, evidence-based decision-making in IOL management.

In our study, the maternal age was 34.72 (SD 4.66) years, and the BMI was 28.31 kg/m^2 (SD 4,17). These figures follow the current trend to a higher maternal age and higher BMI in Western societies. Previous studies reported a mean maternal age ranging from 23.4 to 33.1 years[1] and did not include the BMI[15,18,19-23] or the BMI was low (23.8 to 28.7 kg/m^2) [1,9,24]. Whether factors such as maternal age and BMI have an impact on acupuncture and the initiation of labor was outside the scope of this study and have yet to be determined.

In relation to admission according to the scheduled IOL date, the acupuncture group had a shorter time from recruitment to admission, with an increased rate of SOL, and thus delivery, compared to the control group Likewise, acupuncture was associated with a decrease in the time from enrollment to delivery in the studies by Ralb *et al.*[20]. and Harper *et al* [21]., although in the latter study the differences did not reach statistical significance. This could be due to differences in the study design. The enrollment date and IOL date (10 days post-EDD) in the study by Rabl *et al.*[20] was standardized, providing a homogeneous time from recruitment to IOL admission. On the contrary, in the study by Harper *et al* [21]. the decision and date for IOL was made by healthcare providers. Additionally, the sample size was small in both studies[21].

When reviewing the findings of other groups, there is a lack of agreement on the main outcomes to evaluate. Some studies chose a successful vaginal delivery rate within 24h[18], the length of delivery or the use of oxytocin[22.] As in the study by Neri *et al*.[9], we chose SOL, as we considered this to be a relevant outcome

that women in whom IOL is indicated and have a scheduled date may seek. In the study of Neri *et al* [9]. (n=402), women undergoing acupuncture presented a higher rate of SOL (75% vs. 52.8%; p<0.01) and the use of oxytocin and prostaglandins was lower. However, the study was not randomized, and women were allocated to receive acupuncture, or standard care based on their preference, representing an important selection bias.

Finally, cesarean rates, perinatal outcomes and the length between admission and delivery did not differ between groups, similar to several studies using other regimens.[15,19-21,23] The fact that a higher number of spontaneous labors is not translated into an improvement in these outcomes might be explained by acupuncture facilitating spontaneous onset of labor in those women who would have had a good response to pharmacological or mechanical methods, in any case. In the scenario of equivalent perinatal and maternal outcomes, women's choices and preferences must be considered in the decision-making process of labor and delivery, and any intervention that could potentially help fulfil her expectations related to the delivery process (such as acupuncture in the present study) should be considered relevant. In fact, our study shows that women receiving acupuncture reported greater satisfaction, albeit with no significant differences, despite not presenting SOL.

Research implications

Taking into account that the gestational age for IOL is decreasing following the publication of the ARRIVE trial [2,25,26], the results of our study should be reproduced in this new clinical context. In addition, since acupuncture appears

to be safe, future studies should determine whether acupuncture may also be useful and safe in high-risk pregnancies.

Strengths and Limitations.

The main strength of this study is its prospective and randomized nature. Indeed, the fact that it is a multicenter study including 3 different hospitals, strengthens the external validity of the results in the present clinical practice. Another strength of this study is that the characteristics of the women included (i.e., maternal age, parity and BMI) show a population profile very similar to that found in current clinical practice compared to previously published literature on the topic. Finally, in contrast to other studies on the safety of acupuncture, we evaluated potential adverse maternal outcomes, such as postpartum hemorrhage, manual placenta removal, maternal fever, 3rd or 4th degree perineal tear, uterine rupture, ICU admission, and death as well as fetal outcomes of interest, including abnormal umbilical artery pH, NICU admission and death. However, we must acknowledge some limitations. Blinding was not possible due to the nature of the intervention. This limitation was assumed considering that studies comparing real acupuncture with sham acupuncture reported that blinding may not be effective due to the neural and dermal effects that occur each time a needle is inserted into the skin, independently of the depth or the site[19].

