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The Use of Electroacupuncture for Cervical Ripening in Pregnant Women

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**THE USE OF ELECTROACUPUNCTURE FOR CERVICAL RIPENING
IN PREGNANT WOMEN**

by

Becky Nauta

A DISSERTATION

Presented to the Faculty of
The University of Nebraska Graduate College
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Philosophy

Nursing Graduate Program

Under the Supervision of Diane Brage Hudson, Ph.D., RN

University of Nebraska Medical Center
Omaha, Nebraska

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Supervisor: Diane Brage Hudson, Ph.D., RN

The purpose of this study was to compare cervical ripening outcomes, based on Bishop scoring methodology, of pregnant women receiving usual care treatment (UC) with those receiving electroacupuncture plus UC. A sample of 36 pregnant women completing their 39th week of gestation was randomized into one of the two groups. The women in the UC group continued to meet with their provider on a weekly basis until delivery. The women in the electroacupuncture plus usual care group met with their provider on a weekly basis and also received electroacupuncture treatments: three in the 39th gestational week and two in the 40th gestational week. Conceptual basis for the study was guided by and adapted from the Complementary and Alternative Medicine Model (Figure 1). An experimental research design was used for this pilot study with a sample size of 36 women; 18 in each group. The demographic data were analyzed using descriptive statistics. Means and standard deviations were calculated for the participant's age, gestational age, parity, and Bishop score. Frequencies and percentages were calculated for ethnicity, use of induction methods, types of interventions and mode of delivery. A Mann-Whitney test was used to compare changes in the Bishop score and time in labor. Apgar scores below seven at 5 minutes were calculated using Chi Square methodology. Results from this study found that electroacupuncture plus UC positively influenced the timing of delivery ($p = 0.051$) and the method of delivery (94.4% vaginal delivery rate) compared to UC treatment alone (83.3% vaginal delivery rate). Electroacupuncture plus UC was not shown to be more effective for cervical ripening than UC treatment alone ($p = .633$); however, only 5.6% of participants in the electroacupuncture plus UC group required induction with Cervidil® and Pitocin® compared to 22.2% of participants in the UC group. The use of

electroacupuncture may be beneficial for cervical ripening, initiation of spontaneous labor, reduction of the time in active labor, and an increased potential for a vaginal birth.

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LIST OF ABBREVIATIONS

| | |
|---------|--|
| ACOG | American College of Obstetricians and Gynecologists |
| ACTH | Adrenocorticotrophic Hormone |
| AWHONN | Association of Women's Health, Obstetric, and Neonatal Nurses |
| CAM | Complementary and Alternative Medicine |
| CONSORT | Consolidated Standards of Reporting Trials |
| EBM | Evidence Based Medicine |
| FDA | Food and Drug Administration |
| Hz | Hertz: one unit of frequency equal to one cycle per second |
| ISMP | Institute of Safe Medicine Practices |
| NCCAM | National Center for Complementary and Integrative Health |
| NIH | National Institute of Health |
| PGE2 | Prostaglandin |
| Qi | Energy |
| STRICTA | Standards for Reporting Interventions in Controlled Trials of Acupuncture |
| TCM | Traditional Chinese Medicine |
| UC | Usual Care |

Chapter 1: Introduction

The Use of Electroacupuncture for Cervical Ripening: A Research Proposal

Acupuncture may be effective for use as a cervical ripening agent. The available literature published demonstrates various results; however, all have several components in common. The findings were acupuncture is low risk and carries limited if any side effects (Roemer, Weigel, Zeiger, & Melchert 2000; Mayor, 2007; Smith, Crowther, & Collins, 2012). Trials of acupuncture were reviewed by Curtis, Coeytaux, and Hapke (2006). Acupuncture stimulates the release of beta-endorphins from the hypothalamus and Adrenocorticotrophic hormone (ACTH). Acupuncture may affect uterine contractility through central oxytocin release or by local parasympathetic stimulation of the uterus. Authors proposed that prenatal acupuncture acting through peripheral sensory pathways mediates higher levels of PGE2 and increases cervical dilatation (Curtis et al., 2006).

Roemer, Weigel, Zeiger, and Melchert (1998) treated primiparous women ($n = 329$) weekly using four acupuncture points (25 minutes per session) from the 36th week of pregnancy onward and compared them with women ($n = 224$) receiving a placebo acupuncture and primiparous women ($n = 325$) receiving conventional care. The true acupuncture group demonstrated a significant reduction of labor duration, increased Bishop scores and funnel formation of the cervix, although the specifics regarding p values and incidence rates are not fully specified.

In a second trial, Rabl, Ahner, Bitschau, Zeisler, and Husslein (2001) conducted a randomized clinical trial enrolling 45 women who were not in active labor and compared the control group with those receiving a series of up to three 20-minute acupuncture treatments. Cervical ripening was significantly improved by acupuncture with a reduction in inpatient induction rates and delivery occurring 69 hours earlier in the acupuncture group. Dunn, App, Rogers, and Halford (1989) utilized transcutaneous electrical stimulation of acupuncture points in the lower leg (SP6) and foot (LR3) to monitor contraction patterns in the third trial. Participants

were randomized into a true acupuncture group and a placebo stimulation group. The true acupuncture group experienced more contractions; however, progressive labor did not occur within 24 hours (Dunn et al., 1989).

In two studies electroacupuncture was compared with conventional treatment (weekly follow-up appointments with their physicians) for health and satisfaction outcomes (Gribel, Coca-Velarde, & Moreira de Sa, 2011; Harper, 2006). Gribel et al. demonstrated a statistically significant increased frequency of vaginal deliveries ($p = 0.014$), the absence of obstetric complication ($p = 0.036$), and increased patient satisfaction ($p = 0.046$) (2011). Women in the acupuncture group more often started labor spontaneously (70% vs. 50%, $p = 0.12$) and were less likely to delivery by cesarean section (17% to 39%, $p = 0.07$) than women receiving conventional treatment (Harper, 2006).

Citkovitz, Klimenko, Bolyai, Applewhite, Julliard, and Weiner (2009) conducted a case-control pilot study with 45 patients receiving acupuncture during labor and delivery alongside standard care and compared them with 127 historical controls, matching for maternal age, gestational age, parity and use of oxytocin. Patients receiving acupuncture underwent significantly fewer cesarean sections (7% versus 20%, $p = 0.004$). The acupuncture was well tolerated by patients with 87% responding that acupuncture helped them (Citkovitz et al., 2009).

In three different studies, researchers found no significant difference in patients in the control group versus acupuncture group regarding labor induction or cesarean section rates (Asher, Coeytaux, Chen, Reilly, Loh, & Harper, 2009; Modlock, Nielsen, & Uldbjerg, 2010; Smith, Crowther, Collins, & Coyle, 2008). However, all authors stated in their limitations that the timing of their acupuncture intervention was problematic. Modlock et al. (2010) and Smith et al. (2008) began acupuncture intervention late (41 weeks and 1 or 2 days respectively before pharmacological induction). Asher et al. (2009) began the acupuncture intervention early (38 weeks) and also changed the treatment protocol from electroacupuncture (acupuncture with a

small charge attached) to traditional acupuncture (acupuncture utilizing needling techniques only) suggesting that electroacupuncture may be more effective for cervical ripening.

Park et al. (2008), utilizing four data-bases (Pub Med, Cochrane Library, AMED and Embase from inception to October 2007), conducted a literature review and suggested that acupuncture use for cervical ripening is promising. The researchers summarized that further research is required with consideration given to the use of appropriate controls in randomized clinical trials for cervical ripening and labor induction. Smith and Crowther (2012) conducted a comprehensive Cochrane review utilizing multiple databases and concluded women receiving acupuncture treatments required less use of induction methods compared with those receiving standard care (conventional care). The researchers also noted there is a need for well-designed randomized controlled trials to evaluate the role of acupuncture to induce labor.

Significance

In 2011 there were almost 4 million births in the United States; one million of those births required labor induction (Hamilton, Martin, & Ventura, 2011). Data on labor augmentation are usually similar to the induction rate (Menacker & Martin, 2008); therefore, based on reported data, approximately half the women laboring in the United States received artificial labor induction, demonstrating an increase of 146% of artificial labor induction since 1990 (Martin, Hamilton, Ventura, Oysterman, Wilson, & Mathews, 2012).

Women frequently complain of discomfort regarding the strength and frequency of oxytocin-induced contractions often resulting in the use of epidural anesthesia, which in turn increases the risk of complications such as maternal hypotension and fetal heart rate decelerations (American College of Obstetricians and Gynecologists, 2002). Oxytocin and its' potential mismanagement has become a significant factor in perinatal liability (Clark, Simpson, Knox, & Garite, 2009). In 2007 intravenous oxytocin was designated as a high-alert medication (Institute for Safe Medication Practices, 2007). Oxytocin use requires many interventions throughout the labor process to meet the new standard of care (Simpson, 2013). Interventions include

intravenous fluids and continuous monitoring with an external monitor until sufficient dilation is achieved allowing an intrauterine pressure catheter (IUPC) be placed to facilitate internal monitoring (Simpson, 2013). After an IUPC is placed, the patient is no longer able to ambulate, utilize hydrotherapy, or use the birthing ball/movement therapy (Simpson, 2013).

Labor inductions expend significant financial and human resources. The intrapartum length of stay is much longer when labor is induced, especially in the context of an unfavorable cervix (Simpson & Creehan, 2014). When labor is induced, a 1 to 1 nurse to patient ratio is required to maintain adequate monitoring of mother and baby as well as perform a maternal-fetal assessment at least every 15 minutes as recommended by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology in the Guidelines for Perinatal Care. (2012).

Building on past studies, this feasibility study focused on a current gap in the literature regarding the use of electroacupuncture beginning after the completion of 39 weeks gestation, randomizing participants and utilizing industry standard methodology to measure results. By conducting this initial study, the potential for future studies exist that may demonstrate significant potential to increase the percentage of natural births, reduce morbidity and mortality rates related to the use of oxytocin, as well as improve patient satisfaction and experience.

Study Goal and Objectives

Problem Statement/Specific Questions

While most pregnant women begin labor without difficulty, use of cervical ripening and pharmacological agents for induction of labor is becoming more prevalent. In 2011 there were almost 4 million births in the United States; one million of those births required labor induction (Hamilton et al., 2011). For nulliparous women with an unfavorable cervix (a Bishop score of 6 or less), there is a twofold increase in the risk of cesarean birth (American College of Obstetricians and Gynecologists, 2009). Cervical status is the most important factor in predicting the success of labor as well as labor induction (Simpson, 2013).

The purpose of this pilot study was to compare cervical ripening outcomes, based on Bishop (Bishop, 1964) scoring methodology (Table 1), of pregnant women receiving conventional standard of care treatment with those receiving conventional standard of care treatment plus electroacupuncture. The questions answered by this study are:

1. Is conventional standard of care treatment plus electroacupuncture more effective for cervical ripening than the conventional standard of care treatment alone?
2. Does conventional standard of care treatment plus electroacupuncture positively influence the timing of delivery compared to conventional standard of care treatment alone?
3. Does conventional standard of care treatment plus electroacupuncture positively influence the method of delivery compared to the conventional standard of care treatment alone?

Research Designs and Methods

A comparative research design was used for this feasibility pilot study. A fully powered study size was calculated for a Mann-Whitney test using G*Power 3.1.8. A sample size of 134 participants would be needed with 67 in each group to have a power of 80% for a fully powered study with a medium effect size of 0.50 and an alpha of 0.05. For this feasibility study, a 10% population ($n = 14$) or 7 participants per group would suffice (Hertzog, 2008). It was common practice to add 10 to 20% more patients to the number estimated by sample size calculation to account for dropouts or missing data (Witt & Linde, 2010), adding 2 participants per group (9) or total $n=18$. Even though we determined a minimum of 9 per group, we had resources to have 18 per group for a total $n = 36$. The total number of births per month at Mercy Health Saint Mary's was 160 with approximately 90 deliveries to first-time parents. Approximately 38% of the 100 births are scheduled for induction due to post-date indication further validating the need for this study. This sample size was adequate for the feasibility study.

The sample included participants recruited from primary care provider offices within the Mercy Health-Saint Mary's Physician Partners system in Grand Rapids, MI. Primary care providers include obstetrician practices. Office staff identified potential participants based on women completing 38 weeks gestation. The study primary investigator (PI) was notified by office staff and was available at their scheduled appointment time to screen for inclusion and exclusion criteria. Potential participants meeting inclusion criteria had the study explained to them by the primary investigator. A study flyer (Appendix A) and copy of the informed consent (Appendix B) was given to potential participants for their review. At the completion of 39 weeks, baseline data (Bishop Score) was obtained by the physician and inclusion/exclusion criteria reviewed and shared with the PI. The PI reviewed the study with participant and consent was obtained. A baseline CBC (Appendix C) was drawn and platelet count was reviewed. Subjects were randomized through the computer-generated system. Study arm assignments and subsequent information were collated by a statistician so the PI remained blinded to randomization. The PI provided additional instruction regarding follow-up appointments based on group assignment.

The setting for the electroacupuncture intervention was the Mercy Health Saint Mary's Wege Institute for Mind, Body, and Spirit. The Institute was selected due to the availability of four licensed Traditional Chinese Medicine providers on site although for this study the same Traditional Chinese Medicine provider (Jackie K.) was used for all participants. The site was in proximity to the Labor and Delivery Unit with fetal monitoring capability if needed; however, currently available studies document minimal risk with only needle site irritation noted. Letters have been obtained from each primary care provider office stating their consent to recruit (Appendix D).

Inclusion criteria were (a) completion of 39 weeks gestation, (b) a singleton pregnancy, (c) no prior cesarean sections, (d) a Bishop score of 6 or less at 39 weeks, (e) cephalic presentation, (f) the ability to read and speak English, and (g) adults 21 years of age or greater.

Exclusion criteria were (a) fetal demise, (b) presence of major medical complications of pregnancy such as eclampsia or pre-eclampsia, (c) intrauterine growth restricted fetus (IUGR), (d) history of blood disorder, (e) conditions with abnormal placental implantation such as placenta previa or vasa previa, (f) transverse fetal lie, (g) umbilical cord prolapse, (h) active genital herpes infection and (i) have a pacemaker, and (j) platelet count less than 50,000.

Instruments: Reliability and Validity

The Bishop Scoring methodology (Bishop, 1964) was used to assess the primary outcome (Table 1). The scoring system was developed in 1964 and measures the following criteria: cervical dilation, cervical effacement, cervix consistency, the position of cervix, and fetal station. Scores were assigned based on specified criteria. Nielsen, Howard, Crabtree, Batig, and Pates (2012) further validated the value of the Bishop score as it related to predicting the success of labor induction at term. The Bishop scoring methodology was the gold standard in obstetrics practice, concluding it had predictive validity as noted in numerous citations, most recently in the updated AWHONN guidelines for labor induction (Simpson, 2013). Maternal age, parity, gestational age, ethnicity, baseline Bishop scores and final Bishop scores were obtained through the medical record located in the primary care provider office. Secondary outcomes were obtained through hospital medical record review in the post-delivery period. The date and the time of delivery as well as the mode of delivery (vaginal delivery or cesarean section delivery), treatment methodology and Apgar data were captured (Appendix F).

Procedures

Institutional Review Board (IRB) approval was obtained from Mercy Health Regional Institutional Review Board and the University of Nebraska Medical Center Institutional Review Board (Appendix E and F). Letters from supporting physician practices were included for review (Appendix D). Eligible subjects were identified through prenatal chart review in provider offices and subsequent review by the primary investigator (PI) of criteria. Interested and eligible subjects received information regarding the research study at the completion of 38 weeks

gestation from the primary PI. At the completion of 39 completed weeks, baseline data (Bishop Score) was obtained by the physician and inclusion/exclusion criteria reviewed and shared with the PI. The PI reviewed the study with participant and consent was obtained. A baseline CBC was then drawn and platelet count was reviewed.

Subjects were randomized through the computer-generated system. Study arm assignments and subsequent information were collated by a statistician so the PI remained blinded to randomization. A consecutively numbered, sealed manila envelope containing the study arm assignments was opened by the PI with each participant after all entry criteria were confirmed and written consent obtained. Participants in the conventional standard of care plus electroacupuncture group were given a booklet that explained the process in detail (Appendix H). Each participant was assigned a code that was used for data review. The participants' names, demographic information, and their assigned code are housed separately from all other data and stored in a secured in a locked fireproof file cabinet, in a locked office with access only to the PI.

After randomization, the first acupuncture treatment was performed within 24 hours of consent for subjects in the conventional standard of care plus electroacupuncture group. Four additional acupuncture visits were scheduled at times convenient for the participants. The conventional standard of care treatment group and conventional standard of care treatment plus electroacupuncture group received routine obstetric care with weekly visits and delivery planned only for the development of maternal or fetal indications or by 42 weeks gestation. All participants were asked to keep their group selection and Bishop scoring information confidential to assist with blinding for the study.

Electroacupuncture treatments were performed by one consistent Traditional Chinese Medicine provider (Jackie K.) for a minimum of one treatment and a maximum of five treatments over a 2-week period. After the initial assessment including obtaining a fetal heart rate by a doppler, the following acupuncture points were accessed utilizing Seirin J brand individual sterile needles. (Sizes .25x.30; .25 x .40; sizes 32 gauge; 1 inch needle and 1.5 inch needle respectively):

- Hegu L.I.-4 (Hand) Needling Perpendicular insertion 0.5 to 1 cun; ii. Oblique insertion directed proximally 1 to 1.5 cun.
- Sanyinjiao SP6: (Lower Leg) Needling perpendicular or oblique proximal insertion, 1 to 1.5 cun.
- Shangliao BL-31 (Lower Back) Perpendicular insertion 0.5 to 1 cun, or 1.5 to 2 cun through the foramen. Needling through the foramen is facilitated by a slightly oblique medial and inferior insertion.
- Ciliao BL-32 – (Lower Back) Needling perpendicular insertion 0.5 to 1 cun or 1.5 to 2 cun through the foramen. Needling through the foramen is facilitated by a slightly oblique medial and inferior insertion.
- Jianjing GB 21: (Shoulder) Needling posterior oblique insertion 0.5 to 1 cun.
- Kunlun BL 60 (Ankle) Needling perpendicular insertion 0.5 to 1 cun, or directed superiorly to join with Taixi KID-3, 1.5 to 2 cun (Deadman, 2007; Mayor, 2007; Betts, 2006).

The points-GB 21, LI 4, SP6, and BL 60 were needled first. The needles were advanced and manipulated until 'deqi' (unique sensation) was elicited. Low-voltage (2 Hz) electrostimulation was administered to connect points LI4 to SP6 for 20 minutes. The same point and electrostimulation protocol were performed on the opposite side of the body with the addition of bilateral needling of BL 31 and 32. A post procedure fetal heart rate was obtained by a doppler. The TCM provider documented according to the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) protocol (MacPherson, White, Cummings, Jobst, & Niemtzw, 2002).

