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Acupuncture to Initiate Labor (Acumoms 2): A Randomized, Sham-controlled Clinical Trial

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Abstract

Objective—To evaluate the efficacy of acupuncture for labor stimulation.

Methods—Nulliparous women at 38 weeks or greater were randomized to Traditional Chinese Medicine (TCM) acupuncture, sham acupuncture, or usual care only groups. Acupuncture points LI4, SP6, BL32 and BL54 were needled bilaterally. The primary outcome was time from enrollment to delivery. Secondary outcomes included rates of spontaneous labor and cesarean delivery. Medical records were abstracted for maternal demographic, medical, and delivery outcome data. ANOVA, Student's t-test, Chi-square, and Kaplan-Meier statistics were used to compare groups.

Results—89 women were enrolled and randomized. Maternal age, gestational age, prior acupuncture experience, tobacco, alcohol and drug use, gravida, and history of gynecological surgery were similar among the groups. There were no statistically significant differences among groups for time from enrollment to delivery (p=0.20), rates of spontaneous labor (p=0.66), or rates of cesarean delivery (p=0.37). Rates of maternal and neonatal outcomes were not significantly different.

Conclusion—TCM acupuncture was not effective in initiating spontaneous labor or reducing the rate of cesarean delivery compared to sham acupuncture or usual medical care.

Keywords

Acupuncture; obstetric labor; labor onset; induced labor; parity; randomized controlled trial

INTRODUCTION

Pregnancies that extend beyond the 40thweek of gestation are known to be at greater risk for maternal and neonatal morbidity and mortality.[1] Neonatal post-term complications include death (with twice the risk compared to term deliveries); chronic intrauterine growth

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restriction due to uteroplacental insufficiency, which occurs in approximately 20% of neonates; meconium aspiration; and intrauterine infection.[2–4] Post-date pregnancy increases risk of shoulder dystocia, severe perineal injury, and cesarean delivery.[5] Clinical guidelines recommend close fetal monitoring and awaiting cervical favorability from weeks 41 – 42 with labor induction planned based on these factors.[3] However, induction of labor is associated with higher rates of cesarean delivery[6], which confers increased risk for complications such as endometritis, post-partum hemorrhage, and thromboembolic disease.[7] Additionally, the cost of delivery after induction of labor is higher than for spontaneous onset of labor.[8] Safer and more effective approaches to increasing the rate of spontaneous onset of labor would likely result in cost savings as well as lower rates of complications associated with cesarean delivery.

There is limited evidence in the published literature that suggests that acupuncture may be safe and useful for several indications during pregnancy. Acupuncture has long been used in China and other Asian countries for pregnancy-related conditions, including breech presentation[9], labor pains[10], and hyperemesis gravidarum[11]. The Shanghai College of Traditional Medicine recommends acupuncture for labor induction[12], and it is used routinely for labor induction in some societies[13]. Additionally, there do not appear to be significant maternal or fetal risks associated with acupuncture.[14–16]

The results of a meta-analysis and two recently published randomized controlled trials of acupuncture for labor induction suggest that a short series of acupuncture treatments at or near term may initiate labor or prevent post-term pregnancy. In a Cochrane review, Smith and Crowther concluded that fewer women receiving acupuncture required use of induction methods compared to standard care (RR 1.45, 95% CI 1.08, 1.95; three trials).[17] Rabl et al. [18] demonstrated that women who receive acupuncture near term show a decrease in time to delivery of approximately three days. Our team of investigators previously conducted a randomized clinical trial that suggests that acupuncture is associated with a lower risk of cesarean delivery (17% vs 39%, p=0.07) and improved spontaneous labor rates (70% vs 50%, p=0.12) compared to usual care only.[19] However, neither of these recent trials included a placebo or sham acupuncture comparison. Lack of a sham acupuncture comparison precludes differentiating between specific effects associated with acupuncture needling from non-specific effects associated with the administration of acupuncture treatments. A sham acupuncture comparison is also necessary to mask both patients and their care providers to treatment allocation. Masking care providers is especially important when assessing outcomes that are largely dependent on clinical decision-making, such as whether or when to induce labor or to deliver via cesarean section.