Randomization was also not stratified by centers or blocks. However, inclusion was consecutive and therefore, the risk of bias might be minimized. Another limitation is that the Bishop score was not evaluated at inclusion and therefore, potential differences in the obstetrical conditions at randomization cannot be

excluded. However, since institutional practice favors minimizing cervical examinations, this reproduces the current clinical practice. Also, despite the presence of a standard protocol of induction management, individual differences in management may be present as this is a very woman-centered and shared clinical decision-making process. Randomization may balance these differences between groups. Finally, 37.7% of the women in the control group did not answer the satisfaction questionnaire and indeed, our questionnaire arise limited information. Therefore, experience of the process might have only partially been evaluated in this group.

Conclusions

The use of acupuncture using filiform needles prior to the planned IOL date, increased the percentage of SOL or admission for PROM compared to the control group.

Montserrat Zamora-Brito: Investigation, Conceptualization, Methodology, Validation, Resources, Formal analysis, Visualization, Writing – original draft, Writing – review & editing, Data curation. **Federico Migliorelli:** Formal analysis, Methodology, Writing – review & editing. **Raquel Pérez-Guervós:** Validation, Investigation, Resources. **Rosa Solans-Oliva:** Validation, Investigation, Resources. **Angela Arranz-Betegón:** Project administration, Supervision, Validation. **Montse Palacio:** Conceptualization, Methodology, Supervision, Visualization, Writing – review & editing.

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Table 1.
Socio-demographic and obstetric baseline characteristics

Characteristic	Acupuncture group N:106	Control group N:106	*P* value
Maternal Age (years) mean (SD)	34.95 (4.11)	34.95 (5.15)	.43[a]
Country of Origin, n (%)			.88[b]
Spanish	71 (67.0%)	72 (67.9%)	
Foreign	35 (33%)	34 (32.1%)	
GA at enrollment (weeks) mean (SD)	40.55 (0.48)	40.48 (0.58)	.46[a]
Parity, n (%)			.64[b]
Primiparous	75 (70.8%)	78 (73.6%)	
Multiparous	31 (29.2%)	28 (26.4%)	
Prepregancy BMI (kg/m^2), mean (SD)	23.59(4.02)	23.48 (4.50)	.85[a]
BMI At recruitment (kg/m^2), mean (SD)	28.26 (4.03)	28.39 (4.32)	.81[a]
Weight gain >15 kg, n (%)	43 (40.6%)	46 (43.4%)	.64[b]
Obstetric Risk*			.67[b]
Low	57 (53.8%)	60 (56.6%)	
Medium	49 (46.2%)	46 (43.4%)	
ART, n (%)	8 (7.5%)	9 (8.5%)	.80[b]
Assigned Hospital, n (%)			.91[b]
HCB	41 (38.7%)	43 (40.6 %)	
HSCSP	53 (50%)	50 (47.2%)	
Hospiten SUR	12 (11.3%)	13 (12.3%)	
Reason for Induction, n (%)			.51[b]
Late-term pregnancy	91 (85.8%)	83 (78.3%)	
BMI ≥ 30 kg/m^2	4 (3.8%)	8 (7.5%)	
Maternal age ≥ 40 years	10 (9.4%)	13 (12.3.%)	
Others	1 (0.9%)	2 (1.9%)	

EP values indicate the statistical testing result from 2-sample t tests for normally distributed continuous variables or Pearson chi-square or Fisher exact tests for categorical variables.
[a] Student *t* test, [b] Chi-square test.
*Supplementary material 1
BMI, Body mass index; *GA*, Gestational age; *ART,* Assisted reproduction technique; *HCB*, Hospital Clinic Barcelona; *HSCSP,* Hospital de la Santa Creu i Sant Pau.

Table 2.