There was a slight risk of discomfort at the site of needle insertion when electroacupuncture was used. It was possible that some participants experienced

the enhanced sensation when electroacupuncture was used. Other side effects included fatigue, headache, and insertion site redness or tenderness. Rare side effects included swelling, bruising, or infection. The Traditional Chinese Medicine provider (acupuncturist) was actively involved in the care and worked with the participants to resolve their discomfort, staying within study protocols. There were no side effects reported other than slight discomfort at one needle site.

A gap noted in the literature review delineated specific reporting guidelines were needed in future research; therefore, Traditional Chinese Medicine providers documented according to the STRICTA protocol (MacPherson et al., 2002). STRICTA protocol includes acupuncture rationale, needling details, treatment regimen, cointerventions, practitioner background and control interventions. Subsequent electroacupuncture treatments were scheduled for those in the conventional standard of care treatment plus electroacupuncture group to accommodate two additional treatments in week 1 and two treatments in week 2. Participants continued to follow-up with their primary care providers who documented the final Bishop scoring information in the office. Most patients, however, were seen in the Labor and Delivery triage unit before their final provider appointment so registered nurses and obstetric in-house attending physicians provided the final Bishop Score documentation. Since electroacupuncture treatments were provided at the Wege Institute, Traditional Chinese Medicine providers did not have access to Bishop scoring information. Primary care physicians provided the conventional standard of care to all participants and assessed patients based on Bishop scoring methodology and were not privy to patient grouping information.

Human Subjects Research

Protection of Human Subjects

Permission to conduct this study was obtained from the Mercy Health Regional Institutional Review Board (IRB) and the University of Nebraska Medical Center IRB (Appendix F and G).

Risks to the Subjects

Pregnant women who have completed their 39th week of gestation and have a documented Bishop score of 6 or less were randomized into one of two groups, conventional treatment, and conventional treatment plus electroacupuncture. All participants received conventional standard of care treatment; which was comprised of weekly visits to their primary care provider office for the purpose of maternal-fetal assessment including Bishop scoring methodology. If participants were selected to participate in the conventional standard of care treatment plus electroacupuncture group, they received a minimum of one and a maximum of five electroacupuncture treatments over a period of 2 weeks.

Permission to enroll 36 women who have completed their 39th week of pregnancy, had a Bishop score of 6 or less and were 21 years or older was obtained from the IRB. Participant eligibility criteria were designed to recruit a population that was currently at risk for pharmacological induction and may have benefitted from a non-pharmacological approach. Inclusion and Exclusion criteria have been described previously. Pregnant women or fetuses may be involved in research if all of the following conditions were met:

- A. Where scientifically appropriate preclinical studies provide data for assessing potential risks to pregnant women and fetuses. The synthesis of the literature utilizing electroacupuncture for cervical ripening in pregnant women demonstrated only the risk of slight discomfort at the site of needle insertion and many potential benefits such as an increase in Bishop score, initiation of spontaneous labor and decrease in labor duration (Gribel et al., 2011; Harper et al., 2006; Rabl et al., 2001; Roermer et al., 1998).
- B. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. As stated in prior literature reviews, the risk to the woman and fetus is minimal (Harper, 2006).
- C. Any risk is the least possible for achieving the objectives of the research. Literature reviews demonstrate a minimal risk to the woman and fetus (Harper, 2006).

- D. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus, her consent is obtained in accord with the informed consent provision. All participants will provide consent in accord with the informed consent provision.
- E. The research holds out the prospect of direct benefit to the fetus and the pregnant woman, not just solely the fetus.
- F. Each providing consent was fully informed regarding the reasonably foreseeable impact of the research on the fetus.
- G. Children who are pregnant did not meet the inclusion criteria as the criteria stipulate 21 or older.
- H. No inducements, monetary or otherwise will be offered to terminate the pregnancy.
- I. Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- J. The research team will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy or in determining the viability of a neonate.

The study was conducted at Mercy Health-Saint Mary's, and affiliate consented (Mercy Health Physician Partners) primary care provider offices in Grand Rapids, MI.

Sources of Materials

Research material included data collected through medical record reviews in the Traditional Chinese Medicine and primary care provider offices at the beginning and after completion of treatment as well as in-patient hospital records post-delivery. The medical record data obtained included gestational age, parity, ethnicity, maternal age, baseline Bishop scoring before randomization grouping, final Bishop scoring after intervention completion, mode of

delivery; date and time of delivery, and specific electroacupuncture information recorded according to STRICTA protocol.

Data was linked to participants by a study-specific ID code number only. Each participant was assigned a code number through the REDcap security system by the PI. The only link between a participant's name and ID code was through this system that is encrypted.

All data and records were collected as described above will be for research purposes only.

Potential Risks

This was a minimal risk study, in that probability and magnitude of harm anticipated was not greater than those encountered during conventional standard of care visits. There was a slight risk of discomfort at the site of needle insertion when electroacupuncture was utilized.

Participants may have experienced enhanced sensation when electroacupuncture was utilized.

Other side effects may have included fatigue, headache, and insertion site redness or tenderness.

Rare side effects include swelling, bruising, or infection. The Traditional Chinese Medicine provider (acupuncturist) was actively involved in the care and worked with the participants to resolve their discomfort, staying within the study protocols.

There was a risk of a loss of confidentiality; however, every effort was made to secure participant information as described in the following section.

ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent

The office nurse identified prospective participants through prenatal chart review in provider offices. When the patient had completed 38 weeks of pregnancy, the nurse notified the researcher of the prenatal appointment, so the researcher was readily available. If the baseline Bishop score was 6 or less and the patient met all study criteria, the researcher introduced the study to the patient and provided the patient with study information and a copy of the informed consent. The researcher was available at the following appointment. When the patient still met all study criteria, the study was described in detail, and all questions were answered. The formal

written consent process was initiated after the participant gave verbal consent. Baseline data collection took place during the appointment time after written consent was obtained.

Process of Informed Consent

The researcher, who had completed the NIH approved training required by Mercy Health Saint Mary's and the University of Nebraska Medical Center, completed informed consent in person. The researcher explained the study to potential participants at 38 completed weeks of gestation and provided them with a flyer discussing study specifics and a copy of the informed consent document. One week later when the participants met study criteria and were interested in participating in the study, the primary care provider office exam room or conference room was the setting for the consent process, providing a private area where confidentiality was assured. Formal written consent by the participant was obtained.

Protection Against Risk

The potential risk of physical discomfort was minimized by assuring participants that the Traditional Chinese Medicine provider (acupuncturist) listened intently to their needs and when possible adapted the approach to meet their needs. Participants were advised that they could call the researcher if they were concerned about their intervention. The potential risk of loss of confidentiality was mitigated through the utilization of the REDcap system as well as the intentional securing of all data and study materials in locked file cabinet with researcher only access. All electronic data was encrypted and stored on a password-protected network.

POTENTIAL BENEFITS OF THE PROPOSED STUDY TO THE PARTICIPANTS AND OTHERS

Potential Benefits

Participants may not receive any benefit from study participation. Some participants found the electroacupuncture intervention beneficial, especially those patients with enhanced cervical ripening and lessened or eliminated the need for pharmacologic induction. Participants receiving electroacupuncture also received this intervention free of charge, so that was a

perceived benefit. There is a potential benefit for pregnant women in the future, as the study provides new knowledge regarding electroacupuncture for cervical ripening.

Risk/Benefit Assessment

This was a minimal risk study that helped current participants as well as provided additional information for future research in hopes of reducing the need for pharmacologic induction of labor and subsequent interventions. The potential risks of this study were believed to be outweighed by the potential benefits for the participants as well as other pregnant women in the future.

Follow-Up

If any participant reported an adverse event at any time during the study, they were to notify the researcher (Becky Nauta) immediately. After an investigation, the researcher would consult with the Office of Research and Innovation at Mercy Health Saint Mary's and the University of Nebraska Medical Center and complete the required documentation. Further, each report would warrant evaluation regarding the continuation of the study. There were no adverse events reported.

Data Management and Safety Monitoring Plan

Data was collected from each of the medical records (Traditional Chinese Medicine and primary care providers) by the researcher. The primary outcome data was that of the Bishop score from the pre-intervention visit to the post-intervention visit. Secondary outcome measures included mode of delivery, time from first intervention visit until delivery, time in labor and Apgar scores. The outcome measures corresponded directly to the study questions comparing the conventional standard of care treatment plus conventional standard of care treatment plus electroacupuncture for cervical ripening.

Descriptive statistics were used to analyze the demographic data. Means and standard deviations were calculated for the participant's age, her gestational age, parity, and her Bishop score. Frequencies and percentages were calculated for ethnicity, use of induction methods, types

of interventions and mode of delivery. A Mann-Whitney test was utilized to assess changes in Bishop scores from baseline to post-intervention. Secondary outcome measures included mode of delivery and time from the first intervention visit until delivery, time in labor, treatment methodology and Apgar scores below seven at 5 minutes, utilizing Chi Square methodology.

All data was secured and maintained utilizing REDCap to assure the confidentiality of data. All paper files were kept locked in a fireproof cabinet, in a locked environment by the PI. The primary care providers had access only to their office/medical files. The TCM providers had access only to their patient files in the Wege Institute. The data was collated after delivery by the researcher with the assistance of a statistician. All data was maintained for review. Data was interpreted by the researcher and disseminated for review and report. Dr. Brage Hudson served as the Data Safety Monitor.

Quality Assurance

After the first four participants, data was reviewed by the researcher and the Data Safety Monitor assuring data captured met the objectives of the study and assessed for any needed changes in protocol. If needed, the study would have been stopped until protocol changes were approved by IRB. Data was also entered twice to assure accurate data entry.

Dissemination of Results and Publication Policy

Results will be published in a manuscript dissertation format. A manuscript for publication will also be submitted with the researcher as first author and Dr. Brage Hudson as the second author. Recognition of the study site will be included in all written word as well as subsequent presentations.

Problems Anticipated

Non-Supportive Physicians: Because complementary therapy had not been piloted in the area of labor and delivery, there could have been physicians who were reluctant to refer patients to the study. To avoid this problem, one on one conversations occurred between the researcher and providers, providing them an opportunity to review prior study information and to seek their

support for new research. Providers had some exposure to acupuncture in the hospital setting as Mercy Health Saint Mary's has an integrative medicine center located on site. (Peter M. Wege Center for Health and Learning – Mind Body and Spirit).

Inadequate recruitment rate (feasibility): Because acupuncture involves needles, some people were reluctant to try this therapy. To assist patients in the understanding of acupuncture, a plastic model with acupuncture points was available during the explanation of the study. Acupuncture needles were also available for patients to view, so they recognized needles are flexible and very small. Prenatal class participants were surveyed regarding their openness to acupuncture use for cervical ripening. Forty-two percent of prenatal class participants stated interest.

Limitations

Multiple primary care providers: The limitation of this study included the fact that multiple examiners were used to document the Bishop score. All providers were experienced attending physicians and a standardized Bishop scoring methodology was used. Additionally, pre-intervention interviews were conducted to clarify aspects of conventional standard of care to assure consistent practice among providers.

In Traditional Chinese Medicine, providers practice using differential diagnosis and individualize acupuncture treatment accordingly. By using set acupuncture sites and technique for this study, the results may not reflect true TCM practice results as only a percentage of the population may respond to standard acupuncture sites and treatment.

Participants will not be blinded: Another limitation of this study is that the participants themselves were not blinded to the intervention. All participants were requested to keep their treatment method confidential, requesting they not disclose it to their primary care physicians. Conventional treatment was currently the standard of care, and the knowledge of the treatment arm did not change the care provision.

Project Management

Primary Investigator and researcher – Becky Nauta – had primary responsibility for all aspects of the study including recruitment, scheduling, data collection and management, statistical analysis and dissemination of study results.

Co-Investigator – Dr. Diane Brage Hudson – served as faculty oversight for Becky Nauta and was responsible for reviewing all aspects of said study. Dr. Brage Hudson also served as the Data Safety Monitor.

Ethics

Mercy Health Saint Mary's follows the Ethical Religious Directives (ERD's) of the Catholic Church. If an issue arises needing ethical consideration, Mercy Health had a member of the Ethics Committee available 24 hours a day; seven days a week for consultation.

Informed Consent (Appendix B).

The Use of Electroacupuncture for Cervical Ripening

Part II – Research Protocol

Budget:

| <u>Item</u> | <u>Description</u> | <u>Cost</u> |
|---|---|-------------|
| IRB Fee | Full Board Submission | \$ 500.00 |
| Copies | Flyer for Study | |
| | Informed Consent | |
| | Educational information regarding acupuncture | \$ 200.00 |
| Statistical | | |
| Support | \$60.00 per hour | |
| | Validation of data | \$ 240.00 |
| TCM provider | See treatment overview | |
| Treatments | | |
| A. | Initial consult with treatment - \$105.00 | \$6,930.00 |
| B. | Follow-up Acupuncture Visit - \$70.00 each | |
| C. | Total cost for 5 treatments: \$385.00 | |
| N=36 with 18 participants in the acupuncture group. | | |
| All acupuncture participants will have a minimum of | | |
| 1 treatment and a maximum of 5. | | |
| Baseline Complete Blood Count for each participant | | |
| | 36 participants x \$20.00 | 740.00 |
| | Specific phone line for research study (annual) | 100.00 |
| | UNMC “Business cards” with Researcher name and contact information | 50.00 |

| | |
|---------------------------------------|---------------------------|
| <u>Total</u> | <u>\$ 8,760.00</u> |
| Grants obtained: | |
| Sigma Theta Tau – Lambda Zeta Chapter | \$ 500.00 |
| University of Nebraska Medical Center | |
| Nellie House Craven Scholarship | \$ 5,379.00 |
| University of Detroit Mercy | |
| Faculty Research Grant | \$ 2,992.00 |
| Total Funded: | <u>\$ 8,871.00</u> |

Table 1. Bishop Scoring System

| Factor | | | | | |
|--------|------------------|-------------------|---------|-------------|-----------------------|
| Score | Dilation (cm) | Effacement (%) | Station | Consistency | Position of Cervix |
| 0 | Closed | 0-30 | -3 | Firm | Posterior |
| 1 | 1-2 | 40-50 | -2 | Medium | Midposition |
| 2 | 3-4 | 60-70 | -1, 0 | Soft | Anterior |
| 3 | ≥ 5 | ≥ 80 | +1, +2 | ----- | ----- |

Total: _____

(Bishop, 1964)

Chapter 2: Manuscript 1

Cervical Ripening in Pregnant Women

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Cervical Ripening in Pregnant Women

Spontaneous labor and birth is a natural process. One trigger for spontaneous labor is the ripening of the cervix and the subsequent release of endogenous prostaglandins and cortisol from the fetus and oxytocin from the mother (Coeytaux, Curtis & Hapke, 2006; Gribel, Coca-Velarde, & Moreira de Sa, 2011). Cervical ripening is the process of thinning, softening, and stretching the cervix in preparation for labor (Amorosa & Stone, 2015; Simpson, 2013). Measures taken to enhance cervical ripening before the onset of labor can minimize the risk of cesarean birth as well as generate spontaneous labor without the need to induce labor (Amorosa & Stone, 2015; Kunz, Loftus, & Nichols, 2013; Simpson, 2013). The purpose of this paper is to provide a concept analysis of cervical ripening in pregnant women using Walker and Avant (2011) methodology as well as describe a derivation of the Complementary and Alternative Healthcare Model adding a practice component for further study.

Key Concept: Cervical Ripening in Pregnant Women

Cervical ripening is the process that results in the physical softening and stretching of the cervix in preparation for active labor and birth and is the focus of the concept analysis. For nulliparous women with an unfavorable cervix, defined as a Bishop score of six or less, one consequence is a twofold increase in the risk of cesarean birth (American College of Obstetricians and Gynecologists, 2009; Amorosa & Stone, 2015). Cervical status is the most important factor in predicting the success of labor as well as the need for labor induction. The antecedents for the concept of cervical ripening in pregnant women include a favorable cervix and pre-induction cervical ripening. A favorable cervix can minimize the risk of cesarean birth as well as generate spontaneous labor without the use of oxytocin (Laughon, Branch, Beaver & Zhang, 2012; Simpson, 2013).

Attributes essential to cervical ripening include cervical dilation, effacement, station, consistency and the position of the cervix. The referent for cervical ripening would include the

total points assigned to the attributes indicating an overall Bishop score. The consequences of a Bishop score of greater than six increases the success of labor induction or spontaneous labor whereas a Bishop score of six or less increases the risk of cesarean birth (Amorosa & Stone, 2015; Bishop, 1964; Simpson, 2013).

Antecedent: Mechanical and Pharmacologic Methods for Cervical Ripening

Many mechanical and pharmacologic methods have been used to ripen the cervix. The most adventitious method should work in a timely fashion, be non-invasive, and should not increase maternal or fetal morbidity. Several types of mechanical methods used for cervical ripening include balloon catheters, osmotic dilators, and laminaria tests (Simpson, 2013).

Mechanical ripening uses a mechanism of action that causes direct pressure and overstretching of the lower uterine segment and cervix, stimulating a local prostaglandin release. Evidence supports the use of the mechanical methods for cervical ripening because of its low cost compared with prostaglandins, and reduced risk for uterine tachysystole with or without fetal heart rate changes (Hill & Harvey, 2013; Jozwiak et al., 2012; Simpson, 2013). There are three disadvantages of the mechanical methods including maternal discomfort, small increase risk of maternal and neonatal infection and the potential disruption of a low-lying placenta (Perry, Hockenberry, Lowdermilk, & Wilson 2014; Simpson, 2013).

Pharmacologic methods for cervical ripening include the use of various hormonal preparations such as prostaglandin E1 (PGE1) misoprostol and prostaglandin E2 dinoprostone. These pharmaceutical agents stimulate cervical ripening by softening the cervix, relaxing the smooth muscle and stimulating uterine contractions. Dinoprostone is the only FDA approved the medication for cervical ripening and labor induction. The vaginal insert is used most frequently, as it is easy to remove if adverse effects occur. Potential adverse effects include a headache, nausea, and vomiting, hypotension, uterine tachysystole with or without an abnormal fetal heart rate and pattern or fetal passage of meconium (Perry et al., 2014).

Dinoprostone (cervidil®) is an FDA approved the medication for cervical ripening and labor induction. The vaginal insert is used most frequently, as it is easy to remove if adverse effects occur. A treatment success is defined as an increase of at least 3 in a Bishop score during the 12-hour observation period, attainment of a Bishop score of \geq six during a 12-hour observation period or vaginal delivery occurring during the 12-hour observation period. Potential adverse effects include a headache, nausea, and vomiting, hypotension, uterine tachysystole with or without an abnormal fetal heart rate and pattern or fetal passage of meconium (Forest Pharmaceuticals, 2010).

Misoprostol (cytotec®) was originally approved by the FDA for prevention of peptic ulcers, not for cervical ripening. The FDA removed the contraindication for the use of misoprostol for women during pregnancy due to its widespread use for cervical ripening and labor induction and was part of an FDA-approved regime for use to induce abortion in pregnancies of 49 days or less. The FDA included warnings about potential adverse effects including uterine tachysystole, uterine rupture, or a decrease in uteroplacental blood flow, or amniotic fluid embolism and led to adverse fetal heart changes (Pfizer Pharmaceuticals, 2012). Advantages of misoprostol include low cost, ease of insertion, and quick action.

