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# Effects of Acupuncture During Labor and Delivery in a U.S. Hospital Setting: A Case—Control Pilot Study

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# **Abstract**

*Objective:* The objective of this study was to assess clinical effects and logistical feasibility of acupuncture given during labor and delivery in a U.S. hospital setting.

**Design:** A case—control pilot study was conducted with 45 parturients receiving acupuncture during labor and delivery alongside standard care. Primary outcome endpoints were incidence of cesarean section, amount of parenteral opioids used, use of epidural anesthesia, and duration of labor. Secondary endpoints included patient satisfaction and nursing staff acceptance as assessed by postpartum questionnaire, maximum flow rate of oxytocin, incidence of instrumental delivery, Apgar score, and incidence of adverse event.

**Results:** Forty-five (45) patients receiving acupuncture were compared to 127 historical controls matched for maternal age, gestational age, parity, and use of oxytocin (augmentation and induction were matched separately). Acupuncture patients underwent significantly fewer cesarean sections (7% versus 20%, p = 0.004). No significant differences were noted in other clinical endpoints. Seventy-eight percent (78%) of nurses reported a subjective perception of improvement in patients' comfort with acupuncture, while 83% reported that the acupuncturists' presence never interfered with their work. Eighty-seven percent (87%) of patients reported that acupuncture had helped them.

*Conclusions:* Acupuncture during labor and delivery is well tolerated by patients and medical staff. It should be further evaluated for its promise in potentially reducing the incidence of cesarean section.

# Introduction

**S** TIMULATION OF ACUPUNCTURE POINTS traditionally used in labor causes distinct hormonal and histological effects on the uterus in human and animal models.<sup>1-4</sup> A growing body of clinical evidence suggests that acupuncture during labor and delivery is associated with effects such as decreased use of epidural analgesia,<sup>5</sup> decreased use of parenteral pain medications,<sup>6,7</sup> decreased use of oxytocin,<sup>8-10</sup> decreased duration of labor,<sup>8,11</sup> and increased patient perception of relaxation.<sup>5,7</sup> Specific effects reported differ between studies and also—markedly—between countries of origin (Table 1). No trials of acupuncture during labor and delivery have been published in the United States, leaving an open question of what effect acupuncture may have on obstetrical outcomes in this country.

In 2005, a pilot study was conducted with two objectives: to evaluate the effect of acupuncture on key clinical outcomes and to assess the feasibility of offering the service in a hospital setting.

### **Materials and Methods**

This case—control pilot study took place in the Labor and Delivery unit of an urban community hospital between February and September 2005. Patients admitted to the unit in early labor were recruited by acupuncturists on duty 2–4 days and nights per week. Informed consent was obtained at that time. Approval for the study was obtained from the hospital's Institutional Review Board. Exclusion criteria were previous cesarean section (C-section), diabetes mellitus, chronic hypertension, chronic drug use, and maternal age

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Table 1. Comparison of Studies by Country of Origin and Outcome

Primary author, date Country	Country	Study design	Use of oxytocin <sup>a</sup>	Duration of labor <sup>a</sup>	Use of analgesia <sup>a</sup>
Hantoushzadeh, 2006 <sup>8</sup>	Iran	RCT: acupuncture $(n=70)$ vs. minimal Less oxytocin acupuncture $(n=74)$	Less oxytocin (5.63 vs 7.81 units)	Active phase shorter (3.41 vs 4.45 hrs)	Not reported
Ziaei, 2007 <sup>9</sup>	Iran	RCT: acupuncture $(n = 30)$ vs. sham acupuncture $(n = 30)$ (A third group receiving no acupuncture is not	Fewer oxytocin augmentations "No significant differences" (50% vs 77%)	"No significant differences"	Not reported
Nesheim, 2003 <sup>6</sup>	Norway	reported here). Norway RCT: acupuncture ( $n = 106$ ) vs. acupuncture ( $n = 92$ ). (A third group of matched case controls is not	Not reported	Duration of labor insignificantly longer in acupuncture group	Fewer used meperidine (11% vs 29%)
Ramnero, $2002^5$	Sweden	reported here). Sweden RCT: acupuncture $(n=46)$ vs. no	"Same in both groups"	"No significant differences"	Fewer used epidural
Skilnand, 2002 <sup>7</sup>	Norway	06) vs. $= 104$ ).	Fewer oxytocin augmentations (14% vs 35%)	Fewer oxytocin augmentations Shorter duration (212 vs 283 min) (14% vs 35%) nonsignificant after exclusion of patients using epidural analgesia	Ŧ