Characteristics at hospital admission and delivery outcomes

	Acupuncture group N=106	**Control group N=106**	***P* value***
Admission for SOL or PROM	69 (65.1%)	42 (39.6%)	<.001[b]
Reason for admission, n (%)			.001[b]
PROM	18 (17.0%)	12 (11.3%)	
SOL	51 (48.1%)	30 (28.3%)	
Induction	35 (33.0%)	62 (58.5%)	
*Others***	2 (1.9%)	2 (1.9%)	
Admission according to scheduled date, n (%)			.001[b]
Before	68 (64.2%)	43 (40.6%)	
Planned	38 (35.8%)	63 (59.4%)	
Bishop at admission, median [IQR]	8 [4-10]	4 [2-7,5]	<.001[c]
Induction of labor needed***	45 (42.5%)	70 (66.0%)	.001[b]
Cervical ripening method used, n (%)			0.35[b]
Misoprostol	18/45 (40,0%)	22/70 (31,4%)	
Dinoprostone	12/45 (26.7%)	22/70 (31.4%)	
Balloon	11/45 (24.4%)	21/70 (30.0%)	
Balloon + Dinoprostone	4/45 (8.2%)	2/70 (2.9%)	
Oxytocin	0 (0%)	3/70 (4.3%)	
Use of oxytocin, n (%)	64 (60.4%)	75 (70.8%)	.148[b]
Peridural, n (%)	81 (76.4%)	87 (82.1%)	.39[b]
Use of Beta-mimetics	7 (6.6%)	12 (11.3%)	.22[b]
Cesarean deliveries, n (%)	24 (22.6%)	22 (20.8%)	.73[b]
In women admitted before the scheduled date	9/68 (13.2%)	7/43 (16.3%)	.65 [b]
In women admitted at the planned scheduled date	15/38 (39.5%)	15/63 (23.8%)	.095 [b]
GA at delivery (weeks), mean (SD)	41.09 (0.48)	41.03 (0.57)	.61[a]
Composite Maternal outcome	9 (8.4%)	11 (10.9%)	.49[b]
Postpartum hemorrhage, n (%)	3 (2.8%)	4 (3.8%)	1.0[b]
Manual removal of the placenta, n (%)	1 (0.9%)	4 (3.8%)	.36[b]
Maternal fever, n (%)	2 (1.9%)	2 (1.9%)	1.0[b]
3rd or 4th degree perineal tear, n (%)	3 (2.8%)	1 (0.9%)	.62[b]
Uterine rupture, n (%)	0 (0%)	0 (0%)	
ICU admission, n (%)	0 (0%)	0 (0%)	
C**omposite** Neonatal outcomes	3 (2.8%)	8 (7.5%)	0.12[b]
5-min APGAR < 7, n(%)	0 (0%)	2 (1.9%)	.49[b]
*pH <7, n (%)****	0 (0%)	2 (2.6%)	.63[b]
Shoulder dystocia, n(%)	2 (1.9%)	0 (0%)	.49[b]
NICU admission, n (%)	2 (1.9%)	8 (7.5%)	.052[b]
Neonatal weight (g),mean (SD)	3483,46 (426.88)	3459,20 (388.73)	.66[a]

Continuous variables are presented as mean ± standard deviation and categorical variables are presented as number (percentage) or as the median and interquartile range (IQR) in the case of non-normal data distribution.

*P values indicate the statistical testing result from 2-sample t tests for normally distributed continuous variables or Pearson chi-square or Fisher exact tests for categorical variables or Mann-Whitney *U* test for quantitative variables for non-normal data distribution. [a]Student *t* test, [b] Chi-square test, [c] Mann-whitney *U* test .

**Admission for others reason such a maternal desire (n=1 in control group) , fetal monitoring with alterations in normal fetal heart rate pattern (Two in acupuncture group -one participant started labor after admission and the other one required induction-, one in Control group).

*** Includes inductions required due to medical reasons, or due to PROM /others without SOL
****Sample collection consisted of n=73 participants in the Acupuncture group and n=76 participants in the Control group.