Antecedent: Acupuncture for Cervical Ripening

Acupuncture is defined as "stimulating specific anatomic points in the body for therapeutic purposes" (Freeman, 2009, p. 311). Acupuncture is grounded in Eastern medicine, believing that the body has energy that runs through distinct meridians. Acupuncture stimulates particular energy points in the body to open energy channels that run along the meridians (Deadman & Al-Khafaji, 2007). Based on the concept of wellness, acupuncture assists the body in rebalancing itself. When comparing western neurology and eastern energy meridians, consistencies exist that bridge the gap between the two practices (Freeman, 2009).

Acupuncture therapy is often thought of as the application of a needle into the skin.

Although puncturing the skin is the usual method of application, heat, pressure, friction or suction

also may be used (Freeman, 2009). Needles are inserted into key acupoints identified as being in need of stimulation to treat the condition or regain body balance. The angle and depth of insertion at each point is critical (Deadman & Al-Khafaji, 2007). Acupuncture for cervical ripening has been used in several studies internationally with promising results (Curtis et al., 2006; Mayor, 2007; Roemer, 2000; Smith & Crowther, 2012). Specific points have been identified to facilitate cervical dilation. More than one treatment may be needed to ripen the cervix (Gilbert, 2011; Moleti, 2009).

In a landmark review by Curtis et al. (2006), the mechanism of action regarding the use of acupuncture for cervical ripening was explained. Acupuncture stimulated the release of beta-endorphins from the hypothalamus, and the adrenocorticotrophic hormone (ACTH) was released as well. Acupuncture may affect uterine contractility through central oxytocin release or by local parasympathetic stimulation of the uterus. Authors proposed that prenatal acupuncture acting through peripheral sensory pathways mediates higher levels of PGE2 and increases cervical dilatation (Curtis et al., 2006). There are many advantages in using Acupuncture for cervical ripening. Acupuncture is minimally invasive, is cost effective, and has no reported adverse effect on the fetal heart rate or maternal uterine contractions such as tachysystole. Adverse effects reported are slight discomfort at the needle insertion site as well as the feeling of fatigue (Roemer, 2000).

Sub-Concept of Acupuncture Antecedent: Electroacupuncture

Electroacupuncture uses a small electrical charge that stimulates the neurotransmitter in the body (Mayor, 2007). Electroacupuncture may or may not use the traditional method of needling and skin puncture, depending on the provider's preference (Deadman & Al-Khafaji, 2007). Electroacupuncture may be chosen for many reasons. Electroacupuncture allows stronger stimulation that is continuously resulting in less tissue damage (Mayor, 2007). Electroacupuncture uses a consistent electrical charge providing an objective and standardized approach that is more easily measured than that of manual acupuncture (Mayor, 2007). Advantages of

electroacupuncture include techniques that are minimally invasive, may lessen or eliminate the need for pharmacologic intervention, and is deemed low risk and carries limited if any side effects. A disadvantage of electroacupuncture may include needle discomfort at the site of insertion and fatigue.

Conceptual Map: CAM Healthcare Model – Fouladbakhsh and Stommel, 2007

Electroacupuncture use for cervical ripening is a relatively new concept for those who practice predominately in Western medicine cultures. The Complementary and Alternative Medicine (CAM) Healthcare Model (Fouladbakhsh & Stommel, 2007) is useful in bridging the gap between Western and Eastern medicine. Nurses may use the CAM Healthcare Model as a framework for their nursing practice or research with patients experiencing electroacupuncture for cervical ripening.

The CAM Model is based on the theoretical framework of Andersen's Behavioral Model of Health Service Use (Aday & Andersen, 1974). The Behavioral Model of Health Service Use has been used to predict the access to and utilization of health services. The focus of this model is the use of health services determined by three dynamics: (a) predisposing factors such as race, age, and health beliefs; (b) enabling factors such as family support or the ability to access to insurance; and (c) need for services either perceived need or actual need (Andersen, 1995). This model has not been widely used in the area of complementary medicine other than to investigate the use of alternative and nonprescription medication for chronic pain.

With the growing number of people in the United States turning to complementary or alternative medicine, the CAM Healthcare model (Fouladbakhsh & Stommel, 2007) builds on Andersen's Behavioral Model of predictors and enhances the predictability comparing the use of conventional health care and CAM. The CAM Healthcare Model (Fouladbakhsh & Stommel, 2007) includes the three factors evident in the Behavioral Model and adds the following factors: (a) health service use and (b) outcomes of care. Since many CAM therapies are used to

complement conventional medicine not substitute for it, a framework uniting both entities seemed prudent (Fouladbakhsh & Stommel, 2007).

The CAM Healthcare model includes five factors (Fouladbakhsh & Stommel, 2007). These factors include predisposing factors, enabling factors, need for care factors, health service use, and outcomes of care. Predisposing factors may include demographic information such as age and race, the social structure such as cultural practices and CAM knowledge, beliefs and values, risk perceptions as well as personal factors such as self-care ability (Fouladbakhsh & Stommel, 2007).

Enabling factors could include the ability access to resources such as health insurance or income ample enough to private pay for care. Geographical issues such as the location of the facility, availability of transportation, and availability of CAM providers could also be enabling factors. An illness experience or changes in health status are examples of an evaluated need; however, an individual's perceived health status and need for health care demonstrates a perceived need for care.

Health service use describes the manner of use, the purpose of use as well as the products used (Fouladbakhsh & Stommel, 2007). Finally, outcomes of care focus on improved quality of life determined by a decrease in symptoms, decreased limitations, decrease in symptom burden and an increase in well-being, satisfaction and perceived control (See Figure 1)

Conceptual Map: The Complementary and Alternative Healthcare (CAM)

The conceptual framework created by the author (figure 2) is derived from the Complementary and Alternative Healthcare Model (Fouladbakhsh & Stommel, 2007). The original model was a grand theory, necessitating some adaptations to the model. The model has been adapted to explore the concept of cervical ripening in pregnant women.

The conceptual framework begins with predisposing factors such as demographic information (female, gestational age of 39 completed weeks, current Bishop (Bishop, 1964) score of six or less, age, and ethnicity). The criteria selected would enable the results to be stratified in

a purposeful manner, providing future selection criteria as well as outcome success. Enabling factors include aspects of availability of providers as well as financial resources to pay for care.

The need for care (concept) focus is the readiness for labor. A woman with a Bishop score (Bishop, 1964) of six or less at the completion of 39 weeks indicates cervical ripening (concept) has not yet occurred. A woman with a Bishop score of six or greater has a higher incidence of spontaneous labor (Laughon et al., 2012; Simpson, 2013). If the patient meets the initial demographic criteria, the model progresses to defining characteristics for care that include the criteria of a singleton pregnancy in cephalic position, appropriate fetal size (excludes small for gestations age and large for gestational age infants) no prior cesarean sections, and the absence of any high-risk maternal or fetal health factors such as gestational diabetes or pre-eclampsia (American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 2012).

The need for health service use (antecedent) is that of the intervention modality. A Bishop score of 6 or less in pregnant woman completing 39 weeks of pregnancy demonstrates the need for intervention (Nielsen, Howard, Crabtree, Batig & Pates, 2012). Conventional treatment is defined as weekly appointments with the pregnant woman's physician or conventional treatment plus intervention such as mechanical, pharmacological, or acupuncture methods. Electroacupuncture treatments would include weekly appointments with the pregnant woman's physician as well as up to five electroacupuncture treatments provided by a traditional Chinese practitioner over a two week period are the two intervention modalities (American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 2012; Betts, 2006). The health service use component integrates the randomization of the groups. The physician will examine the woman and determine the Bishop score (Bishop, 1964). If the pregnant woman agrees to take part in a research trial, she would be randomized into one group.

After the woman is randomized into the conventional treatment or the conventional treatment plus intervention group, the specific mode of treatment will commence. Mediating

variables (referents) would include spontaneous labor before intervention or spontaneous rupture of membranes before active labor requiring more active management of labor. The final component of the model is the outcome of care section (consequences). The primary outcome measures cervical ripening using the Bishop scoring methodology (Bishop, 1964). The secondary outcome measures the efficacy of conventional treatment plus electroacupuncture compared to conventional treatment regarding the timing of delivery (from enrollment in study and start of intervention to delivery time) and methodology of delivery (cesarean birth, vaginal birth, birth with pharmacological induction).

Supporting Literature

Nulliparous women who were induced with an unfavorable cervix demonstrated a twofold increase in the risk of cesarean birth (American College of Obstetricians and Gynecologists, 2009). Spontaneous labor is usually associated with less risk of cesarean birth; however, favorable cervix or pre-labor cervical ripening can minimize the risk of cesarean birth associated with induced labor for nulliparous women (Clark, Miller, Belfort, Dildy & Meyers, 2009; Vahratian, Zang, Troendle, Sciscione, & Hoffman, 2005). When the Bishop score is less than 6, elective induction for nulliparous women significantly increases the risk of cesarean birth (Nielsen et al., 2012). Conversely, Clark et al. (2009) found a cesarean birth rate of zero for women admitted for elective induction with a cervical dilation of 5 centimeters or greater. Adequate cervical ripening is a critical component for spontaneous labor and subsequent vaginal delivery (Frederiks, Lee, & Dekker, 2012).

Acupuncture may be effective for use as a cervical ripening agent. Trials of acupuncture were reviewed by Curtis et al. (2006). Over 50 articles were identified; however, only three studies met the criteria for review (Curtis et al., 2006). The largest trial by Roemer, Weigel, Zeiger, and Melchert (1998) treated primiparous women ($n=329$) weekly using four acupuncture points (25 minutes per session) from the 36th week of pregnancy onward and compared them with women ($n=224$) receiving a placebo acupuncture and primiparous women ($n=325$) receiving

conventional care. The true acupuncture group demonstrated a significant reduction of labor duration, increased Bishop scores and funnel formation of the cervix, although the specifics regarding p values and incidence rates were not fully specified.

In a second trial, Rabl, Ahner, Bitschau, Zeisler, and Husslein (2001) described a randomized clinical trial enrolling 45 women who were not in active labor and compared the control group with those receiving a series of up to three 20-minute acupuncture treatments. Cervical ripening was significantly improved ($p= 0.03$) by acupuncture with a reduction in inpatient induction rates and delivery occurring 69 hours earlier in the acupuncture group. Dunn, App, Rogers, and Halford (1989) used transcutaneous electrical stimulation of acupuncture points on the lower leg (SP6) and the foot (LR3) to monitor contraction patterns in the third trial. Participants were randomized into a true acupuncture group and a placebo stimulation group. The true acupuncture group experienced more contractions than the placebo group; however, progressive labor did not occur within 24 hours (Dunn et al., 1989).

In another study, investigators compared electroacupuncture with Cervidil (Misoprostol) for cervical ripening (Gribel et al., 2011). Sixty-seven women with a Bishop score less than seven were enrolled in the study. Dual intermittent electrostimulation applied at fixed acupoints was able to satisfactorily substitute pharmacologic cervical ripening with a statistically significant increased frequency of vaginal deliveries ($p= 0.014$) and higher satisfaction of patients ($p= 0.046$) (Gribel et al. 2011). The limitations noted in this study were that patients could not be blinded to the treatments, and the number of participants in the study was small.

Investigators enrolled nulliparous women at 39 and 4/7 weeks or greater with a Bishop score of less than 7 and randomized to usual medical care (control group, $n=26$) versus usual care (routine medical care and follow-up) and three outpatient acupuncture treatments ($n=30$) using the bilateral points of LI4; SP6; UB 31 and UB 32 (Harper et al., 2006). Electroacupuncture at 2Hz was added to UB 31 and UB 32 points during the entire 30-minute treatment. The results demonstrated women in the acupuncture group tended to be more likely to labor spontaneously (p

= 0.12) and less likely to deliver by cesarean section ($p = 0.07$) (Harper et al., 2006). There were no side effects noted. Limitations of the study included a small sample size, differences in gestational age and enrollment and a lack of blinding of the participants or the participants' healthcare providers. Strengths of the study included 100% compliance with the study protocol. An investigator blinded to the study arm assessed outcome measures reported that the study could be easily replicated by other researchers (Harper et al., 2006).

Ajori, Nazari, and Eliaspour (2013) conducted a double-blind, randomized controlled trial to evaluate whether the use of acupuncture could initiate labor at term and thus reduce post-term induction. Eighty women were enrolled in the study, and 75 women completed the study. Participants with gestational ages between 38 and 42 weeks were assessed for eligibility to enter the study. Routine care was given to all participants. A licensed acupuncturist using true acupuncture points performed acupuncture treatment. Sham acupuncture points included non-acupuncture points with shallow needle insertion. Manual stimulation was provided with the procedure administered up to a maximum two times over a one week period. The conclusion revealed no effect of acupuncture on initiation of labor in term pregnancies. The mean number of procedure in acupuncture group was less than the sham acupuncture group. The lower number of procedures in the acupuncture group was due to a shorter time from entry to delivery (Ajori et al., 2013).

Researchers documented varied results in their studies; however, all studies have several components in common. Acupuncture is low risk and carries limited if any side effects. Over 25% of the population currently uses acupuncture (Freeman, 2009), so the healthcare provider population needs to readily respond to questions as well as provide complementary alternatives. Several studies cited throughout this paper show promising aspects to be integrated into future acupuncture studies. Subjects receiving acupuncture treatments demonstrated a higher percentage of vaginal deliveries, less obstetric complications and higher patient satisfaction rates than those receiving conventional care including pharmacological methods for cervical ripening or labor

induction (Curtis et al., 2006; Gribel et al., 2011; Harper et al., 2006). Acupuncture is safe and tolerated well by women at the end of the pregnancy (Harper et al., 2006). Pain in stimulation points can be present; however, it is considered a minor complication (Gribel et al., 2011). The next step for nurse researchers is to continue to aggregate the data, noting acupuncture points that have been successful as well as the suggested correct timing and population for design and multi-components of methods of study.

Significance of the Conceptual/Theoretical Framework

Complementary and alternative medicine form a significant number of health care practices worldwide. Since CAM encompasses much diverse health care and medical practices, selecting a conceptual framework that would meet the needs of both eastern and western worlds is essential. The CAM healthcare model is adapted from a western behavior model by Anderson with the eastern complementary component added by Fouladkakhsh and Stommel (2007). The CAM healthcare model can be adapted specifically to compare conventional treatment to conventional treatment plus electroacupuncture for cervical ripening.

Evidence-based medicine (EBM) in CAM is often pluralistic using an individualized plan for care. The integrity of individual CAM practice therapies and principles need to be respected within a rigorous EBM framework. The practice of acupuncture brings another level of complexity, as it is one methodology in complementary therapy that has specific reporting requirements associated with Consolidated Standards of Reporting Trials (CONSORT) that includes Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) (Lewith, Jonas, & Walach, 2011). CONSORT and STRICTA standards assure that studies involving acupuncture include standardized reporting tools to assist with comparative analysis.

The Complementary Healthcare Model for cervical ripening in pregnant women (derived from Fouladbakhsh & Stommel, 2007) provides the framework to be rigorous in nursing research yet offers the flexibility to add in the practice component for further study according to the

CONSORT and STRICTA guidelines. This model bridges the gap between eastern and western practices providing a format for study.

Several gaps in knowledge exist specific to the laboring population and the use of acupuncture for cervical ripening. The first gap is that the exact mechanism of action triggering labor is still unknown. Maternal factor and fetal factor theories are numerous, and there is not a conclusive study pointing to the exact mechanism stimulating labor. The second gap is the limited number of randomized trials available currently. The database continues to grow with over 300 total acupuncture trials cited in the literature since 1985; however, studies of acupuncture trials in the laboring population with a cervical ripening focus following the STRICTA protocol (MacPherson, White, Cummings, Jobst, & Niemtzw, 2002) are limited. The third gap recognizes that acupuncture entails many different styles, techniques, and practitioners. It may be difficult to generalize specific treatment protocol to populations who will use different practitioners (Betts, 2009). The fourth gap identified is the number of acupuncture points that have been used for cervical ripening. Acupuncture studies in the past have not always noted specifics regarding needle site, technique, depth and time of treatment currently creating a gap in knowledge.

Conclusion

In summary, the articles presented in this concept analysis and subsequent framework most closely relate to the subject regarding the use of different interventions for cervical ripening including electroacupuncture. Based on a literature overview as well as on-going review of practice and further studies, acupuncture may be as effective for cervical ripening as mechanical and pharmacological agents and subsequently can allow the body to produce adequate uterine contractions leading to progressive labor, vaginal delivery and a well-oxygenated fetus without utilization of pharmacological agents and subsequent invasive interventions. The derivation of the Complementary and Alternative Healthcare Model for the concept, cervical ripening in pregnant

women, provides the framework to be rigorous in nursing research yet offers the flexibility to add in the practice component for further study according to the CONSORT and STRICTA guideline

Figure 1. The Complementary and Alternative Healthcare Model.