In light of the previously published studies that suggest acupuncture is a safe and potentially effective intervention for inducing labor, and given the lack of placebo-controlled clinical trials of acupuncture for this clinical indication, we conducted a randomized, 3-arm, partially blinded, sham acupuncture-controlled trial designed to evaluate whether outpatient acupuncture treatments can shorten the time from acupuncture to delivery, reduce rates of labor induction, or decrease rates of cesarean delivery in term, nulliparous women.

METHODS

This study was conducted at the University of North Carolina at Chapel Hill (UNC) Family Medicine Center from February 2005 to March 2007. The study protocol was approved by the biomedical Institutional Review Board at the UNC School of Medicine, and all subjects were provided informed written consent to participate on their date of enrollment.

Women were eligible for enrollment if they were nulliparous, between 38 and 41 weeks of gestation, able to communicate in English, and at least 18 years old. Exclusion criteria included uncertain dating as described by the American College of Obstetricians and Gynecologists (ACOG) induction criteria[20], transportation difficulties, breech presentation, or a previous inability to tolerate acupuncture.

Eligible subjects were identified through prenatal chart review and through web-based advertising in the local community. Interested and eligible subjects were scheduled for an initial visit, at which time consent was obtained, subjects were randomized, and the first acupuncture treatment was performed for subjects allocated to either of the acupuncture arms. Appointments for four additional acupuncture sessions were scheduled at times convenient for the subject during this visit.

Subjects were randomly allocated to one of three study arms: Traditional Chinese Medicine (TCM) acupuncture, sham acupuncture, or no acupuncture. Study arm assignment was determined by using a list of random numbers generated using Stata (v8, Statacorp, College Station, TX) with equal proportions of blocks of two and four. A consecutively numbered, sealed, manila envelope containing the study arm assignment was opened by the principal investigator for each participant after all entry criteria were confirmed, and after written informed consent was obtained. Subjects were allocated to receive either TCM acupuncture along with routine prenatal care (TCM acupuncture group), sham acupuncture along with routine prenatal care (sham acupuncture group) or routine prenatal care alone (usual care group). Participants were told they would be receiving either TCM or sham acupuncture or no treatment. Prenatal care providers and subjects were masked to the treatment arm assignment if they were receiving acupuncture (TCM or sham acupuncture) but not if they were in the usual care group.

Acupuncture treatments were administered at the UNC Family Medicine Center (FMC) for up to a maximum of five treatments over a two-week period. Acupuncture was performed by one of two licensed acupuncturists (ACR and WC). Acupuncture treatments consisted of the insertion of sterile, single-use, disposable Seirin J-type acupuncture needles (0.16 × 30 mm for hand and leg points, 0.24 × 40 mm for back points). True acupuncture points included LI4, SP6, BL32, and BL54 which are located on the hands, legs, and lower back (see Figure), and needles were advanced or manipulated until ‘deqi’ was elicited. Sham acupuncture points included non-acupuncture points in the hands, legs, and lower back, and needle insertion at these points was shallow (see Figure). Needles were inserted at all points bilaterally and retained for 30 minutes for both groups. This treatment regimen was devised based on a clinical reference manual commonly used in Chinese acupuncture training and treatment.[21] No individualized treatments were performed. All subjects received routine prenatal care as provided by their regular care providers.

The primary outcome measure was time from enrollment (first acupuncture treatment) to time of delivery. Patients receiving either TCM or sham acupuncture were treated within 30 minutes of enrollment. Time of delivery was established by chart review whenever possible or by phone call to the study participant. A sample size of 30 subjects per group was estimated *a priori* to provide 82% power to detect a 3-day difference between groups with a two-tailed alpha of 0.05. Statistical analyses were performed using STATA software (v9.2, Statacorp, College Station, TX).

Secondary outcome measures included rates of inpatient induction for postterm pregnancy, spontaneous rupture of membranes (SROM), c-section, assisted delivery, chorioamnitis, endometritis, post-partum hemorrhage or uterine atony, maternal length of stay (LOS), intrapartum fetal distress, and neonatal outcomes (e.g., Apgar scores, post -delivery oxygen

requirement). All charts were reviewed by an investigator who was blinded to treatment arm assignment throughout the data abstraction process.