BMI, Body mass index; *GA*, gestational; age; *NICU*, Neonatal intensive care unit; *PROM*, Prelabor rupture of membranes **.**

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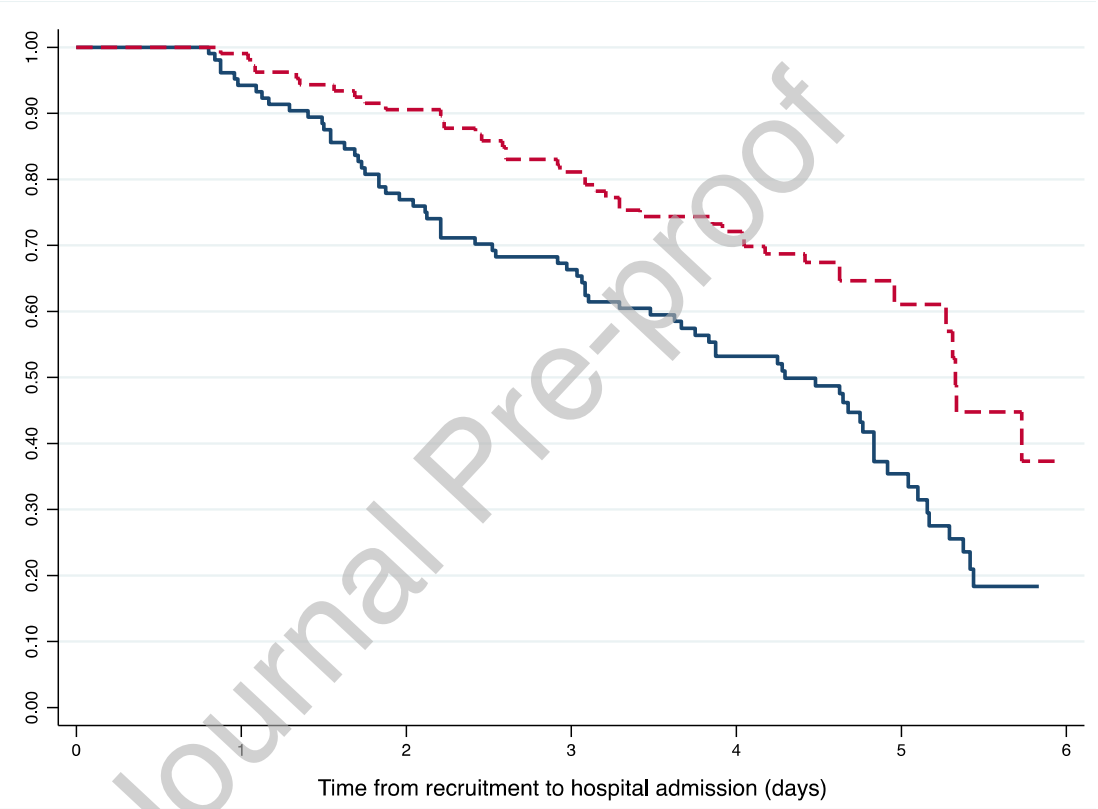

Figure 2. Kaplan-Meier curves illustrating the probability of spontaneous labor onset or prelabor rupture of membranes (PROM), categorized by group allocation. The solid blue line represents the acupuncture group, while the dashed red line depicts the control group. Time from recruitment to hospital admission is plotted in days on the x-axis.

Figure 3.Satisfaction

			Allocation group		*p-value*
			Acupuncture	Control	
			104/106, 98.1% 12.98 (2.82)	*66/106, 62.3%* 10.23 (4.18)	<0.001
Admission	Before planned	*79/111, 71.2%* 13.47 (2.92)	*67/68, 98.5%* 14.01 (2.06)	*12/43, 27.9%* 10.42 (4.80)	<0.001
	When planned	*91/101, 90.1%* 10.56 (3.71)	*37/38, 97.4%* 11.11 (3.07)	*54/63, 85.7%* 10.19 (4.08)	0.2462
p-value		<0.001	<0.001	0.8638	

Figure 1.Consort Flow Diagram