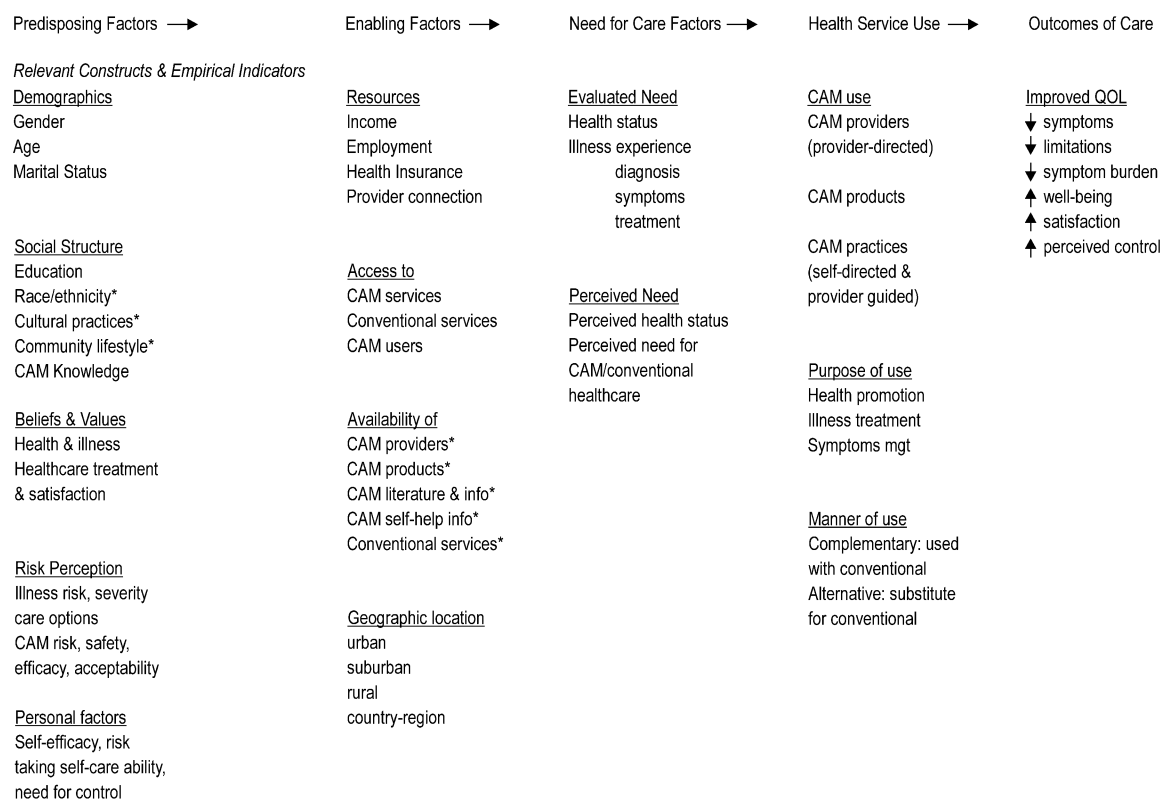
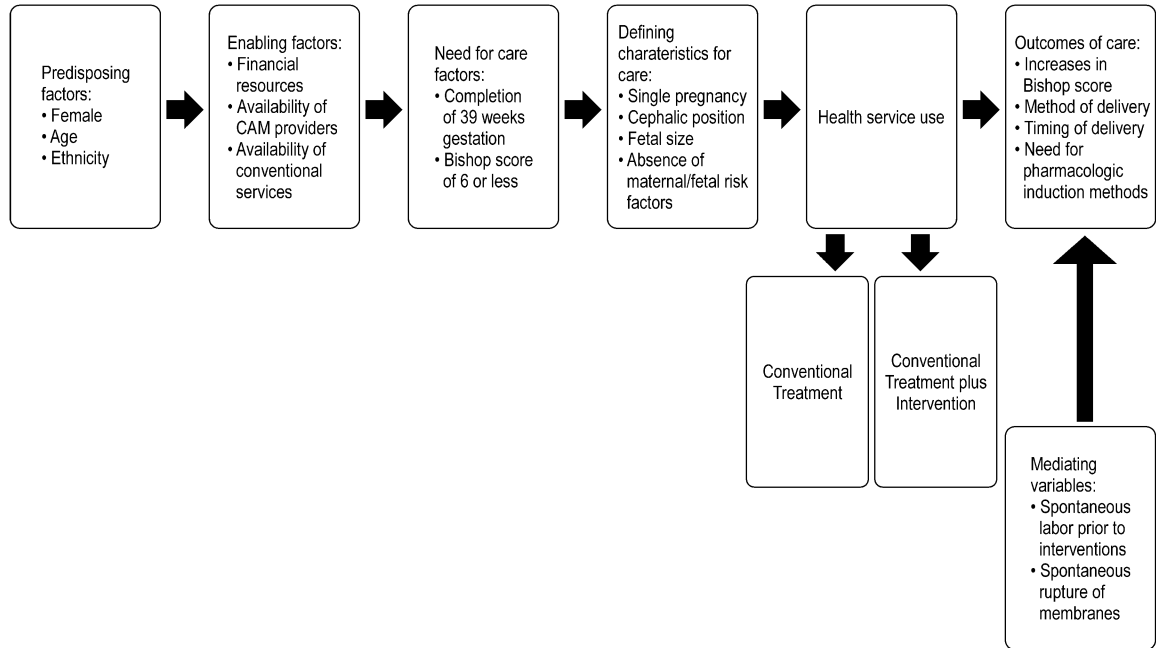


Figure 2. Complementary and Alternative Healthcare Model for in Cervical Ripening in Pregnant Women (Nauta 2016). Derived from The Complementary and Alternative Healthcare Model by Fouladbakhsh and Stommel (2007).



Chapter 3: Manuscript 2

Submitted to the Journal of Obstetric, Gynecologic & Neonatal Nursing

(Appendix J)

State of the Science on Acupuncture for Cervical Ripening and Labor Induction

Becky Nauta

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Diane Brage Hudson, Ph.D., RN

Dr. Susan Wilhelm, Ph.D., RN

Dr. Bernice Yates, Ph.D., RN

State of the Science on Acupuncture for Cervical Ripening and Labor Induction

Abstract

Objective: To report the state of the science on acupuncture as a method for promoting cervical ripening and induction of labor.

Data Sources: PubMed, Embase, Cumulative Index to Nursing and Allied Health Literature Database, Medline, Cochrane, and Scopus were searched for relevant studies published between January 1, 1985 and December 3, 2015. The following search terms were used: cervical length, cervical effacement, cervical ripening, labor induced, induced labor, acupuncture, electroacupuncture, traditional Chinese medicine, complementary therapy, pregnancy, primigravida, delivery, and nulliparous.

Study Selection: The initial search yielded 317 published articles. A detailed review of the search results retained only empirical studies written in English and focused on using acupuncture, electroacupuncture or sham acupuncture for promoting cervical ripening or labor induction (15 studies and 5 systematic reviews).

Data Extraction: Results reported by empirical studies contributing to the knowledge base regarding acupuncture use for cervical ripening and induction of labor.

Data Synthesis: Various acupuncture protocols have been applied for promoting cervical ripening and induction of labor. There is no specific recommendation or consensus regarding needling sites, timing, or strategy (needle parameters, insertion depth, and needle rotation technique). The recommendation noted in all studies was the need for well-designed randomized controlled studies using a consistent approach.

Conclusion: There is a need for future randomized studies using industry-standard methodology to assess the outcomes of electroacupuncture for promoting cervical ripening.

Keywords: Acupuncture, Electroacupuncture, Cervical Ripening, Labor, Induction

Précis: There is a need for future randomized studies using industry-standard methodology to assess the outcomes of electroacupuncture for promoting cervical ripening.

Introduction

The American College of Obstetricians and Gynecologists (ACOG) defines post-term pregnancy as a gestation beyond 42 weeks or 294 completed days from the date of the last menstrual cycle (ACOG, 2002). The risk for perinatal mortality increases as pregnancy continues beyond 41 weeks (ACOG, 2002). Annually, over one million pregnant women in the United States have labor induced (artificial initiation of the birth process) using pharmacological methods (Hamilton, Martin, & Ventura, 2011). Labor induction, however, carries risks as well. The use of oxytocin has been shown to increase the risk of hypotension, fetal heart rate deceleration, and fetal morbidity and mortality (Kunz, Loftus, & Nichols, 2013; Simpson & James, 2008). For the mother, labor induction with oxytocin involves administration of intravenous medication, bed rest, continuous electronic fetal monitoring, amniotomy, and insertion of an intrauterine pressure catheter. The latter is used to more closely monitor the fetus but can result in heightened discomfort during contractions for the mother (Simpson, 2013).

Induction should not be an elective intervention, and is reserved for those who have a documented medical need such as post-term pregnancy, premature rupture of membranes, fetal compromise, gestational hypertension, preeclampsia, or eclampsia (Simpson, 2013). A decision to induce labor represents a decision to deliver, so it is important that there is confidence that the initiation of labor will be successful. Among several factors to consider before initiating labor, ensuring adequate cervical ripening is key to a successful outcome. The potential for successful cervical ripening and subsequent positive initiation of labor can be assessed by using a pre-labor scoring system such as the Bishop score. A Bishop score of 6 or greater (ACOG, 2009) indicates the cervix is favorable for initiation of labor (pre-induction cervical ripening), which is associated with a lower risk for requiring cesarean birth and typically leads to spontaneous labor without the use of oxytocin (Simpson, 2013).

Acupuncture is a non-pharmacological method currently being explored in the clinical setting for its ability to promote cervical ripening in pregnant women. Acupuncture has been studied internationally with promising results in areas such as the management of chronic back pain, dental pain, fibromyalgia, idiopathic headache, postoperative nausea and vomiting, and osteoarthritis of the knee (Ernst, Pittler, & Wider, 2010). The purpose of the present paper is to report the state of the science on the use of acupuncture for promoting cervical ripening in pregnant women.

History of Acupuncture

Acupuncture is a small branch of Traditional Chinese Medicine (TCM) that is thought to have originated in China around 6000 BCE (MacPherson, Hammerschlag, Lewith, & Schnyer, 2008). The first document that outlines an organized system of diagnosis and treatment using acupuncture is *The Yellow Emperor's Classic of Internal Medicine*, dating back to 100 BCE (Ernst, Pittler, & Wider, 2010). The concept of energy meridians or Qi (energy) flow was well established at that time. Acupuncture was introduced in Europe in the 17th century as a part of TCM practice (Roemer, 2000). It was not until the 19th century that acupuncture was conducted as a simple needle pricking procedure, without consideration for the Chinese fundamental principles of holism. In the mid-20th century, principles of TCM began to be integrated into Western culture (Roemer, 2000).

Acupuncture uses metal needles and is performed on specific points on the body for diagnostic or therapeutic purposes. Acupuncture is a holistic therapy, exerting its effect not only at the location of the therapeutic stimulus, but also throughout the entire body. Acupuncture therapy is often called “energetic equilibrium”, as it has the ability to balance the disharmonic functions of the body by applying appropriate stimulation (Deadman & Al-Khafaji, 2007).

Background and Clinical Significance

The term labor refers to the process of moving the fetus from the intrauterine to the extrauterine environment. Clinically, labor is defined as regular uterine contractions resulting in

progressive cervical effacement and dilation, accompanied by fetal descent into the maternal pelvis. While there are multiple theories to explain the physiologic factors that initiate labor, the process is still not clearly understood (Simpson & Creehan, 2014).

During labor, the myometrium of the uterus changes from a quiet, stretched state to a contractile organ (Liao, Buhimschi, & Nichols, 2005). This change is precipitated by biochemical factors that stimulate myometrial activity and ultimately impact the cervix uteri. The cervix, a neck-like structure located at the bottom of the uterus, is composed of connective tissue and is usually firm and closed. When labor begins, the cervix undergoes rapid changes including ripening (becoming soft and distensible), effacement (thinning and shortening of the cervical canal), and dilation (becoming open to the uterus). Prostaglandin and oxytocin are the most important biochemical stimulators of myometrial activity. Prostaglandin synthesis during cervical ripening prepares the myometrium to respond to oxytocin (Liao et al., 2005). The release of endogenous oxytocin is caused by sensory stimulation of the lower genital track and cervical stretching, resulting in uterine contractions through Ferguson's reflex. Despite extensive research, the exact mechanisms underlying the initiation of spontaneous labor remain unclear (Simpson & Creehan, 2014).

Of the approximately 4 million births in the United States in 2011, one million required labor induction (Hamilton et al., 2011). The rate of induction has more than doubled since 1990 (Hamilton et al., 2011). If labor augmentation is considered in the calculation of the induction rate, approximately half of the laboring women in the United States receive artificial labor induction (Menacker & Martin, 2008).

The most important factor in predicting the success of labor and labor induction is cervical status (Simpson, 2013). Women who have labor induced with a Bishop score of less than 6 face multiple risk factors such as longer labors, maternal hypotension, fetal heart rate deceleration, and increased risk of cesarean delivery. Nulliparous women with an unfavorable cervix have a two-fold increase in the risk of cesarean birth (ACOG, 2009). Hofmeyr (2003)

noted that a Bishop score of 5 or less predicts that artificial rupture of membranes and oxytocin infusion are not likely to be successful. Further, a Bishop score of 5 or less is predictive of a higher incidence of cesarean delivery (Nielsen, Howard, Crabtree, Batig, & Pates, 2010).

Acupuncture may provide an effective solution for promoting cervical ripening. The mechanism underlying the effect of acupuncture on cervical ripening was proposed in a systematic review performed in 2006 (Curtis, Coeytaux, & Hapke, 2006). Specifically, acupuncture stimulates the release of beta-endorphins and adrenocorticotrophic hormone from the hypothalamus, which increases the levels of prostaglandin E2, resulting in thinning of the cervix (Curtis et al., 2006). The use of acupuncture for promoting cervical ripening has been documented in studies conducted worldwide (see Table 1). While the available literature demonstrates various results, all reports agree that acupuncture is a minimally invasive, low-risk procedure with minimal, if any side effects (Mayor, 2007; Roemer, 2000; Smith et al., 2012).

Methodology

For the present systematic review, the following databases were searched: PubMed, Embase, Cumulative Index to Nursing and Allied Health Literature Database, Medline, Cochrane, and Scopus. The following search terms were used: cervical length, cervical effacement, cervical ripening, labor induced, induced labor, acupuncture, electroacupuncture, traditional Chinese medicine, complementary therapy, first pregnancy, primigravida, first delivery, and nulliparous. The databases were searched for relevant papers published between January 1, 1985 and December 3, 2015.

The initial search yielded 317 published articles. We further considered only empirical studies published in English and focusing on the use of acupuncture, electroacupuncture, or sham acupuncture for cervical ripening or labor induction in pregnancy prior to labor (46 articles). After the full-text articles were reviewed for specific terminology describing cervical ripening or labor induction, 26 studies were excluded because they focused on topics such as acupressure, pain management, acupuncture during labor, transcutaneous electrical nerve stimulation, or

provided broad overviews of complementary therapy or acupuncture. Five systematic reviews and 15 studies were included in the final analysis (see Figure 3).

Results

Systematic Reviews

In a systematic review performed by Curtis, Coeytaux, and Hapke (2006), the authors searched for relevant papers published between 1988 and 2006 in the following databases: the Cochrane Database of Systematic Reviews, the Cochrane Pregnancy and Childbirth Group trials, Medline, Allied and Complementary Medicine, and Alt-Health Watch. Using the keywords acupuncture, obstetrics, labor, delivery, induction, and birth preparation, they retrieved more than 50 relevant articles, of which 30 were in English and addressed the aspect of acupuncture for induction of labor; however, early studies were usually descriptive case reports. Only three studies met the criteria for critical review (Harper et al., 2006; Rabl et al., 2001; Roemer et al., 1998). One of the issues highlighted by this systematic review is that there is a lack of clarification regarding the acupuncture procedure (e.g., selection of needling site, needle characteristics, type of stimulation, dose, frequency, depth of needle insertion, etc.) suitable for cervical ripening. The authors concluded that the mechanism of action should be studied further, especially via well-designed and adequately powered clinical trials, in order to clarify whether acupuncture could become a valid and cost-effective support to the management of induction and parturition (Curtis et al., 2006).

Lim, Wilkinson, Wong, and Cheng (2009) conducted a review of studies describing the use acupuncture for the induction of labor and published in English between 1970 and 2008. Their inclusion criteria covered all human acupuncture employed in pregnant women carrying a viable fetus due for third-trimester induction of labor. Only ten studies fit these criteria, all assessing the impact of acupuncture on labor induction. Two randomized controlled trials reported no statistically significant effects of acupuncture (Harper et al., 2006; Selmer-Olsen et al., 2007), and described results that are more suggestive than definitive, because of small sample

size, lack of uniformity of gestational age at enrollment, and lack of specification regarding sweeping of membranes. The conclusion of this review was that, although the definitive role of acupuncture in inducing labor is yet to be established, the available data suggest that acupuncture may be beneficial in labor induction, but further randomized clinical trials are needed to establish the effectiveness of acupuncture for labor induction (Lim et al., 2009).

Xu and MacKenzie (2012) reviewed seven studies to assess present theories regarding the mechanisms underlying the effect of acupuncture, current clinical uses, methodology, and clinical outcomes. The authors expressed concern that published studies may not distinguish between nulliparae and multiparae women, which would strongly bias the results regarding the duration of labor or the need for induction. Only two studies included in this review accounted for parity in their analysis (Gaudermack et al., 2006; Selmer-Olsen et al., 2007). Gaudermack et al. (2006) reported a shorter duration of active labor ($p = 0.03$) and decreased need for oxytocin ($p = 0.018$) for women receiving acupuncture therapy, while Selmer-Olsen et al. (2007) reported no significant difference ($p = 0.34$). Xu and MacKenzie (2012) also noted the need for more rigorous randomized trials to explore the use of acupuncture for intrapartum care for cervical ripening, and concluded there was no clinical benefit in using acupuncture for labor induction, based on lack of significant improvement observed in six of the seven intervention studies analyzed.

A fourth review by Dowswell, Kelly, Livio, Norman, and Alfirevic (2010) included 28 studies involving a total of 2616 women, and examined different methods of labor induction. Women who received treatment at home or were sent home after initial treatment and monitoring at the hospital were included in the study. This extensive review included women receiving vaginal prostaglandin (five studies), intracervical prostaglandin (seven studies), vaginal misoprostol (four studies), different doses of misoprostol (one study), oral misoprostol (one study), vaginal isosorbide mononitrate (three studies), mifepristone (five studies), estrogens (one study), and acupuncture (one study). The acupuncture study (Harper, 2006) included only

primiparous women and concluded that the mean time to delivery was shorter (by approximately 21 hours) in the acupuncture group than in the control group receiving conventional medical care. Other findings, such as vaginal delivery not achieved within 24 hours with additional induction agents, did not reach statistical significance (Doswell et al., 2010).

The final systematic review found in the Cochrane database was authored by Smith and Crowther (2012). Their selection criteria retrieved 14 clinical trials comparing the effect of acupuncture (used for third-trimester cervical ripening or labor induction) with that of placebo, no treatment, or other methods. Evidence of a change in cervical maturation was found in women receiving acupuncture compared with the those receiving sham control (mean difference, 0.40; 95% confidence interval [CI], 0.11 to 0.69; one trial; 125 women), or usual medical care (mean difference, 1.30; 95% CI, 0.11 to 2.49; one trial; 67 women) (Smith & Crowther, 2012). Nevertheless, the duration of labor was shorter in women who received usual care than in those who received acupuncture (average standardized mean difference, 0.67; 95% CI, 0.18 to 1.17; one trial; 68 women).

The conclusion from all five reviews was that there was a need for well-designed randomized controlled trials to evaluate the role of acupuncture for cervical ripening and labor induction.

Factors Influencing the Effectiveness of Acupuncture Therapy

Many factors are thought to influence the effectiveness of acupuncture for cervical ripening and induction of labor in pregnant women, including the type of intervention (acupuncture, electroacupuncture, sham acupuncture), gestational age, needling sites, and the frequency of the interventions. Gestational age is a particularly important aspect, as fetal maturity and well-being are related to the number of completed weeks in utero. These factors should be considered when evaluating the outcomes of cervical ripening and labor induction (Deadman & Al-Kahfaji, 2007; Simpson, 2013).

Type of Intervention

Three primary types of acupuncture interventions have been used. A standard acupuncture needling technique applies stimulation of anatomical points using a manual process of needle insertion and manipulation along specific meridians (traditionally defined as pathways of energy flow in the body). Sham acupuncture (placebo) applies stimulation of acupuncture points that do not lie along a true meridian, and uses a manual process of shallow needle insertion or site pressure without insertion (Deadman & Al-Khafaji, 2007). Electroacupuncture uses a small electrical charge attached to the acupuncture needle, stimulating the neurotransmitters along specific meridians (Deadman & Al-Khafaji, 2007). Several researchers have used the standard acupuncture and sham acupuncture treatments for cervical ripening and labor induction (Ajori et al., 2012; Asher et al., 2009; Modlock et al., 2010; Roemer et al., 1998; Smith et al., 2008). Roemer et al. (1998) determined that acupuncture using standard needling techniques was associated with reduced labor duration. However, Asher et al. (2009) used the same standard needling techniques and reported that, compared to sham acupuncture, acupuncture was not effective in initiating spontaneous labor or reducing the rate of cesarean delivery.