<sup>a</sup>Significant results are in bold type. RCT, randomized clinical trial. less than 18 or greater than 40. Inclusion criteria were uncomplicated singleton pregnancies with cephalic presentation, gestational age 37–41 weeks, and cervical dilation of 2–5 cm. All acupuncture patients received conventional obstetrical care (including offers of pain medication) administered according to standard hospital protocols and at the discretion of the attending physician.

Five licensed acupuncturists trained in Traditional Chinese Medicine administered the acupuncture treatment throughout the labor. Use of a study protocol manual lallowed a semistandardized approach, with some points used for all patients and others selected for given symptoms or presentations (e.g., back pain, nausea, anxiety, or insufficient contractions). The acupuncture points used and their indications are summarized in Table 2. The needles used were Seirin and NanoTech brand, with 15-mm 36-gauge Seirin needles used for ear points, and 30-mm and 40-mm 32-gauge NanoTech needles used for body points. Electrical stimulation was provided using a Pantheon Research 4cPro electrostimulation device at a continuous frequency of 10 Hz, with amplitude set to the patient's comfort level, between 3 and 6 mA.

Each acupuncture patient was matched with 1-3 patients drawn in reverse chronological order on the basis of matching parameters from the labor and delivery cases completed during the acupuncture study period. All patients had at least 1 matched control; if 2 or 3 matches were available, they were used. With limited funds and availability of acupuncturists, the goal was to treat as many patients as possible during the study period and compare them to as many appropriate controls as possible. Controls were matched according to the four parameters deemed most likely to affect the clinical outcomes being studied: maternal age, gestational age, parity, and use of oxytocin (3 groups: used for augmentation, used for induction, and not used). Patient matching and collection of data from charts was performed during the study period by research assistants unfamiliar with the study design (in order to avoid bias).

Primary endpoints were incidence of C-section, amount of parenteral opioids used (recorded as number of hospital-

Table 2. Points Used and Indications

Indication	Points used (sequentially, in order given)
All patients	Auricular: ear <i>shen men</i> , uterus, endocrine, LI4, SP6
Cervical ripening and dilatation	BL31–34 (pressure then needling of two most tender points, with needles taped for retention), BL67, KI1 (pressure), GB21 (pressure), GB34, LR3, GV20
Insufficient or irregular contractions	UB 67, ST36, KD3 (points stimulated at onset of contraction)
Pelvic pain	GB34, LR3
Back labor pain	LR3, BL31–34 (needled as above), BL60
Patient fatigue	ST36
Occiput posterior	BL67
Nausea/vomiting	PC6
Anxiety	Yintang, HT7, KI1, PC6, GV20

Table 3. Patient Characteristics

	Acupuncture group (n = 45)	Control group (n = 127)
Mean maternal age (SD)	25.9 (4.9) yr	26.4 (4.9) yr
Mean maternal weight (SD)	158.4 (32.6) lb	158.5 (33.0) lb
Race/ethnicity		
Asian (%)	10 (22)	35 (28)
Hispanic (%)	20 (42)	47 (37)
African American (%)	4 (9)	2 (2)
White (%)	6 (13)	22 (17)
Other or not available (%)	5 (11)	21 (17)
Mean gestational age (SD)	39.2 (1.3) wk	39.3 (1.1) wk
Mean birth weight	3359 g	3366 g

SD, standard deviation.

standard doses), use of epidural analgesia, and duration of labor, all as recorded in the hospital chart. Secondary endpoints were patient satisfaction and nursing staff acceptance as assessed by postpartum questionnaires. In addition, maximum flow rate of oxytocin, incidence of instrumental delivery, Apgar score at 1 and 5 minutes, and incidence of adverse event (as recorded in chart) were assessed. Baseline demographics recorded included maternal age, weight, race/ethnicity, gestational age, and birth weight.