We used ANOVA to compare means of continuous variables, Student's t-test for pairs, and chi-squared tests to compare categorical outcomes except when the expected number of values per cell was less than five, in which case Fisher's exact test was used. Survival analysis was performed using the Kaplan–Meier test for equality of survivors; spontaneous labor was used to define failure; survival time was defined as the time from enrollment to delivery. The log-rank test was used to compare Kaplan-Meier curves. Results were considered statistically significant for *p*-values less than or equal to 0.05. Analyses were performed according to the intent-to-treat principle.

RESULTS

A total of 89 nulliparous women were randomized: 30 to the true acupuncture group, 29 to the sham acupuncture group, and 30 to the control group. One subject in the sham group refused to receive any treatments, and one woman in the routine care group received acupuncture outside of the study, but both participants were analyzed with respect to their assigned group. Complete delivery outcome data were available for all participants and there were no dropouts.

The mean maternal age was 29.6 years (SD 4.8 years) and the mean gestational age at enrollment was 38 5/7 weeks (SD 4.3 days). Eighty percent of participants were naïve to acupuncture treatments. Tobacco use (defined as any use during pregnancy) was reported by two participants, and there was no self-reported drug use. Twelve participants reported alcohol use during pregnancy (defined as any alcohol use). The mean number of acupuncture sessions completed was 3.4 (+/− 1.5) and 3.3 (+/− 1.6) for the TCM and sham groups respectively (p=0.36). Group frequencies are reported in Table 1.

Time to delivery from enrollment tended to be shorter for the sham acupuncture group (9.3 days; 95% CI: 7.1, 11.5) compared to the usual care group (11.9 days; 95% CI: 9.7, 14.2) and the TCM acupuncture group (12.2 days; 95% CI: 10.0, 14.4). However, these differences were not statistically significant (p=0.20, Log-rank test) [Figure 2].

Spontaneous labor occurred in 72% of participants with equally divided proportions among the three groups (Table 2). There were no significant differences among the three groups for maternal peripartum complications such as hemorrhage, uterine atony, chorioamnitis, and endometritis or maternal length of stay (Table 2). Similarly, there were no significant differences found among the groups for neonatal outcomes such as 1-and 5 -minute Apgar scores, post-partum neonatal oxygen requirement, neonatal intensive care unit admission, or neonatal length of stay. The occurrence of intra-partum fetal distress, defined as non-reassuring fetal status documented as variable or late decelerations, was similar among groups (Table 2).

DISCUSSION

In this randomized controlled trial, we sought to evaluate the efficacy of acupuncture for outpatient stimulation of labor compared to both a sham acupuncture intervention and usual care only. We did not find any significant differences among the three study arms for the primary outcome measure. These findings are in contrast to those of our first study (Acumoms 1) where the rate of spontaneous labor improved from 50% in the control group to 70% in the TCM acupuncture group (p=0.12) and the cesarean section delivery rate decreased from 39% in the control group to 17% in the TCM acupuncture group (p=0.07); and those reported by Rabl et al[18], which demonstrated a decrease in time to delivery from

estimated date of confinement (EDC) of 2.9 days (p=0.03). Both of these studies demonstrated that acupuncture was associated with a decrease in time to delivery for term pregnancies compared to no acupuncture.

Several potentially important differences between the current study and the two prior studies may help to explain the results of this trial. Three important changes were introduced to the treatment protocol for this study, compared to Acumoms 1. First, while electrical stimulation was used in Acumoms 1, we decided to remove it from the treatment protocol in Acumoms 2. This was done to improve the masking between the TCM and sham acupuncture groups since it is difficult to fully simulate electrical stimulation without running a noticeable current. Electrical stimulation is commonly used in acupuncture treatments for labor induction and excluding it may account for the lack of efficacy seen in Acumoms 2. Second, point selection for Acumoms 2 differed slightly from Acumoms 1 based on acupuncture texts for initiation of labor[21] (BL54 was substituted for BL31). This change was made in an attempt to improve the efficacy of the protocol. Third, in Acumoms 2 prenatal care providers were masked to study arm allocation for the subjects allocated to either TCM or sham acupuncture, while in Acumoms 1 prenatal care providers were aware of subject allocation. Knowledge of group allocation in Acumoms 1 may have influenced a care provider's decision to prolong the pregnancy, especially if their patient was in the treatment group.