In five randomized studies, the outcomes were compared between groups receiving standard acupuncture and control groups, to assess if acupuncture was effective for cervical ripening and initiation of labor (Gaudermack et al., 2006; Mucuk & Baser, 2013; Neri et al., 2013; Rabl et al., 2001; Selmer-Olsen et al., 2007). All researchers used a standard needling approach, without electrostimulation. Two trials (Neri et al., 2013; Selmer-Olsen et al., 2007) reported no reduction in the need for mechanical or pharmacological induction. On the other hand, Mucuk and Baser (2013) and Rabl et al. (2001) described a reduction in labor duration in the acupuncture groups, although acupuncture did not appear to be effective for labor induction. Only Gaudermack et al. (2006) reported a reduction in the need for oxytocin ($p = 0.018$) as well as a shorter duration of labor ($p = 0.03$) and shorter active phase of labor ($p = 0.002$) for women in the acupuncture group.

Citkovitz et al. (2009) investigated an acupuncture group matched to historical controls consisting of labor and delivery cases managed during the study period. Controls were matched to four metrics that were most likely to affect the clinical outcomes being studied: maternal age, gestational age, parity, and oxytocin use (for augmentation, induction, or not at all). Each woman was matched to at least one control. If two or three matches were available, all were used. Citkovitz et al. (2009) used electrostimulation at a continuous frequency of 10 Hz and reported that women who received acupuncture were less likely to require cesarean section (7% of the acupuncture group vs. 20% on the historical control group; $p = 0.004$).

Anderson et al. (2013) compared four types of intervention: sweeping of membranes, acupuncture, acupuncture with sweeping of membranes, and no intervention (control). They used traditional needling techniques and no electrostimulation. No difference between the acupuncture and control groups ($p = 0.76$) was found regarding the rate of spontaneous labor prior to induction. Significantly more women went into labor before planned induction ($p = 0.02$) after receiving sweeping (with or without acupuncture) than after receiving only acupuncture or no intervention.

Gribel et al. (2011) used two intervention methods, one involving the use of intravaginal misoprostol, and the other involving electroacupuncture, and found similar results regarding frequency and time of induction. However, absence of obstetric complications, longer duration of labor ($p = 0.036$), and higher satisfaction ($p = 0.046$) were noted for participants in the acupuncture group, whereas higher frequency of cesarean section ($p = 0.014$) and obstetric complications (9.3%) were noted for participants in the misoprotol group (Gribel et al., 2011).

Harper et al. (2006) and Gaudet et al. (2008) used electroacupuncture as well; however, Harper and colleagues (2006) used a control group as a comparison, whereas Gaudet et al. (2008) used sham acupuncture. Harper et al. (2006) used electroacupuncture with 2 Hz and two specific sites, and found that participants in the electroacupuncture group had a higher tendency to labor spontaneously (70%) than did participants in the control group (50%), and were less likely to

deliver by cesarean section (17% vs. 39%). Gaudet et al. (2008) used electroacupuncture at 2 Hz and demonstrated a delivery interval of 62 hours in favor of the acupuncture group. Participants in the acupuncture group also had shorter labor (mean, 9.42 ± 4.0 hours) than that noted in the sham acupuncture group (mean, 11.78 ± 4.1 hours) (Gaudet et al., 2008).

In summary, while results vary, the researchers who used electroacupuncture (Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006) generally obtained positive results, demonstrating adequacy for cervical ripening, spontaneous labor, shorter duration of labor, and reduced rate of cesarean section.

Gestational Age

A full-term pregnancy is defined as completion of 40 weeks or 280 days of gestation. Fetal lung maturity depends on achieving full-term pregnancy and is important in predicting the risk of morbidity and mortality. Furthermore, children born before 39 weeks of gestation may also demonstrate negative neurologic effects (Simpson, 2013). The Association of Women's Health Obstetric and Neonatal Nurses (AWHONN) have instituted the "Don't Rush Me. . . Go the Full 40" campaign (2014) in an effort to promote the value of a full-term pregnancy.

Therefore, the timing of the acupuncture intervention and its subsequent effectiveness should be carefully considered in relation to supporting a gestation of 40 weeks, as well as preventing the onset of spontaneous labor prior to the need for pharmacological induction. According to the American Academy of Pediatrics and ACOG (2012), pharmacological induction is often scheduled at the completion of 41 weeks and 3 days of gestation.

Sensitivity to acupuncture was reported to vary with gestational age. Use of acupuncture (acupuncture and sweeping of membranes, acupuncture and sham, and acupuncture) at 41 weeks of gestation was not effective in reducing the need for pharmacological induction of labor (Andersen et al., 2013; Modlock, Nielsen, & Uldbjerg, 2010; Smith, Crowther, Collins, & Coyle, 2008). However, acupuncture at 40 weeks of gestation demonstrated more promise for cervical ripening and labor induction.

Neri, Monari, Salvioli, and Facchinetti (2013) found that, compared to women in the control group, women receiving acupuncture did not achieve labor induction or decreased duration of labor ($p < 0.09$). On the other hand, Gribel, Coca-Velarde, and Moreira de Sa (2011) reported a significant difference ($p = 0.014$) in the rate of vaginal delivery between the acupuncture group (22 deliveries) and the control group (10 deliveries). In another study involving women at 40 weeks of gestation, Rabl, Ahner, Bitschnau, Zeisler, and Husslein (2001) noted that the average time from the estimated date of confinement to delivery was 5.0 days in the acupuncture group and 7.9 days in the control group ($p = 0.03$).

Participants were enrolled in studies by Gaudet et al. (2008) and Harper et al. (2006) at the completion of at least 39 weeks of gestation. Both studies reported that the interval from intervention to delivery was significantly shorter in the acupuncture group (by 62 hours in the study by Gaudet et al., and by 21 hours in the study by Harper et al.). Gaudet et al. (2008) also reported that participants in the acupuncture group had shorter labor (by 2 hours and 20 minutes) than that noted for participants in the sham acupuncture group. Harper et al. (2006) reported that spontaneous labor tended to be more common in the acupuncture group than in the control group (70% vs. 50%), and women receiving acupuncture were less likely to deliver by cesarean section (17% vs. 39% in the control group).

Participants enrolling in acupuncture trials beginning at 38 weeks of gestation did not demonstrate a reduced need for induction of labor (Ajori et al, 2012; Asher et al., 2009) after receiving acupuncture than after receiving sham acupuncture or no intervention. In another study, outcomes in participants enrolled at 36 weeks of gestation were compared between the acupuncture group and a sham (placebo) group, or between the acupuncture group and a group receiving conventional care (Roemer et al., 1998). The true acupuncture group demonstrated reduced labor duration, increased Bishop scores, and improved funneling. Mucuk and Baser (2013) enrolled participants during active labor, who received acupuncture at various needling sites. The time from intervention to initiation of labor was 6.2 ± 6.0 hours in the LI4 acupuncture

group, 7.2 ± 6.1 hours in the SP6 acupuncture group, and 8.2 ± 9.9 hours in the control group, indicating that the acupuncture groups tended to have shorter duration of labor.

In summary, based on studies reviewed, acupuncture therapy initiated at the completion of 39 and 40 weeks of gestation appears to be more effective for cervical ripening and allows women to labor spontaneously (Citkovitz et al., 2009; Gaudermack et al., 2006; Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006; Rabl et al., 2001). When initiated prior to the completion of 39 weeks of gestation or after 41 weeks of gestation, acupuncture did not appear to be effective for cervical ripening or reducing the need for mechanical or pharmacological induction of labor, as reported in six studies (Ajori et al., 2012; Andersen et al., 2013; Asher et al., 2009; Modlock et al., 2010; Selmer-Olsen, 2007; Smith et al., 2008). Only one study reported that acupuncture performed once weekly beginning at 36 weeks of gestation was effective for promoting cervical ripening (Roemer et al., 1998). Similarly, only one study found that patients in the acupuncture group enrolled during the active phase of labor experienced a reduction in labor duration (Mucuk & Baser, 2013).

Needling Sites (Acupoints) and Frequency of Treatments

The acupuncture protocol represents another potential factor influencing the sensitivity of the cervix to acupuncture therapy. Acupuncture uses acupoints along meridians, which represent channels for transporting qi (energy) throughout the body, enabling to protect the body, respond to dysfunction, and transmit qi to diseased areas (Deadman & Al-Khafaji, 2007). By stimulating an acupuncture point, it is believed that the qi and blood of the entire meridian may be regulated (Deadman & Al-Khafaji, 2007). Needling protocols are defined in terms of the acupoints, number of needles used, and number of acupuncture treatments administered.

For example, needling protocols involving the L14 point are thought to have a strong effect on promoting cervical ripening and promoting labor. The L14 point is found on the dorsum of the hand, between the first and second metacarpal bones, at the midpoint of the second metacarpal bone, close to its radial border (Deadman & Al-Khafaji, 2007). Many researchers

have used this particular acupoint for promoting cervical ripening and inducing labor (Ajori et al., 2012; Andersen et al., 2013; Asher et al., 2009; Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006; Modlock et al., 2010; Mucuk & Baser, 2013; Neri et al., 2013; Rabl et al., 2001; Smith et al., 2008). Citkovitz et al. (2009), Selmer-Olsen et al. (2007), and Gaudernack et al. (2006) individualized their approach using a variety of acupoints based on patient symptoms, fetal position, and the acupuncturist diagnosis regarding the balancing of qi. Several researchers have also used the acupoint SP6, located on the medial side of the lower leg, while five studies used acupoint ST36, located on the cheek. Both acupoints stimulate cervical ripening and labor induction. Other acupoints used in at least one study for cervical ripening and labor induction include LI3, BL23, GV20, BL 67, LR3, BL60, BL31, BL54, ST43, UB31, UB32, and CV4/REN4 (Ajori et al., 2012; Andersen et al., 2013; Asher et al., 2009; Gaudernack et al., 2006; Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006; Modlock et al., 2010; Roemer et al., 1998; Selmer-Olsen et al., 2007; and Smith et al., 2008).

Unfortunately, the number of needles and acupuncture sites in a single treatment was often not specified. Betts (2006) recommends using only six to eight needles or sites, to prevent excessive stimulation, and all reviewed studies follow this recommendation to limit the number of needles used to eight or fewer. Neri et al. (2013), Mucuk and Baser (2013) and Rabl et al. (2001) used two acupoints, whereas other researchers used three acupoints (Ajori et al., 2012) or four acupoints (Asher et al., 2009; Gaudet et al., 2008; Harper et al., 2006; Modlock et al., 2010) for cervical ripening and labor induction. Smith et al. (2008) and Gribel et al. (2011) used six acupoints, while Anderson et al. (2013) used eight acupoints. Citkovitz et al. (2009), Selmer-Olsen et al. (2007), and Gaudernack et al. (2006) used a semi-standardized approach based on patient symptoms and fetal position, and did not report the number of acupoints used.

The frequency of acupuncture treatment varies greatly. Several researchers administered acupuncture two to three times within a 24–48-hour period (Gribel et al., 2011; Modlock et al., 2010; Mucuk and Baser 2013; Smith et al., 2008), while other researchers offered acupuncture

treatments every other day over a period of 1 to 2 weeks (Ajori et al., 2012; Andersen et al., 2013; Asher et al., 2009; Gaudet et al., 2008; Harper et al., 2006; Neri et al., 2013; 2008; Rabl et al., 2001).

When considering all aspects of the use of acupuncture for promoting cervical ripening and induction of spontaneous labor, the following aspects may be concluded: use of key acupoints (L14, SP6) seems essential; electroacupuncture was more effective than the traditional needling technique (Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006); repeated treatments appeared to be more effective for inducing spontaneous labor, reducing labor duration, and reducing the rate of cesarean section (Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006); acupuncture is not effective at 41 completed weeks of gestation, and may have limited benefit at 40 completed weeks; patients completing 39 weeks of gestation who receive electroacupuncture at key acupuncture points over a period of 2 weeks were less likely to deliver by cesarean section, demonstrated a reduction in labor duration, and were more likely to deliver spontaneously without the need for labor induction.

Implications for Clinical Practice, Education, and Research

The increase in the use of labor induction methods over the past decade has forever changed the clinical arena for all care providers. Many women who require labor induction have an unfavorable cervix (Bishop score of less than 6), which is associated with higher rates of failed induction and subsequent cesarean section (Amorosa & Stone, 2015). Cervical ripening, particularly in nulliparous women, may take many hours. Cervical ripening performed safely in an outpatient setting may be an option in the future (Amorosa & Stone, 2015). Nurses who once cared for women who labored spontaneously now spend a significant amount of time administering oxytocin and closely monitoring the effects of oxytocin on the pregnant woman and fetus. Staffing requirements have increased, necessitating one on one staffing during oxytocin administration, thus increasing the cost of healthcare for childbearing women (Simpson, 2013).

Moreover, oxytocin mismanagement is now a significant factor in perinatal liability (Simpson, 2013).

Educating women about the risks and benefits of labor induction is essential, to enable pregnant women to make informed choices. Educational resources should include information regarding the physiological benefits of a full-term pregnancy for both the mother and the infant. AWHONN's recent campaign, "Don't Rush Me...Go the Full 40" provides an excellent starting point for creating relevant educational resources (AWHONN, 2012). The new patient education initiative "Choosing Wisely", developed by ACOG, also represents a helpful educational resource for women considering labor induction (ACOG, 2013). ACOG advises women against scheduling elective, non-medically indicated inductions of labor between 39 and 41 weeks unless the cervix is deemed favorable (ACOG, 2013). Gestational age, pelvic adequacy, fetal size, fetal presentation, and cervical status should also be assessed prior to labor induction (Simpson, 2013). Educating women about the complementary option for cervical ripening with acupuncture could potentially decrease the rate and severity of complications associated with labor induction.

If induction is deemed medically necessary, the use of acupuncture at the completion of 39 weeks of gestation as means to stimulate cervical ripening and subsequent positive initiation of labor may be beneficial in some patients. As noted by Simpson (2013), pre-induction cervical ripening can minimize the risk of cesarean birth as well as induce spontaneous labor without the use of oxytocin (Simpson, 2013). However, the use of acupuncture for cervical ripening and labor induction requires that pregnant women and their healthcare providers be well informed regarding this type of intervention, as well as its risks and benefits.

Unfortunately, the available literature does not always provide a detailed description of the acupuncture and control interventions, especially regarding needle placement, treatment regimen, rationale, and frequency of interventions. After recognizing the gap in the literature, an international group of acupuncture researchers met in July 2001 to discuss the design of clinical trials involving acupuncture. MacPherson, White, Cummings, Jobst, and Niemtzw (2002)

provided a list of new guidelines in a short report called the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) recommendations. The STRICTA recommendations stipulate that the acupuncture rationale, needling details, treatment regimen, co-interventions, and practitioner background should be explicitly described in all studies reporting the outcomes of acupuncture. Future research on the outcomes of acupuncture are expected to adhere to the STRICTA recommendations.

In pregnant women, acupuncture is overall well tolerated and thought to be safe. Several studies have suggested that acupuncture may be associated with increased Bishop scores, initiation of spontaneous labor, and decrease in labor duration (Citkovitz et al., 2009; Gaudernack et al., 2006; Gaudet et al., 2008; Gribel et al., 2011; Harper et al., 2006; Mucuk et al., 2013; Rabl et al., 2001; Roemer et al., 1998). However, the volume of available literature on acupuncture as a method of promoting cervical ripening and labor induction is relatively small, and further research is warranted before definitive recommendations can be issued (Amorosa & Stone, 2015). For example, while outcomes were typically compared between conventional care and acupuncture groups, or between acupuncture and sham acupuncture groups, no studies have concomitantly considered conventional care, traditional acupuncture, and electroacupuncture. Thus, a three-arm comparison study is warranted to determine if electroacupuncture is more effective than traditional acupuncture or conventional care for promoting cervical ripening.

Conclusions

Adequate cervical ripening is a critical component for spontaneous labor and subsequent vaginal delivery (Frederiks, Lee, & Dekker, 2012). To date, the traditional method used to stimulate the initiation of labor involves the use of pharmaceutical agents. However, there is a demand for alternative methods for promoting cervical ripening and inducing labor (Steel et al., 2012; Strouss et al., 2014). The use of acupuncture for promoting cervical ripening and inducing labor represents a minimally invasive and low risk solution, which has been found to be effective in several studies (Citkovitz et al., 2009; Gaudernack et al., 2006; Gaudet et al., 2008; Gribel et

al., 2011; Harper et al., 2006; Mucuk et al., 2013; Rabl et al., 2001; Roemer et al., 1998).

Furthermore, the use of acupuncture is believed to provide an opportunity for using the body's natural energy flow to enhance cervical ripening and initiate labor, as well as to potentially avoid the myriad of interventions required when using pharmacological labor-induction methods. There is a need for future randomized studies using industry-standard methodology to thoroughly assess the outcomes of electroacupuncture for promoting cervical ripening in women completing 39 weeks of gestation. Such randomized controlled studies with adequate power and applying STRICTA protocols may allow to demonstrate the effectiveness and safety of acupuncture for cervical ripening and labor induction. In particular, the use of electroacupuncture for cervical ripening may have a significant potential to increase the percentage of natural births, reduce morbidity and mortality rates related to the use of oxytocin, as well as increase patient satisfaction with the birth experience.