An intention-to-treat analysis was performed. Forty-eight (48) patients were treated with acupuncture, including 8 who elected to discontinue acupuncture during labor. Three (3) patients were excluded from the analysis: 2 were subsequently found to violate inclusion/exclusion criteria and 1 could not be matched. None of these 3 underwent C-section. For the rate of C-section, a generalized mixed linear model was created, with acupuncture versus nonacupuncture as a fixed factor, cluster (case plus 1-3 controls) as a random factor, and C-section versus non-C-section as the outcome. Statistical analyses were performed using GLIMMIX macro, SAS Institute, Cary, NC.

# Results

Forty-five (45) parturients treated with acupuncture in labor were compared to 127 matched historical controls.

No significant differences were found between groups other than minor differences in ethnic and racial composition accentuated by the small group size (Table 3).

Three (3; 7%) of the 45 women receiving acupuncture underwent C-sections, compared with 25 C-sections (20%) among the 127 nonacupuncture controls. The estimated odds ratio of C-section for acupuncture versus nonacupuncture patients was 0.21 (95% confidence interval [0.08, 0.61]) (p = 0.004) (Table 4).

There was a trend toward reduced use of parenteral opioids in the acupuncture group, although it did not reach significance. Thirteen (13; 29%) of the women receiving acupuncture used two or more hospital-standard doses of parenteral pain medications, versus 41 (39%) of controls.

As an artifact of recruitment methods, use of epidural or spinal anesthesia was greater in the acupuncture group than controls (62% versus 34%). Twelve (12) patients had elected epidural anesthesia before initiation of acupuncture. Removal of those patients from calculations reduced this difference (48% versus 34%).

No significant differences were noted in use of oxytocin, Appar score, duration of second stage of labor, or incidence of adverse events (none occurred). Duration of first stage of labor was not included in the final analysis, as patient-reported times for initiation of labor were deemed unreliable.

Nursing staff acceptance was assessed by a questionnaire designed by the nurses and filled out anonymously after each labor was completed. Among 26 nurses, 78% reported a subjective perception of improvement in patients' well-being and comfort during labor and delivery with acupuncture, and 83% of nurses reported that acupuncturist presence had never interfered with their work. Three (3) handwritten notes added subjective perceptions that acupuncture strengthened uterine contractions or helped dilation. Physicians accepted the procedure, with no physician refusing enrollment of a patient meeting inclusion/exclusion criteria.

Safety of patients and staff was assessed as number of acupuncture-related adverse events including acupuncture needlestick injuries. None were reported. No patient adverse effects, major or minor, were reported.

Patient satisfaction was assessed by postpartum survey. Thirty-six (36) of 48 patient satisfaction surveys were

Table 4. Clinical Outcomes

	Acupuncture group $(n = 48)$	Control group (n = 127)	p value (significant values in bold type)
Mode of delivery			
Non-C-section delivery (%)	42 (93)	102 (80)	
C-section (%)	3 (7)	25 (20)	0.004
Adverse event	0	0 `	>0.05
Apgar 7 or below at 1 min (%)	3 (7)	6 (5)	0.61
Apgar 7 or below at 5 min (%)	1 (2)	2 (2)	0.34
Episiotomy (%)	24 (57)	52 (51)	0.65
Mean duration of second stage	37.7 min (37.4)	31.8 min (31.3)	0.76
(C-section patients excluded) (SD)			
Oxytocin: mean max flow rate (SD)	28.5 (16.7)	28.7 (18.0)	0.94
Use of epidural analgesia	28 (62)	43 (34)	n/a
Election of epidural analgesia after acupuncture	16 of 33 (48%)	n/a	n/a
Doses of parenteral analgesia (mean)	1.9	2.1	0.20

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completed. Of these, 87% (65% of total patients) reported that acupuncture had helped them.

#### Discussion

This study shows a statistically significant decrease in C-section rate in the acupuncture group, no acupuncturerelated adverse events, and a high subjective perception of improvement by patients and nurses.