Another difference between the two studies was the gestational age of women included in the studies. In Acumoms 1, the mean gestational age was 40 1/7 weeks. However, in Acumoms 2, the mean gestational age was earlier at 38 5/7 weeks. It is possible that acupuncture administered too early during pregnancy is not effective in initiating labor.

Finally, Acumoms 1 may have included more higher-risk pregnancies. Recruitment for Acumoms 1 was facilitated through the Maternal Fetal Medicine Division of the Department of Obstetrics and Gynecology and, therefore, there was more access to higher-risk patients who were encouraged to participate. Recruitment for Acumoms 2 was centered primarily at the Family Medicine department, and most likely included few, if any, high-risk pregnancies. This observation is supported by the fact that in Acumoms 1, 27% of all subjects delivered via cesarean section, whereas this was the case for only 12% of subjects in Acumoms 2. Our results may indicate that acupuncture does not further decrease the relatively low risk of cesarean delivery in low-risk pregnancies, but may do so in higher risk pregnancies. However, it is premature to draw strong conclusions concerning acupuncture in low-risk pregnancies since Acumoms 2 was not powered to detect a difference in cesarean rates for the low numbers of women who underwent cesarean section in this study.

Several other factors may limit our findings. Among risk factors for post-term pregnancy, newborn gender[22] and maternal weight [23] were not recorded. Additionally, important risk factors for failure of labor induction such as cervical ripeness or Bishop's score were not recorded. Though randomization should have accounted for these factors, they do remain a source of unmeasured potential confounding.

CONCLUSION

In this study, TCM acupuncture was not effective in stimulating spontaneous labor or reducing the rate of cesarean delivery compared to sham acupuncture or usual medical care. There were several modifications to the protocol in Acumoms 2 which may be responsible for the decrease in measured efficacy of the intervention. These variables are may be important targets of any future research as the success of acupuncture for labor stimulation

may rely on acupuncture points used, presence or absence of electrical stimulation, and timing of intervention.

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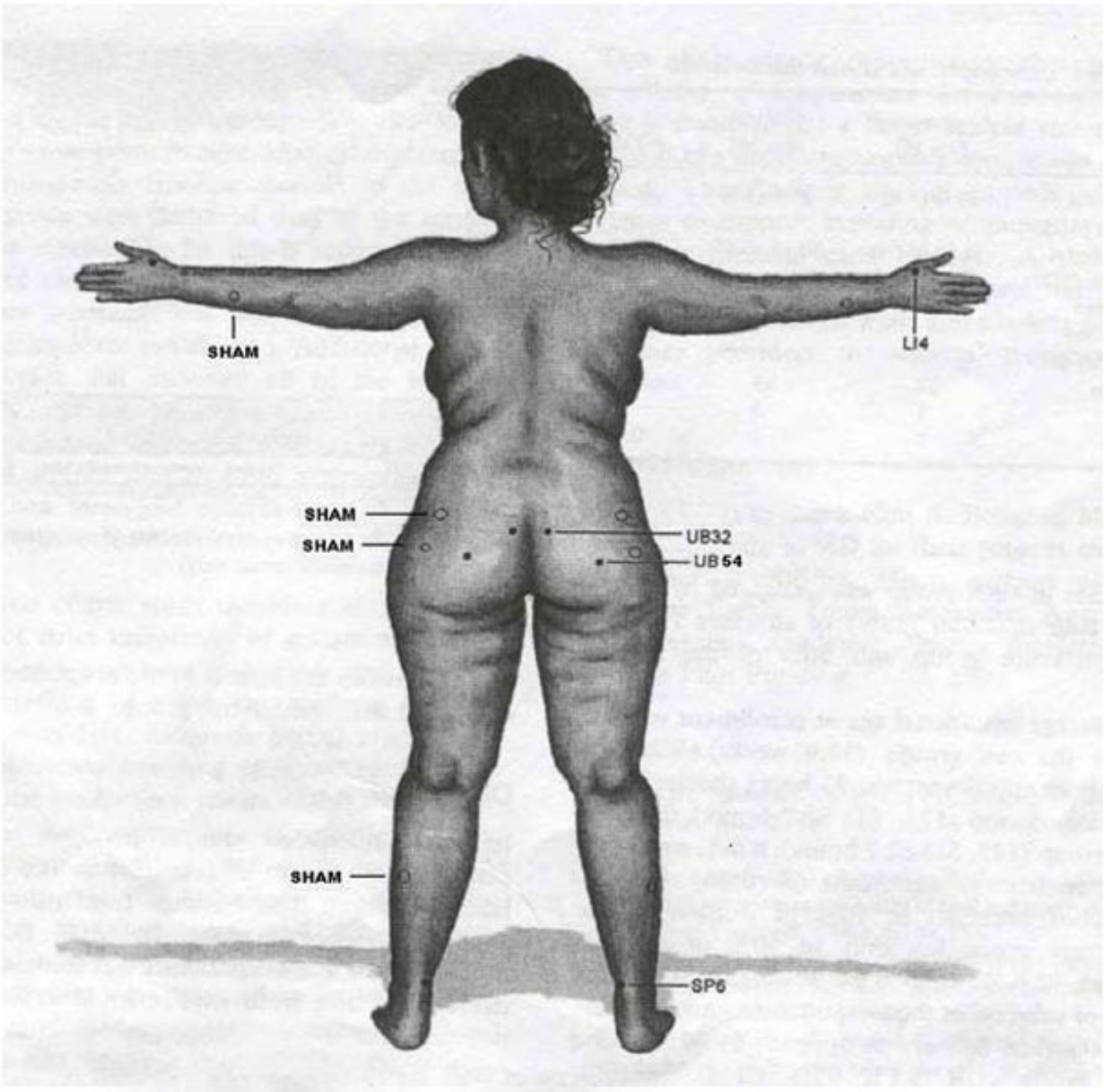