FIGURES

Figure 3: Literature Review Methodology

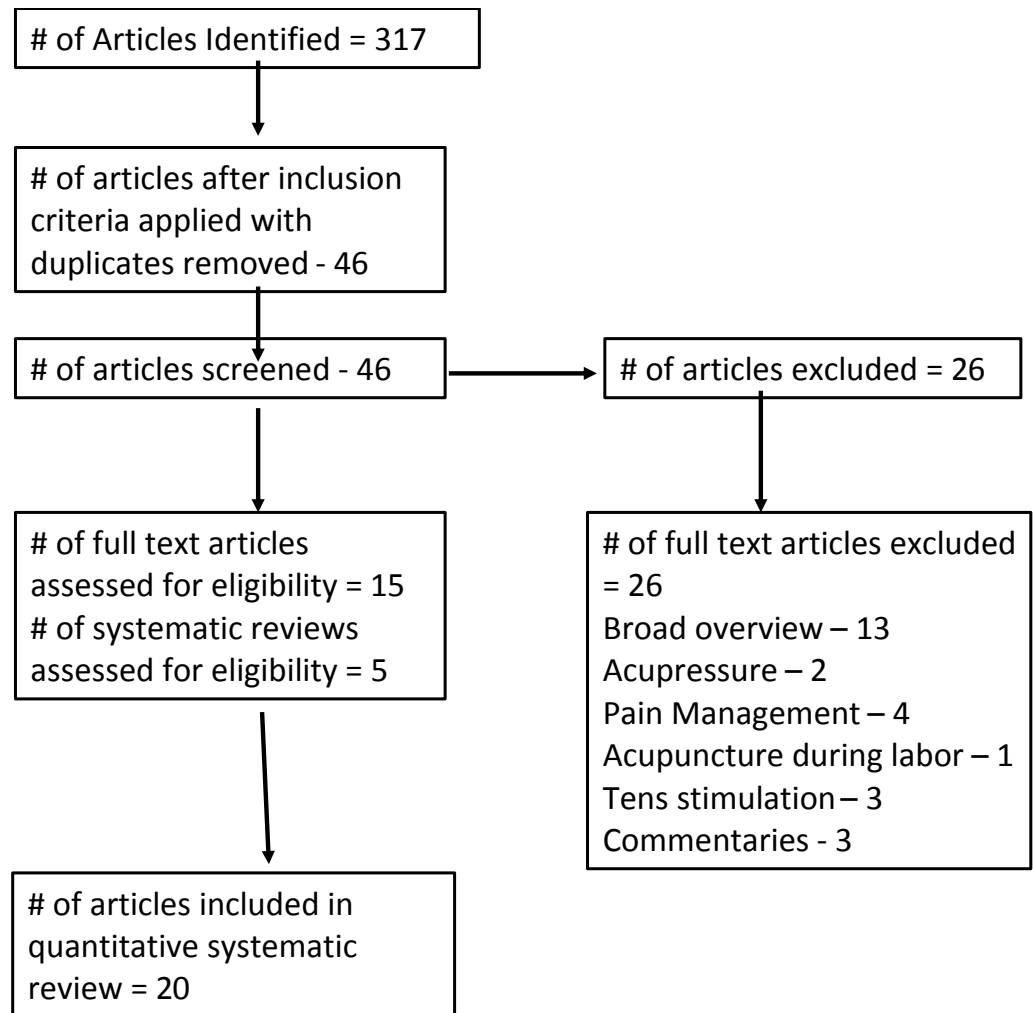


Table 2. Summary of Studies Using Acupuncture for Promoting Cervical Ripening and Inducing Labor

| First Author | N | Groups | Outcomes |
|---|---|--|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Ajori et al. 2012 Iran Double-blind randomized controlled study | 75 ≥38 weeks 30 min, maximum twice weekly | SAC* (<i>n</i> = 37): non-sites AC** (<i>n</i> = 38): • SP6 • L14 • BL67 | Spontaneous labor: • AC, 94.7% • SAC, 89.2% • <i>p</i> = 0.43 Time to delivery: • AC, 7.76 ± 6.84 days • SAC, 9.46 ± 5.97 days • Not significant (<i>p</i> = 0.06) |
| Andersen et al. 2013 Denmark Experimental study | 407 41 weeks 30 min twice, for both groups | Sweeping (<i>n</i> = 103) Control (<i>n</i> = 100) AC (<i>n</i> = 100) AC + sweeping (<i>n</i> = 100) • L14 | No significant difference among the groups in spontaneous labor prior to induction (<i>p</i> = 0.35) Sweeping was |

| First Author | N | Groups | Outcomes |
|--------------------|-----------------|--|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| with control group | | <ul style="list-style-type: none"> • ST36 • LR3 • BL60 • BL31 • BL32 • GV20 • SP6 | <p>associated with higher incidence of spontaneous labor ($p = 0.02$)</p> <p>AC vs. Control, median (95% CI):</p> <ul style="list-style-type: none"> • AC, 53% (42.9%-62.7%) • Control, 54% (43.7%-64.0%) • $p = 0.89$ <p>Sweeping vs. Control:</p> <ul style="list-style-type: none"> • Sweeping, 55% (56.1%-75.0%) • Control, 54% (43.7%-64.0%) • $p = 0.09$ |

| First Author | N | Groups | Outcomes |
|---------------------------------------|---|--|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| | | | <p>AC + Sweeping vs. Control:</p> <ul style="list-style-type: none"> •AC + Sweeping, 64% (53.8%–73.4%) •Control, 54% (43.7%–64.0%) • $p = 0.2$ <p>AC vs. Sweeping:</p> <ul style="list-style-type: none"> •AC, 53% (42.9%–62.7%) •Sweeping, 68% (56.1%–75.1%) • $p = 0.07$ |
| Asher et al. 2009 United States | 89 ≥38 weeks 5 times every 2 weeks for both groups | Control ($n = 30$) SAC ($n = 29$): non-sites AC ($n = 30$) | Compared to SAC or regular medical care, AC was not effective in initiating |

| First Author Year Country Type of Study | N Gestational Age Regimen | Groups Needling Sites | Outcomes |
|--|---|---|--|
| Randomized sham- controlled trial | | <ul style="list-style-type: none"> • L14 • SP6 • BL32 • BL54 | <p>spontaneous labor ($p = 0.66$) or reducing the rate of cesarean delivery ($p = 0.37$).</p> <p>Time to delivery from enrollment, median (95% CI):</p> <ul style="list-style-type: none"> •SAC, 9.3 days (7.1–11.5 days) •Regular medical care, 11.9 days (9.7–14.2 days) •AC, 12.2 days (10.0–14.4 days) •$p = 0.20$ |
| Citkovitz et al. 2009 United States Case-controlled | 45 M: 39.2 weeks Semi-standard approach based on patient symptoms | <p>Historical controls ($n = 127$)</p> <p>EAC*** ($n = 45$):</p> <ul style="list-style-type: none"> • Electrostimulation • Continuous | <p>Required cesarean section:</p> <ul style="list-style-type: none"> • EAC, 3 patients, 7% • Control, 25 patients, 20% |

| First Author | N | Groups | Outcomes |
|----------------------|------------------------|---|--|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| pilot study | and fetal position. | <ul style="list-style-type: none"> • 10 Hz • Amplitude to patient comfort level | <p>Odds ratio of cesarean section (EAC versus control), 0.21 (95% CI, 0.08–0.61)</p> <ul style="list-style-type: none"> • $p = 0.0004$ |

| First Author | N | Groups | Outcomes |
|--|--|---|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Gaudernack et al. 2006 Norway Randomized controlled trial | 91 40 weeks (term) 20 min, one-time intervention | Control ($n = 48$) AC** ($n = 43$) <ul style="list-style-type: none"> • ST36 • CV4 • Individualized tx | AC associated with significantly reduced duration of labor: <ul style="list-style-type: none"> • Mean difference, 1.7 hours • $p = 0.03$ Significant reduction in the need for oxytocin infusion to augment labor for AC: <ul style="list-style-type: none"> • odds ratio, 2.0 • $p = 0.018$ Significantly shorter duration of active phase of labor for AC: <ul style="list-style-type: none"> • Mean difference, 3.6 hours • $p = 0.0002$ |

| First Author | N | Groups | Outcomes |
|--|--|---|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Gaudet et al. 2008 Canada Pilot randomized controlled trial | 16 39 weeks to 40 + 3 weeks (SAC & EAC) • Electrostimulation • 2 Hz • Twice weekly | SAC ($n = 7$) • SAC sites adjacent to AC sites EAC ($n = 9$) • SP6 • ST43 • BI60 • L14 | Mean time from first treatment to delivery • EAC, 146 ± 91.6 hours • SAC, 208 ± 61.0 hours Mean time of labor to delivery • EAC, 9.42 ± 4.0 hours • SAC, 11.78 ± 4.1 hours |
| Gribel et al. 2011 Brazil Randomized | 72 ≥ 40 weeks Misoprostol (M): • 25 mg intravaginal | Misoprostol ($n = 35$) (3 patients excluded, for a total of $n = 32$) EAC ($n = 37$) (2 patients excluded, | EAC and M have similar results for promoting cervical ripening: • $p = 0.28$ |

| First Author | N | Groups | Outcomes |
|------------------|--|--|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| controlled trial | <ul style="list-style-type: none"> • q6h • maximum 4 tablets in 24 hours <p>EAC:</p> <ul style="list-style-type: none"> • Electrostimulation • q7 h • maximum 3 sessions/24 hours | <p>for a total of $n = 35$)</p> <ul style="list-style-type: none"> • L14 • ST36 • L13 • SP6 • BL23 • BL32 | <p>EAC associated with a significantly higher frequency of vaginal delivery:</p> <ul style="list-style-type: none"> • $p = 0.02$ <p>Significant difference regarding labor duration:</p> <ul style="list-style-type: none"> • EAC, 404 ± 201 min • M, 279 ± 161 min • $p = 0.0362$ <p>Delivery type:</p> <p>Normal:</p> <ul style="list-style-type: none"> • EAC, 22 • M, 10 <p>Forceps:</p> <ul style="list-style-type: none"> • EAC, 2 • M, 1 <p>Cesarean delivery:</p> |

| First Author | N | Groups | Outcomes |
|--|---|--|--|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| | | | <ul style="list-style-type: none"> • EAC, 11 • M, 21 • $p = 0.014$ |
| Harper et al. 2006 United States Randomized controlled trial | 56 39 4/7 weeks (control) 41 weeks (EAC) • 3 of 4 days • 30 min • 2 Hz for UB31 | Control ($n = 26$) EAC ($n = 30$) • L14 • SP6 • UB31 • UB32 | Mean time to delivery: • EAC, 124 \pm 86.7 hours • Control, 145 \pm 82.7 hours • $p = 0.36$ Spontaneous labor: • EAC, 70% • Control, 50% • $p = 0.12$ Cesarean delivery: • EAC, 17% • Control, 39% • $p = 0.07$ |

| First Author | N | Groups | Outcomes |
|----------------------|------------------------|---|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Modlock et al. | 125 | SAC (<i>n</i> = 63) | Primary endpoint |
| 2010 | 41 weeks | <ul style="list-style-type: none"> • Same points | (labor or delivery |
| Denmark | Twice on the same | <ul style="list-style-type: none"> • Blunt needles | within 24 hour): |
| | day | AC (<i>n</i> =62) | <ul style="list-style-type: none"> • AC, 7; 95% CI: 5– |
| Double-blind | | <ul style="list-style-type: none"> • L14 | 23 |
| randomized | | <ul style="list-style-type: none"> • SP6 | <ul style="list-style-type: none"> • SAC, 8;95% CI: 6– |
| controlled | | <ul style="list-style-type: none"> • GV20 | 25 |
| study | | <ul style="list-style-type: none"> • BL67 | <ul style="list-style-type: none"> • <i>p</i> = 0.79 |

| First Author | N | Groups | Outcomes |
|--|---|--|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Mucuk & Baser 2013 Turkey Experimental study with control group | 120 Active phase of labor • Bilateral stimulation • 10 min/session • Total: 20 min | Control ($n = 40$) • No stimulation AC L14 ($n = 40$) AC SP6 ($n = 40$) | Cervical dilation values: • LI4, 6.0 cm • SP6, 5.0 cm • Control, 4.5 cm • $p = 0.0001$ Time from hospital admission to delivery: • LI4, 17.1 ± 15.1 hours • SP6, 20.0 ± 14.8 hours • Control, 18.6 ± 15.3 hours • $p = 0.706$ Time from intervention to delivery: • LI4, 6.2 ± 6.0 hours • SP6, 7.2 ± 6.1 hours • Control, 8.2 ± 9.9 hours |

| First Author | N | Groups | Outcomes |
|--------------------------------|---|--|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Neri et al. | 202 | Control ($n = 96$) | Women receiving AC |
| 2013 | 40 2/7 weeks | AC ($n = 99$) | tended to deliver |
| Italy | Every odd day until planned induction at | (7 women dropped out) | earlier than women in the control group ($p =$ |
| Randomized controlled trial | 41 5/7 weeks | <ul style="list-style-type: none"> • L14 • SP6 | 0.09), per the results of a survival analysis that excluded women requiring labor induction. |
| | | | Rate of induction: |
| | | | <ul style="list-style-type: none"> • Control, 20% • AC, 17% |
| | | | Second stage of labor for nulliparous women: |
| | | | <ul style="list-style-type: none"> • Control, 43.14 ± 26.3 min • AC, 58.2 ± 30 min • $p = 0.05$ |

| First Author | N | Groups | Outcomes |
|--|---|---|--|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Rabl et al. 2001 Germany Randomized controlled trial | 45 40 weeks Cervical exam q2 days AC q 2 days | Control ($n = 20$) AC ($n = 25$) • L14 • SP6 | Time from estimated date of confinement to delivery: • Control, 7.9 days • AC, 5.0 days • $p = 0.03$ Time from first positive fibronectin test to delivery: • Control, 4.2 days • AC, 2.3 days • $p = 0.08$ Oxytocin utilization: • Control, 65% • AC, 56% • $p = 0.54$ |
| Roemer et al. | 878 | Control ($n = 325$) | AC group showed |

| First Author | N | Groups | Outcomes |
|------------------|-----------------------|---|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| 1998 | 36 weeks | SAC* (<i>n</i> = 224) | reduced labor |
| Germany | 25 min/weekly | AC** (<i>n</i> = 329) | duration, increased |
| Randomized | | <ul style="list-style-type: none"> • SP6 • ST36 • GB34 • BL67 | Bishop scores, and |
| controlled trial | | | improved funneling. |
| Selmer-Olsen | 102 | Control (<i>n</i> = 51) | Distribution of time |
| et al. | M: 38.9 weeks | AC (<i>n</i> = 51) | from acupuncture |
| 2007 | 30 min/session repeat | <ul style="list-style-type: none"> • CV4 • Ren4 | stimulation to onset of |
| Norway | once on the next day | | active phase of labor: |
| Randomized | | | <ul style="list-style-type: none"> •AC, 15 hours |
| controlled trial | | | (median) |
| | | | •Control, 20.5 hours |
| | | | (median) |
| | | | • <i>p</i> = 0.34 |
| | | | Successful induction: |
| | | | •AC, 6/48 (12.5%) |
| | | | • Control, 9/53 (17%) |
| | | | <i>p</i> = 0.53 |

| First Author | N | Groups | Outcomes |
|---|--|---|---|
| Year | Gestational Age | Needling Sites | |
| Country | Regimen | | |
| Type of Study | | | |
| Smith et al. 2008 Australia Randomized controlled trial | 364 41 weeks 2 × 45 min, twice, over 2 days | SAC (<i>n</i> = 183) • Away from meridian points AC (<i>n</i> = 181) • L14 • UB31 • UB32 • SP6 • ST36 • Liv3 | Time from acupuncture intervention to birth, as median (interquartile range): •AC, 68.6 hours (53.9–79.5 hours) •SAC, 65 hours (49.3–76.3 hours) • <i>p</i> = 0.23 |

*SAC: Sham acupuncture

M: Mean Gestational Age

**AC: Acupuncture

***EAC: Electroacupuncture

Chapter 4: Manuscript 3

Will be submitted to Clinical Nursing Research: An International Journal

The Use of Electroacupuncture for Cervical Ripening in Pregnant Women

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The Use of Electroacupuncture for Cervical Ripening in Pregnant Women

Abstract

The purpose of this study was to compare cervical ripening outcomes, based on Bishop scoring methodology of pregnant women receiving usual care (UC) with those receiving electroacupuncture plus UC. A sample of 36 pregnant women completing their 39th week of gestation was randomized into one of the two groups. An experimental research design was used for this pilot study. The researcher found the electroacupuncture plus UC group influenced the timing of delivery positively ($p = 0.051$), delivering an average of 5.1 hours earlier than those in the UC group. The electroacupuncture plus UC group method of delivery (94.4% vaginal delivery rate) was more effective compared to UC alone (83.3% vaginal delivery rate). Electroacupuncture plus UC was not more effective for cervical ripening than the UC alone. The change in Bishop score did not significantly differ between groups ($p = .633$); however, participants in the electroacupuncture plus UC group required less cervical ripening pharmacologic agents (5.6%) compared to those in the UC group (22.2%). The use of electroacupuncture may be beneficial for cervical ripening, initiation of spontaneous labor, reduction of the time in active labor as well as an increased potential for a vaginal birth.

Keywords

Pregnant Women, Cervical Ripening, Electroacupuncture

The Use of Electroacupuncture for Cervical Ripening in Pregnant Women

The American College of Obstetricians and Gynecologists (ACOG) define term pregnancy as a gestation of 40 weeks (ACOG, 2002). Labor is defined as the process of childbirth from the start of uterine contractions to delivery (Simpson, 2013). Prostaglandin and oxytocin are the most important biochemical stimulators of this activity. Despite extensive research, the mechanism which causes the initiation of spontaneous labor is still unclear (Liao, Buhimschi, & Norwitz, 2005). Cervical status is the most important factor in predicting the success of labor as well as labor induction (Simpson, 2013).

If pregnancy continues beyond 41 weeks, the risk for perinatal mortality increases (ACOG, 2002). While most pregnant women begin labor without difficulty, use of cervical ripening and pharmacological agents for induction of labor is becoming more prevalent. Annually, over one million pregnant women (25%) in the United States have labor induced (artificial initiation of the birth process) using pharmacological methods (Hamilton, Martin & Ventura, 2011). Electroacupuncture may be effective for use in cervical ripening with a significantly higher frequency of vaginal deliveries and without occurrence of obstetric complications (Gribel, Coca-Velarde, & Moeira de Sa', 2011).

Background

Cervical Ripening

Cervical ripening is a process that results in the softening and stretching of the cervix in preparation for labor and birth (ACOG, 2009). A favorable cervix can minimize the risk of cesarean birth and generate spontaneous labor (Laughon,

Branch, Beaver & Zang, 2012). The potential for successful cervical ripening and subsequent active initiation of labor can be assessed by using a pre-labor scoring system such as the Bishop score (Bishop, 1964). A Bishop score of 6 or greater (ACOG, 2009) indicates the cervix is favorable for initiation of labor (pre-induction cervical ripening), which is associated with a lower risk for requiring cesarean birth and typically leads to spontaneous labor without the use of oxytocin (Simpson, 2013). For nulliparous women with an unfavorable cervix (a Bishop score of 6 or less), there is a twofold increase in the risk of cesarean birth (American College of Obstetricians and Gynecologists, 2009). Roemer, Weigel, Zeiger, and Melchert (1998) enrolled 878 women in a study comparing a control group ($n=325$), sham acupuncture ($n=224$) and true acupuncture ($n=329$). The true acupuncture group demonstrated increased Bishop scores and improved funneling of the cervix. Rabl, Ahner, Bitschau, Zeisler, and Husslein (2001) reported significance in cervical ripening ($p = 0.03$) and less time from the study enrollment to delivery ($p = 0.08$) for those in the acupuncture group compared to the control group. In another study, Mucuk and Baser (2013) enrolled 120 women in a study comparing acupuncture at the LI4 point ($n=40$), acupuncture at the SP6 point, ($n=40$) and a control group ($n=40$). The LI4 group had a cervical dilation value of 6.0 cm; the SP6 group a 5.0 dilation value and the control group a 4.5 cm dilation value ($p = 0.0001$).

Electroacupuncture

Electroacupuncture uses a small electrical charge that stimulates neurotransmitters in the body (Mayor, 2007). Compared to manual acupuncture, electroacupuncture is frequently chosen as it allowed for stronger stimulation

resulting in less tissue damage and used a consistent electrical charge which provided an objective and standardized approach that is more easily measured than that of manual acupuncture (Mayor, 2007). Electroacupuncture may be effective for use as a cervical ripening agent. The available literature published demonstrates promising results. Asher, Coeytaux, Chen, Reilly, Loh, and Harper (2009), Modlock, Nielsen, and Uldbjerg (2010), and Smith, Crowther, Collins, and Coyle (2008) found no significant difference in cervical ripening in patients in the acupuncture group versus the control group with p values of 0.66, 0.79 and 0.23 respectively. In another study, change in cervical ripening was significant ($p = 0.03$) for those receiving acupuncture (Rabl et al., 2001). Mucuk and Baser (2013) found acupuncture at LI4 and SP6 was statistically significant ($p = 0.0001$) for cervical dilation. All researchers had two components in common. The findings were acupuncture was low risk and carried limited, if any, side effects (Mayor, 2007; Roemer, 2000; Smith, 2012).