Previous published studies have not reported differences in number of C-sections. Several possible reasons exist for this contrast. First, baseline clinical environments to which the acupuncture intervention is added differ greatly between countries. Without exception, previous international trials reported low C-section rates for both assignment groups: 4% and 8% overall in the Iranian studies, 3% in the Swedish study, and 3% in one Norwegian study. By contrast, the rate of C-section in the United States was 30.2% in 2005. The extensive literature on rising C-section rates distinguishes between a relatively small number of C-sections performed with clear medical indications (e.g., transverse lie) and a rising number that are potentially preventable. It can safely be presumed that the 4%–8% C-section rates of previous studies include mostly "nonpreventable" C-sections.

Second, the acupuncture protocol used in this study differed from those used in other studies. Based on a manual that retained much of the flexibility of normal clinical practice, it included subprotocols for irregular or insufficient contractions and cervical dilatation. In 4 of the 5 published randomized controlled studies, <sup>5,6,8,9</sup> treatment consisted of 5 to 10 needles for analgesia, with 2 to 3 additional needles for miscellaneous indications. By contrast, in one Norwegian study, <sup>7</sup> midwives appear to have been given more latitude for individual selection, with 17 points to choose from at will. It is in that study that the duration of labor was shorter in the acupuncture group.

Based on the findings of our own and previous studies, it can be hypothesized that previously observed effects of acupuncture (reduced use of oxytocin and pain medications) indicate that acupuncture facilitates labor while avoiding a "cascade of interventions" leading to C-section. This hypothesis—that acupuncture during labor can reduce the incidence of C-section in a U.S. hospital setting—would constitute a new research question with major implications for public health outcomes and costs. There is evidence of significantly increased maternal and fetal morbidity associated with C-section, <sup>17,18</sup> in addition to lengthened hospital stay.

Another important research question about acupuncture in relation to U.S. health care practice is its relationship to duration of labor. Revious studies assessing acupuncture as a form of analgesia discontinued treatment when the patient elected epidural analgesia. In this study, acupuncture was continued on patients who elected epidural, and was initiated on some patients with epidural already in place, in order to explore whether Stage II could be shortened. No significant difference in duration of Stage II was observed between acupuncture and control groups.

More patients in the acupuncture group used epidural analgesia (62% versus 34%). While this difference was diminished when patients who initiated acupuncture with epidural already in place were excluded from the analysis, it was not reversed (48% versus 34%). This is in contrast to

previous results in a Scandinavian patient population,<sup>5</sup> where fewer patients in the acupuncture group used epidural analgesia. It is unlikely, however, that this difference accounts for the lower rate of C-section in the acupuncture group. Large studies on epidural analgesia in relation to C-section rate conclude either that it has no effect<sup>19–21</sup> or that it increases risk.<sup>12,15</sup>

The question of acupuncture's effect on the strength and regularity of uterine contractions in humans has not yet been adequately researched. On multiple occasions during the course of this study, physicians, nurses, and acupuncturists observed increases in the apparent strength and/or regularity of contractions on the tocometer after stimulation of needles, particularly UB67. It would be possible in a larger future study to evaluate external and internal monitor readouts for variation in frequency and strength of contractions. The results of such a study would be of particular interest, given the high incidence of C-section after pharmaceutical induction in patients with low Bishop score.<sup>22</sup>

The limitations of this small pilot study are clear. The case-control design did not control for a possible placebo effect, and the sample size of 45 was relatively small, especially given the great variability of patients (first, second, and third pregnancies; inductions and augmentations; any choice of pain medicine including epidural anesthesia). Possible confounders include selection bias and varying C-section rates between physicians. Although controls were carefully matched and screened for inclusion/exclusion criteria, controls may have had comorbidities or complications that were not charted or were otherwise overlooked in the selection process.

#### Conclusions

In conclusion, although previous studies have evaluated acupuncture primarily as a form of analgesia, this study demonstrates that in a U.S. community hospital setting, acupuncture should be evaluated for potential beneficial effects on the course of labor, particularly the incidence of C-section.

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#### **Author Disclosure Statement**

No competing financial interests exist.

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