Figure 1.
Acupuncture points for TCM and sham treatments.
LI=large intestine, SP=spleen, UB=bladder

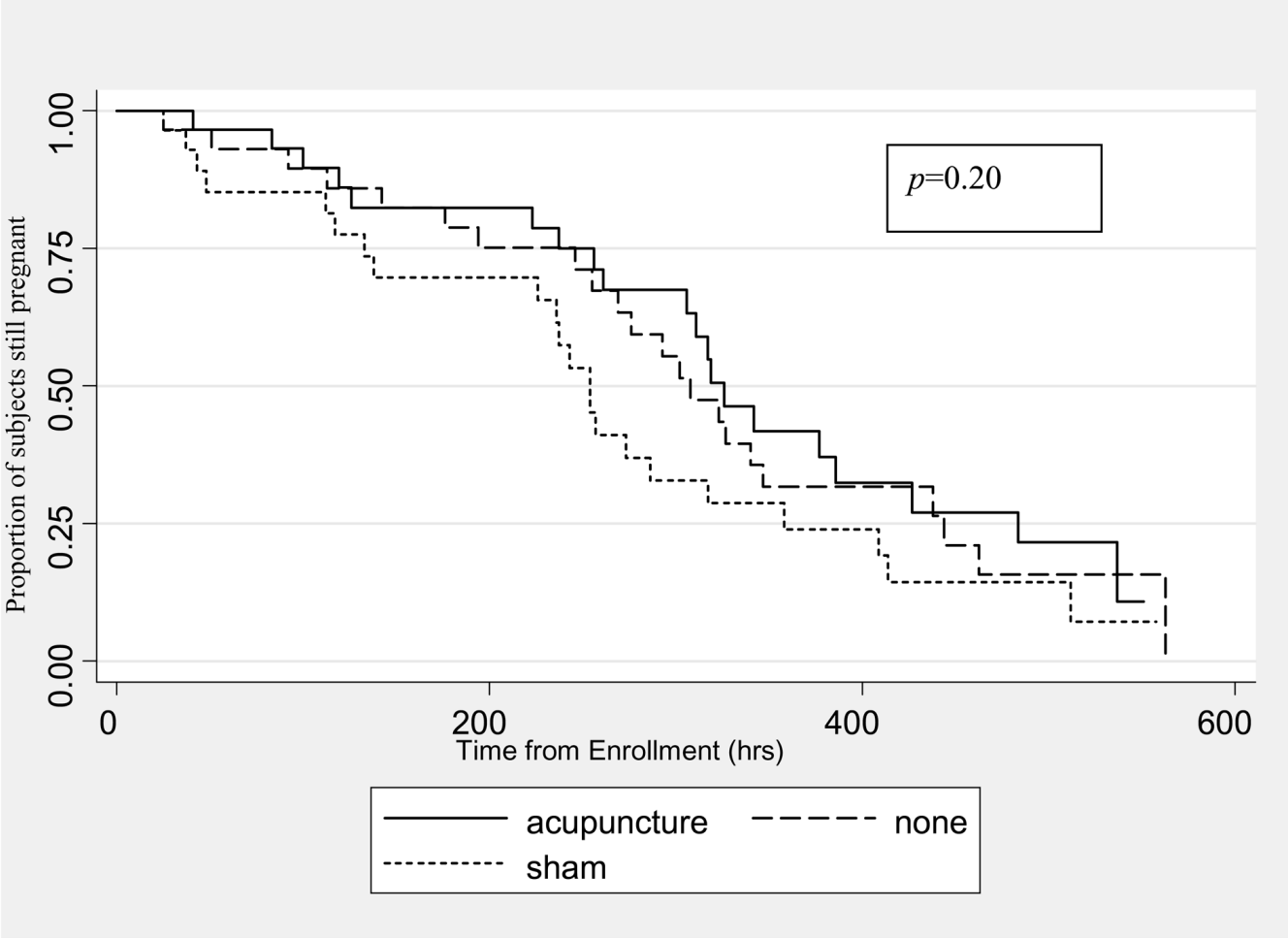

Figure 2.
Kaplan-Meier survival estimates by treatment group.

Table 1

Baseline characteristics

	TCM Acupuncture (n=30)	Sham Acupuncture (n=29)	Usual Care Only (n=30)	*p*-value
Mean maternal age, years (SD)	30.4 (3.9)	29.6 (4.8)	28.9 (5.7)	0.51
Mean gestational age, weeks (SD)	38 5/7 (0.6)	38 5/7 (0.7)	38 5/7 (0.6)	0.87
Acupuncture naïve (%)	26 (87)	22 (76)	23 (77)	0.33
Tobacco/Alcohol/Drug use[a]	0 / 2 / 0	0 / 3 / 0	2 / 7 / 0	0.09 / 0.11 / 1
Gravida 2	1	1	3	0.61
History of gynecological surgery[b]	2	1	2	0.97

[a] Defined as any amount of smoking; alcohol intake, and drug use during pregnancy

[b] LEEP or cone biopsy in acupuncture groups, exploratory laparotomy or ovarian cyst removal in usual care group

Table 2

Maternal and Fetal Secondary Outcomes