Park et al. (2008), using four databases (Pub Med, Cochrane Library, AMED and Embase from inception to October 2007), conducted a literature review and suggested acupuncture use for cervical ripening was promising. The researchers summarized further research is required with consideration given to the use of appropriate controls in randomized clinical trials for cervical ripening and labor induction. Smith and Crowther (2012) conducted a comprehensive Cochrane review utilizing multiple databases and concluded women receiving acupuncture treatments required less use of induction methods compared with those receiving standard care (usual care). The researchers also noted there is a need for well-

designed randomized controlled trials to evaluate the role of acupuncture for cervical ripening and to induce labor.

There are several gaps noted in the literature regarding acupuncture, cervical ripening and their role in delivery. In a review by Curtis et al. (2006), the prominent issue was the lack of clarification regarding acupuncture procedures such as needle characteristics, type of stimulation, dose, frequency, depth of needle insertion and selection of needle site. Lim, Wilkinson, Wong and Chen (2009) identified the lack of uniformity of gestational age at enrollment and a small sample size as gaps in current literature. Smith and Crowther (2012) concluded there was a need for well-designed randomized controlled trials to evaluate the role of acupuncture for cervical ripening and labor induction.

The Complementary and Alternative Healthcare (CAM) Model for Cervical Ripening in Pregnant Women

Electroacupuncture may be effective for use as a cervical ripening agent (Harper, Coeytaux, Chen, Campbell, Kaufman, Moise, & Thorp, 2006). Acupuncture stimulates the release of adrenocorticotrophic hormone from the hypothalamus, which increase the prostaglandin level, resulting in the thinning of the cervix (Curtis, Coeytaux, & Hapke, 2006). The conceptual framework created by the investigator (Figure 2) was derived from the Complementary and Alternative Healthcare Model (Fouladbakhsh & Stommel, 2007). The model served as a bridge between Eastern and Western modalities of care, as it combined tenants that are consistent in both practices.

The model was adapted for use in pregnant women with an uncomplicated pregnancy greater than 39 weeks gestation. On the far left side of the model, *predisposing factors* include demographic information (female, gestational age of 39 completed weeks, current Bishop (Bishop, 1964) score of six or less, age, and ethnicity). *Enabling factors* included aspects of availability of providers as well as financial resources to pay for care. The *need for care* focus was the readiness for labor. A woman with a Bishop score of six or less at the completion of 39 weeks indicated cervical ripening had not yet occurred (Simpson, 2013).

If the patient met the initial demographic criteria, the model progressed to *defining characteristics for care* including a singleton pregnancy, infant in a cephalic position, and absence of maternal/fetal risk factors for this study. The *need for health service use* was that of the birth modality. The *health service use* component integrated the randomization of the groups. The two groups were usual care (UC) and electroacupuncture plus UC. The physician examined the woman and determined the Bishop score. If the pregnant woman agreed to take part in the trial, she was randomized into a group. *Mediating variables* in this study include participants enrolled in the study; however, experienced spontaneous labor before intervention or experienced a spontaneous rupture of membranes before active labor and required more active management of labor. The final component of the model was the *outcome of care* section. The primary outcome measured cervical ripening using the Bishop scoring methodology. The secondary outcome measured the efficacy of electroacupuncture plus UC compared to UC alone, regarding timing and method of delivery and Apgar score of less than or equal to 7 at five minutes.

Purpose

The purpose of this feasibility pilot study was to compare cervical ripening outcomes, based on Bishop scoring methodology (see Table 1), of pregnant women receiving conventional standard of care treatment with those receiving conventional standard of care treatment plus electroacupuncture.

The research questions were:

1. Is electroacupuncture plus UC more effective for cervical ripening than UC alone?
2. Does electroacupuncture plus UC positively influence the timing of delivery compared to UC alone?
3. Does electroacupuncture plus UC positively influence the method of delivery compared to the UC alone?

Method

Design

This study was an experimental design and feasibility pilot study. The feasibility method was used to determine parameters needed to design a larger study such as the willingness of patients to be randomized, a willingness of clinicians to recruit participants, and compliance rates (Whitehead, Sully, & Campbell, 2014). The pilot study method used a version of the larger study run on a smaller scale to determine if the components of the larger study can all work together (Whitehead et al., 2014).

Sample

Inclusion criteria. Inclusion criteria were (a) completion of 39 weeks gestation, (b) a singleton pregnancy, (c) no prior cesarean births, (d) a Bishop score of 6 or less at 39 weeks, (e) a cephalic presentation, (f) the ability to read and speak English, and (g) adults 21 years of age or greater.

Exclusion criteria. Exclusion criteria were (a) fetal demise, (b) presence of major medical complications of pregnancy such as eclampsia or pre-eclampsia, (c) intrauterine growth restricted fetus (IUGR), (d) history of blood disorder, (e) conditions with abnormal placental implantation such as placenta previa or vasa previa, (f) transverse fetal lie, (g) umbilical cord prolapse, (h) active genital herpes infection, (i) the participant had a pacemaker, or (j) platelet count of less than 50,000.

Sample Size

A fully powered study size was calculated for a Mann-Whitney using G*Power 3.1.8. A sample size of 134 participants was needed with 67 in each group to have a power of 80% for a fully powered study with a medium effect size of 0.50 and an alpha of 0.05. Because this study was considered a pilot study with results being used to guide further research, the final sample size was determined by logistical and budgetary constraints. The final sample for this study included 36 prenatal women; 18 in each group

Setting

The setting for recruitment was located at two obstetric offices in the Midwest located 20 miles apart. The setting for the electroacupuncture intervention

was located at a facility specializing in complementary medicine. The facility was selected due to the availability of four licensed Traditional Chinese Medicine providers (TCM) on site although for this study the same TCM provider was used for all participants. The site was also in proximity to a labor and delivery unit with fetal monitoring capability if needed.

Procedures

Institutional Review Board (IRB) approval was obtained from a Midwestern Hospital Regional Institutional Review Board and a university in the Midwestern United States. Participant cost was reduced by obtaining grant funding to cover the cost of acupuncture treatments and the required complete blood count (CBC).

Eligible subjects were identified through prenatal chart review in providers' offices (Figure 4). Interested and eligible subjects received information regarding the research study and a copy of the informed consent at the completion of 38 weeks gestation from the researcher. At the end of 39 completed weeks, baseline data (Bishop Score) were obtained by the physician and inclusion/exclusion criteria reviewed and shared with the researcher. The researcher discussed the study with the participant, and consent was obtained. A baseline CBC was requested by the Mercy Health IRB to assure a platelet count greater than 50,000 prior to taking part in the study. The participant had a CBC drawn and results evaluated.

Subjects were randomized through a computer-generated system. Study arm assignments and subsequent information (patient booklets, lab orders) were collated by a statistician so the researcher initially was blinded to the information in the envelope. A consecutively numbered, sealed manila envelope containing the

study arm assignments was opened by the researcher with each participant after all entry criteria were confirmed and written consent was obtained. Each participant was assigned a code that was used for data review. The participants' names, demographic information, and their assigned code were housed separately from all other data and stored in a secured, locked fireproof file cabinet, in a locked office with access only to the PI.

Treatment

After randomization, the first acupuncture treatment was performed for participants electroacupuncture plus UC group within 24 hours of randomization. Two additional electroacupuncture treatments were scheduled within the same week (39 weeks gestation) for the electroacupuncture plus UC group. The second week (40 weeks gestation) the electroacupuncture plus UC group received two additional treatments of electroacupuncture as well as a usual obstetric care with a weekly visit to the obstetrician.

After randomization, the UC group received routine obstetric care with weekly visits and delivery planned only for the development of maternal or fetal indications or by 42 weeks gestation. All participants were asked to keep their group selection and Bishop scoring information confidential to assist with blinding for the study.

Electroacupuncture treatments were performed by one consistent TCM provider. After the initial assessment including obtaining a fetal heart rate by a doppler, the following acupuncture points were accessed utilizing Seirin J brand

individual sterile needles. (Sizes .25x.30; .25 x .40; sizes 32 gauge; 1 inch needle and 1.5 inch needle respectively):

- Hegu LI-4 (Hand) Needling Perpendicular insertion 0.5 to 1 cun; ii. Oblique insertion directed proximally 1 to 1.5 cun.
- Jianjing GB 21: (Shoulder) Needling posterior oblique insertion 0.5 to 1 cun.
- Sanyinjiao SP6: (Lower Leg) Needling perpendicular or oblique proximal insertion, 1 to 1.5 cun.
- Kunlun BL 60 (Ankle) Needling perpendicular insertion 0.5 to 1 cun, or directed superiorly to join with Taixi KID-3, 1.5 to 2 cun.
- Shangliao BL-31 (Lower Back) Perpendicular insertion 0.5 to 1 cun, or 1.5 to 2 cun through the foramen. Needling through the foramen is facilitated by a slightly oblique medial and inferior insertion.
- Ciliao BL-32 – (Lower Back) Needling perpendicular insertion 0.5 to 1 cun or 1.5 to 2 cun through the foramen. Needling through the foramen is facilitated by a slightly oblique medial and inferior insertion (Betts, 2006; Deadman, Al-Khafaji, & Baker, 2007; Mayor, 2007).

The points GB 21, LI 4, SP6, and BL 60 were needled first. Needles were advanced and manipulated as stated previously until 'deqi' (unique sensation) was elicited. Low-voltage (2 Hz) electrostimulation was administered to connect points LI4 to SP6 for 20 minutes. The same point and electrostimulation protocol were performed on the opposite side of the body with the addition of bilateral needling of BL 31 and 32. A post procedure fetal heart rate was obtained by a doppler. The TCM provider documented according to the Standards for Reporting Interventions

in Controlled Trials of Acupuncture (STRICTA) protocol (MacPherson, White, Cummings, Jobst, & Niemtzw, 2002). The TCM provider also documented potential protocol changes if individualized treatment were possible.

Measures

The Bishop Scoring methodology (Bishop, 1964) was used to assess the primary outcome. The scoring system was developed in 1964 and reliably measures the following criteria: cervical dilation; cervical effacement; cervix consistency, the position of the cervix, and fetal station. Scores were assigned based on specified criteria (see Table1). Nielsen, Howard, Crabtree, Batig, and Pates (2012) further validated the value of the Bishop score as it related to predicting the success of labor induction at term. Prior to the initiation of the study, the obstetric providers were screened for consistency in reporting Bishop scores utilizing a simulation tool. All providers scored within a 1 point range.

The STRICTA protocol was used by the TCM provider for documentation. The STRICTA protocol included documentation of acupuncture rationale, needling details, treatment regimen, cointerventions, practitioner background and control interventions and is an extension of the Consolidated Standards for Reporting Interventions in Controlled Trials (CONSORT) guidelines.

Maternal age, parity, gestational age, and ethnicity were obtained through the medical record located in the primary care provider office. The gestational age in days reflects the day the participant entered the study. The completion of 39 weeks gestation was 273 days. Parity is the number of living children. The Bishop score reflects the first score received at the physician office at 39 completed weeks

of gestation verifying inclusion criteria of a Bishop score of 6 or less. Baseline Bishop scores were assigned and documented by the obstetrician in the primary care provider office. Final Bishop scores were assigned either by the obstetrician in the primary care provider office or by the in-house obstetrician in the OB triage unit at the hospital and documented in the medical record.

Apgar scores were assigned by a labor and delivery registered nurse and were obtained through the medical record. Secondary outcomes were obtained through hospital medical record review in the post-delivery period including the date and time of delivery, the mode of delivery (vaginal delivery, vaginal delivery with forceps, vaginal delivery with vacuum, and cesarean birth), time in active labor (4 cm to delivery) and the birth methodology. Birth methods include no treatment, artificial rupture of membranes (AROM), use of oxytocin (Pitocin®) and use of Cervidil® and Pitocin®.

Data Analysis

Data were analyzed for normality and outliers using IBM SPSS (2013, v.22). Outliers were addressed by looking for entry errors or extreme values. Descriptive statistics (means, standard deviations, medians) were calculated for the participant's age, gestational age, parity, and Bishop score. Frequency and percentages were calculated for ethnicity, use of induction methods, types of birth methods and the mode of delivery. A Mann-Whitney test was used to compare changes in Bishop score from baseline to post-intervention between the UC group and the electroacupuncture plus UC group. A Chi-square test was used to measure secondary outcomes including mode of delivery and a Mann-Whitney test measured

the time in active labor (4 cm to delivery) and compared the UC group with the electroacupuncture plus UC group. Treatment methodology and Apgar scores below seven at 5 minutes were measured using Chi-square comparing the conventional standard of care treatment with conventional standard of care treatment and electroacupuncture.

Results

The demographic and personal characteristics of the sample can be found in Table 3. The overall mean age for all participants ($n = 36$) was 28.69 ± 4.7 years. For participants receiving UC, the mean age was 27.94 ± 4.92 years. For the electroacupuncture plus UC participants, the mean age was 29.44 ± 4.49 . Ethnicity category was selected by participants. There were 32 (89%) Caucasians, and 2 (5.6%) Hispanics or Latinos, 1 (2.8%) African American, and 1 (2.8%) multi-racial participant.

The Mann-Whitney U Test was used to compare the changes in the Bishop score from baseline to post-intervention (see Table 4). The change in Bishop score was not found to significantly differ between the two groups ($p = .633$). Descriptive statistics for study variables of birth methods can be found in Table 5. Sixteen participants (44%) required no intervention methods and were equally distributed in the electroacupuncture plus UC and UC group. Eight participants (22.2%) required artificial rupture of membranes with equal representation in both groups. Pitocin® was used for seven participants (19.4%); five (27.8%) in the electroacupuncture group and two (11.1%) in the conventional standard of care group. The combination of Cervidil® and Pitocin® was used for five participants

(13.9%); one participant (5.6%) in the electroacupuncture group and four participants (22.2%) in the conventional standard of care group.

The Mann-Whitney U-test was used to compare the timing of delivery in minutes between the two groups (see Table 6). The UC group had a mean of 754.6 ± 570.80 minutes. The minimum was 53 minutes, and the maximum was 2337 minutes with a range of 2284 minutes. The electroacupuncture plus UC group had a mean of 424.9 ± 274.79 minutes. The minimum was 89 minutes, and the maximum was 926 minutes with a range of 837 minutes. The Mann-Whitney test was used with a significance value of $p = 0.051$. All Apgar scores were above seven at five minutes in both groups.

Twenty-nine participants (80.6%) delivered vaginally; 15 participants (80.6%) in the electroacupuncture plus UC group and 14 participants (77.8%) in the UC group (see Table 7). Two participants (5.6%) required an operative vaginal delivery with forceps with equal representation in both groups. One participant (2.8%) required an operative vaginal delivery with vacuum attributed to the electroacupuncture plus UC group resulting in 5.6% of electroacupuncture deliveries. Four participants (11.1%) required a cesarean birth; one (5.6%) in the electroacupuncture plus UC group and three (16.7%) in the UC group. A Chi-Square with Fischers Exact Test ($p = 0.603$) was used to calculate the overall vaginal delivery and cesarean birth rate in both groups. In the UC group, 15 participants delivered vaginally (83%) vaginal delivery rate and the electroacupuncture plus UC group with a 94.4% vaginal delivery rate (17 participants).

Discussion

Results from the study revealed there was no significant statistical difference ($p = .633$) in the change in Bishop score between categories of birth treatment indicating electroacupuncture plus UC was not significantly more effective for cervical ripening than UC alone. For this study, obstetricians with similar practice patterns assigned the initial Bishop score. The second Bishop score was assigned by a labor and delivery triage nurse or the in-house obstetric physician and documented in the medical record. The same Bishop scoring tool was used for both scoring sessions.

Similar to the findings in this study, in three different studies researchers found no significant difference in patients in the control group versus acupuncture group regarding labor induction or cesarean section rates (Asher et al., 2009; Modlock et al., 2010; Smith et al. 2008). However, all authors stated in their limitations that the timing of their acupuncture intervention was problematic. Modlock et al. (2010) ($n = 125$; $p = 0.79$) and Smith et al. (2008) ($n = 364$; $p = 0.23$) began the acupuncture intervention late (41 weeks and 1 or 2 days respectively prior to pharmacological induction). Asher et al. (2009) ($n = 89$; $p = 0.66$) began the acupuncture intervention early (38 weeks) and changed the treatment protocol from electroacupuncture (acupuncture with a small charge attached) to traditional acupuncture (acupuncture utilizing needling techniques only) suggesting that electroacupuncture may be more effective for cervical ripening.

Electroacupuncture plus UC had a shortened delivery time compared to UC alone in this research study. While borderline significant ($p = 0.051$), this outcome demonstrated a positive trend with a 44% reduction in labor duration for the

electroacupuncture plus UC group. The shortened delivery time for those receiving electroacupuncture in this study was consistent with several previous studies. Rabl et al. (2001) conducted a randomized clinical trial enrolling 45 women who were not in active labor and compared the control group with those receiving a series of up to three 20-minute acupuncture treatments. Cervical ripening was significantly improved ($p = 0.03$) by acupuncture with a reduction in inpatient induction rates and delivery occurring 69 hours earlier in the acupuncture group.

The researcher found electroacupuncture plus UC positively influenced the method of delivery compared to the UC alone in this study. The study data demonstrated those who received electroacupuncture plus UC had a 94.4% vaginal delivery rate compared to an 83.3% vaginal delivery rate for those receiving the UC only. The Chi-square analysis revealed although there were fewer participants having cesarean births in the electroacupuncture plus UC group, the difference was not significant (Fisher's Exact test $p = .603$). This result could be influenced by the small sample size of the study as well as the lower than an average number of cesarean births. The findings in this study were supported by an earlier control pilot study where patients receiving acupuncture underwent significantly fewer cesarean births than patients in the control group (7% versus 20%, $p = 0.004$) (Citkovitz, Klimenko, Bolyai, Applewhite, Julliard, & Weiner, 2009).

Clinical Application

When meeting with patients at 38 completed weeks of gestation, women's interest relating to the use of electroacupuncture for labor was higher than expected. One key to successful recruitment was that of engaged providers and

office staff. The provider initiated the process with the evaluation of inclusion and exclusion criteria, Bishop scoring methodology, and initial communication with the patient. Without the willingness of providers to recruit participants, the study would not have been successful. The role of the office staff should not be underestimated. Schedules, timing, the flow of the office and communication to the patient were a few vital components the office staff fulfilled. How staff perceived and presented the study opportunity to the patient, set the tone for the conversation with the primary investigator.