	TCM Acupuncture (n=30)	Sham Acupuncture (n=29)	Usual Care Only (n=30)	*p*-value
Maternal Outcomes				
Spontaneous labor (%)	20 (67)	20 (69)	22 (73)	0.66
SROM (%)	14 (47)	13 (45)	13 (43)	0.99
Chorioamnitis (%)	7 (23)	6 (21)	2 (7)	0.20
Endometritis	0	0	0	1.0
Cesarean delivery (%)	6 (20)	2 (7)	3 (10)	0.37
Post-partum complications[a] (%)	3 (10)	2 (7)	1 (3)	0.70
Mean LOS, days (SD)	2.7 (0.9)	2.4 (0.7)	2.4 (0.9)	0.30
Fetal Outcomes				
Intrapartum fetal distress (%)[b]	7 (23)	10 (34)	6 (20)	0.46
Mean apgar score, 1 min (SD)	7.7 (1.8)	7.9 (1.6)	8.2 (1.4)	0.44
Mean apgar score, 5 min (SD)	8.8 (0.8)	8.9 (0.4)	9.0 (0.2)	0.36
NICU admission	0	0	1	0.66
Mean LOS, days (SD)	2.1 (0.5)	2.0 (0.6)	1.9 (0.5)	0.36

[a] post-partum hemorrhage and uterine atony

[b] variable or late decelerations leading to non-reassuring fetal status

SROM – spontaneous rupture of membranes; LOS – length of stay; NICU – neonatal intensive care unit; SD – standard deviation