The second contribution of this study for clinical practice was about the practice of electroacupuncture and addressed the gap concerning lack of specificity in documenting acupuncture practice according to STRICTA guidelines. For this study, specific, consistent acupoints and processes were used for all patients with documentation following STRICTA guidelines (MacPherson et al. 2002). Eastern medicine in its truest sense uses differential diagnostics just as in Western medicine. In current Western medicine practice, if patients have a similar problem or disease process, providers can individualize treatment based on differential diagnosis. As part of the study, the TCM provider added comments on each patients' visit noting what change in acupoint or other protocol (Hz of electroacupuncture) was more desirable.

The timing of electroacupuncture treatments was important as it addressed the gap of the lack of uniformity of gestational age at enrollment. This study started at the completion of 39 weeks gestation. According to this study data, electroacupuncture plus UC is currently not more effective for cervical ripening that

UC alone when starting treatment at the completion of 39 weeks. Using this study data, the timing of electroacupuncture treatments should be started at the completion of 38 weeks so the full number of treatments (5) can be fully realized before the need for a scheduled labor induction at 40 or 41 weeks gestation.

Limitations

There were several limitations to this study. The primary limitation of the study was the small sample size limiting the ability to use more robust analyses and making it difficult to generalize results. The small sample size was also identified as a gap in reviewed studies.

Another limitation was many examiners documenting Bishop scores making the inter-rater agreement in examinations difficult to achieve. Aspects of the Bishop score could be subjective; thus differences in the scoring could occur. To minimize variation in provider scoring differences, the use of ultrasound could provide a more substantiated scoring methodology. However, ultrasound technology adds more cost, may not be readily available in all practice settings, may result in decreased productivity, and requires a skilled provider or technician to perform the ultrasound and interpret the results.

A third limitation of the study was participants were not blinded to the intervention. While participants were requested to keep their treatment method confidential, it was not entirely known if that request was upheld. There is a current gap in the literature comparing traditional acupuncture with electroacupuncture. A future study would compare the groups while incorporating the capability to blind

participants to the intervention (placing the electroacupuncture device but not using it).

The use of set acupoints was also a limitation compared to utilizing acupoints specific to the individual need based on the TCM providers diagnosis. It would be beneficial in future studies to develop a framework/reference manual incorporating the TCM provider suggestions for the treatment of pregnant women. A framework/reference manual would allow flexibility to the TCM provider to use differential diagnosis in the treatment of pregnant women receiving electroacupuncture for cervical ripening.

Conclusion

In conclusion, electroacupuncture plus UC positively influenced the timing of delivery, delivering on average 306 minutes (5.1 hours) earlier than the UC group. The method of delivery for the electroacupuncture plus UC was positive with a 5.6% cesarean birth rate compared to UC alone with a 16.7% cesarean birth rate. Electroacupuncture plus UC was not significantly more effective for cervical ripening than UC alone; however, only 5.6% of participants in the electroacupuncture plus UC required induction with Cervidil® and Pitocin® compared to 22.2% of participants in the UC group. Future study interventions would include the development of a treatment manual allowing for differential diagnoses in TCM to determine acupoints in pregnant women for cervical ripening, and change the electroacupuncture treatment start time to 38 completed weeks of gestation.

Figure 1 - Complementary and Alternative Healthcare Model for Cervical Ripening in Pregnant Women (Nauta, 2016)

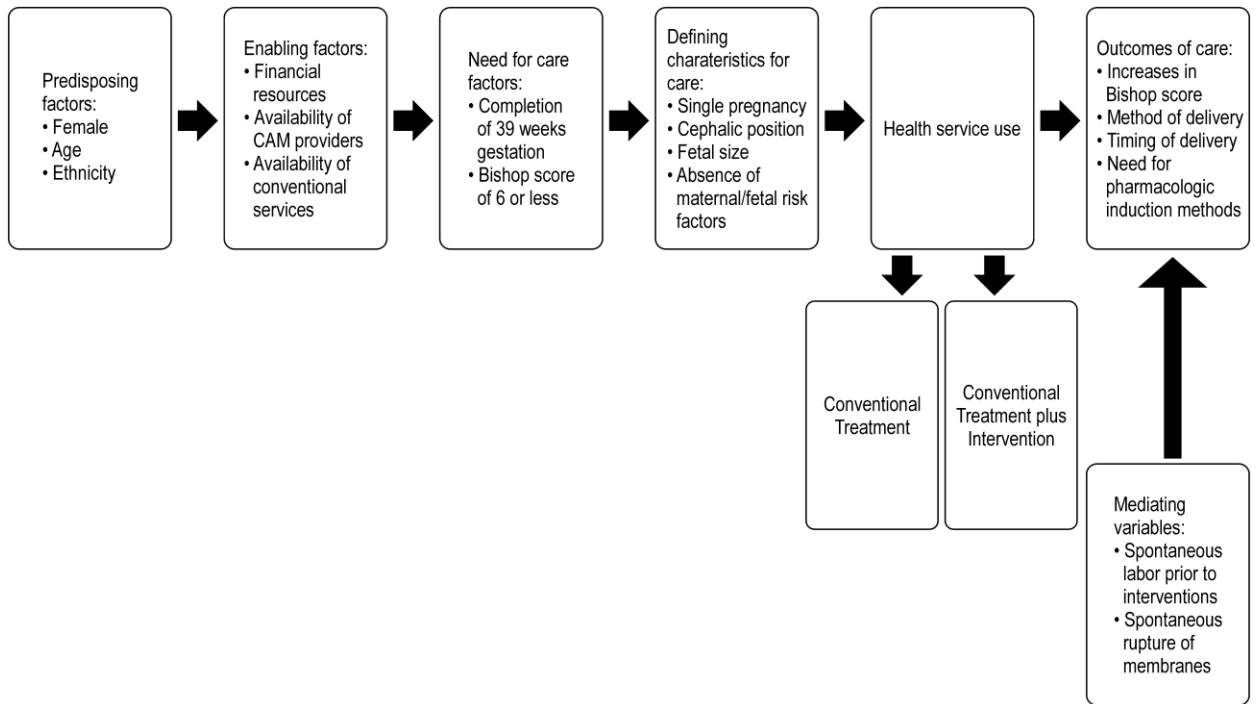


Figure 4: Recruitment and Retention

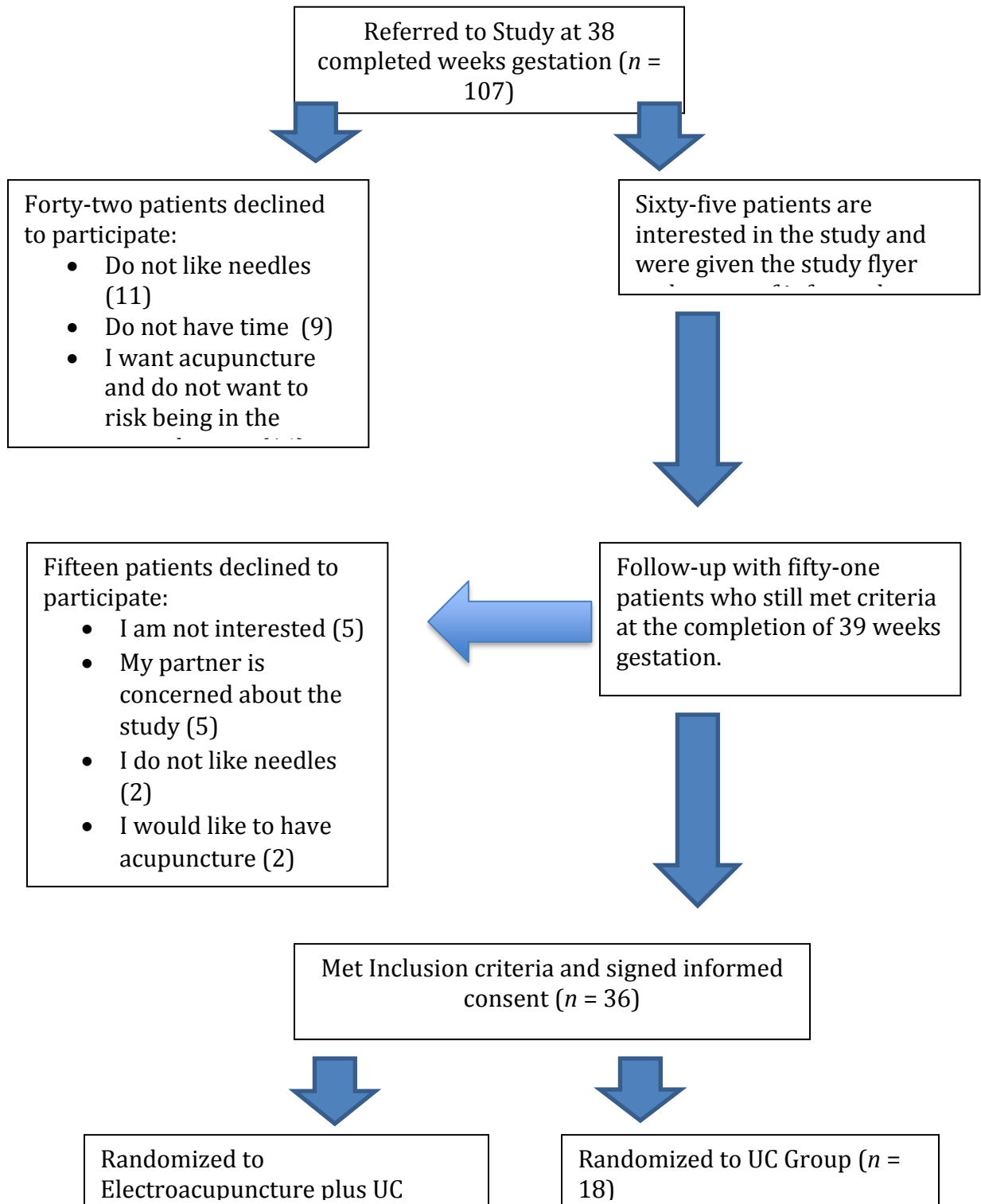


Table 1 Bishop Scoring Methodology

Factor

| Score | Dilation (cm) | Effacement (%) | Station | Consistency | Position of Cervix |
|-------|------------------|-------------------|---------|-------------|-----------------------|
| 0 | Closed | 0-30 | -3 | Firm | Posterior |
| 1 | 1-2 | 40-50 | -2 | Medium | Midposition |
| 2 | 3-4 | 60-70 | -1, 0 | Soft | Anterior |
| 3 | ≥ 5 | ≥ 80 | +1, +2 | ----- | ----- |

Total Score: _____

(Bishop, 1964)

Table 3: Demographic Statistics

| Demographic | Electroacupuncture + UC Mean±SD, Mdn (range) | UC Mean±SD, Mdn (range) |
|-----------------------------|--|-------------------------------|
| Participant Age (years) | 29.44±4.48, 28.0 (22-39) | 27.94±4.48, 27.5 (21-31) |
| Gestational Age in days | 273.7±1.43, 273 (273-278) | 274.5±1.91, 27.3 (273-277) |
| Gestational Age in Weeks | 39.1 | 39.2 |
| Parity | 0.88±.90, 1.0 (0-3) | 0.83±1.15, .5 (0-4) |
| Bishop Score | 3.55±1.68, 4.0 (0-6) | 3.33±1.94, 4.0 (0-6) |
| Ethnicity (<i>n</i> =36) | <i>n</i> = 18 | <i>n</i> = 18 |
| Caucasian | 14 | 18 |
| Hispanic | 2 | |
| African American | 1 | |
| Multi-racial | 1 | |

Table 4:

| Group | Bishop Score Comparison | | |
|---------------------------------------|-------------------------|-------------------------|--------------------------|
| | Baseline | Immediate Pre-birth | Change score |
| | Mean±SD, Mdn (range) | Mean±SD, Mdn (range) | Mean±SD, Mdn (range) |
| UC group | 3.33±1.9, 4.0 (0-6) | 8.28±2.1, 8.0 (5-12) | 4.94±3.15, 4.0 (0-11) |
| Electro- Acupuncture + UC group | 3.56±1.7, 4.0 (0-6) | 8.06±2.8, 8.0 (3-12) | 4.5±2.93, 4.0 (1-11) |

No significant differences were found between groups in the change scores ($p = .633$).

Table 5

Descriptive Statistics of Study Variables of the Pregnant Sample

| | All Intervention Method (IM) (N=36) | Electrocupuncture(N=18) | Conventional(N=18) |
|--------------------------------|-------------------------------------|-------------------------|--------------------|
| | Frequency (%) | Frequency (%) | Frequency (%) |
| No Intervention | 16 (44.4%) | 8 (44.4%) | 8 (44.4%) |
| AROM | 8 (22.2%) | 4 (22.2%) | 4 (22.2%) |
| Pitocin | 7 (19.4%) | 5 (27.8%) | 2 (11.1%) |
| Cervidil® & Pitocin® 5 (13.9%) | | 1 (5.6%) | 4 (22.2%) |

Table 6

Timing of Delivery

| Birth Method | N | Minutes Mean±SD, Mdn, (range) |
|-------------------------|-----------|--|
| UC | 18 | 754.6±570.8, 678.5 (53-2337) |
| Electroacupuncture + UC | 18 | 424.9±274.8, 372.5 (89-926) |
| Total | 36 | |

Z statistic = - 1.946, $p = 0.051$

Table 7: Delivery Mode

| Group | Vaginal Birth | Cesarean Birth |
|--|---------------|----------------|
| Usual care group | 15 (83%) | 3 (17%) |
| Electroacupuncture + Usual Care Group | 17 (94%) | 1 (6%) |

Chi-square results:

Fisher's exact significance = .603

Chapter 5: Conclusions and Discussion

This dissertation represents the progression of knowledge in systematic order from the identification of a problem to a comparative pilot research study focused on the use of electroacupuncture for cervical ripening in women completing 39 weeks of pregnancy. The purpose of the pilot study was to compare cervical ripening outcomes, based on Bishop (Bishop, 1964) scoring methodology (Table 1), of pregnant women receiving conventional standard of care treatment to those receiving conventional standard of care treatment plus electroacupuncture. Three research questions were developed to frame the study:

1. Is conventional standard of care treatment plus electroacupuncture more effective for cervical ripening than the conventional standard of care treatment alone?
2. Does conventional standard of care treatment plus electroacupuncture positively influence the timing of delivery compared to conventional standard of care treatment alone?
3. Does conventional standard of care treatment plus electroacupuncture positively influence the method of delivery compared to the conventional standard of care treatment alone?

In this chapter, the study foundation, results, and implications will be discussed.

Overview of the Problem

As noted in Chapter 1, in 2011, 25% of all laboring patients required labor induction (Hamilton et al., 2011). This alarming statistic reflects a 146% increase of women receiving artificial labor induction since 1990 (Martin et al., 2012). Labor induction is a concern because the use of pharmacologic agents to augment labor has been associated with an increase in perinatal morbidity and mortality (Simpson, 2013). Cervical status is the most important factor in predicting the success of labor as well as labor induction (Simpson, 2013). Electroacupuncture may be effective for use as a cervical ripening agent (Harper et al., 2006)

Literature Review

While the use of pharmacological methods to artificially induce labor is standard of care in the United States, alternative methods for cervical ripening and labor induction have been used successfully in Eastern countries. One alternative found in the literature that shows promise is acupuncture. The use of acupuncture to augment labor is low risk and carries limited, if any, side effects (Mayor, 2007; Roemer, 2000; Smith, 2012). However, very little research has been conducted using acupuncture specifically for cervical ripening. Studies that were identified demonstrated positive results using acupuncture regarding mode and timing of delivery, but there was a paucity of data identified that supported using acupuncture for cervical ripening. The initial search identified 317 articles. After screening, only those empirical studies written in English that focused on using acupuncture, electroacupuncture, or sham acupuncture for promoting cervical ripening or labor induction were included in the final review. Article screening resulted in a final review of 15 studies and five systematic reviews.

Several gaps were identified in the literature. First, a limited number of randomized clinical trials used STRICTA protocols (MacPherson, 2002), which made it difficult to compare study results. Comparative groups of conventional care and traditional acupuncture or acupuncture and sham acupuncture groups were found in the literature; however, the researcher did not identify any studies that compared conventional care, traditional acupuncture, and electroacupuncture for cervical ripening and labor induction. Another gap identified was the lack of uniformity of gestation age at enrollment (Lim, 2009). Smith and Crowther (2012) concluded at the end of an extensive Cochrane Review there was a need for well-designed randomized controlled trials to evaluate the role of acupuncture for cervical ripening and labor induction. As a result of this gap in the literature, the use of electroacupuncture was investigated as a possible alternative to pharmacological methods as a cervical ripening agent in pregnant women.

Subsequently, a framework and methodology were developed to guide practitioners in the use of

acupuncture for cervical ripening. This framework provides a viable alternative option for labor induction in the United States.

Model Development

The Complementary and Alternative Healthcare Model (Figure 1) (Fouladbakhsh & Stommel, 2007) was modified to meet the needs of this a feasibility study, resulting in the development of The Complementary and Alternative Healthcare Model for Cervical Ripening in Pregnant Women (Figure 2). This model included predisposing factors, enabling factors, the need for care, defining characteristics for care, the aspect of health service use (conventional treatment or conventional treatment plus intervention) and finally the outcomes of care, including any mediating variables. This model served as a bridge between Eastern and Western modalities of care, as it combines tenants that are consistent in both practices.

Methods

Pregnant women were recruited to participate in this study through two obstetric offices at the completion of 38 weeks. After the provider reviewed inclusion criteria, the participant was given a study flyer (Appendix A) and a copy of the consent form (Appendix B). The researcher had the opportunity to explain the study to the potential future participant and allow time for questions. The provider met with potential participants at the completion of 39 weeks, completed the Bishop score (Bishop, 1964), confirmed inclusion criteria, and then referred the patient to the researcher. After the study was explained and informed consent was obtained, a baseline complete blood count was ordered and was reviewed (Appendix C). The researcher and the study participant opened the randomized study envelope to reveal the study group. If the participants were in the conventional standard of care plus electroacupuncture group, they received the study booklet explaining in detail the study process (Appendix H).

All participants continued with their conventional standard of care treatment weekly appointment with their providers. Participants in the conventional standard of care treatment plus electroacupuncture group also completed at least one acupuncture treatment but could have as

many as five treatments within the 2-week period. Records of weekly appointments, (TCM) provider notes and Bishop scores were documented consistently (Appendix E). Participants notified the researcher after delivery. The researcher visited the participant in the hospital and completed field notes (Appendix I).

Results

Question 1: Is conventional standard of care treatment plus electroacupuncture more effective for cervical ripening than the conventional standard of care treatment alone?

Results: There were no significant statistical differences in the change in Bishop score between categories of intervention indicating that conventional standard of care treatment plus electroacupuncture is not more effective for cervical ripening than the conventional standard of care alone ($p = .633$). Although there were no significant differences noted, only 5.6% of participants in the conventional standard of care group plus electroacupuncture required induction with Cervidil® and Pitocin® compared to 22.2% of participants in the conventional standard of care group.

Question 2: Does conventional standard of care treatment plus electroacupuncture positively influence the timing of delivery compared to conventional standard of care treatment alone?

Results: Conventional standard of care treatment plus electroacupuncture positively influenced the timing of delivery, delivering on average 305 minutes (5.1 hours) earlier than the conventional standard of care group ($p = 0.051$).

Question 3: Does conventional standard of care treatment plus electroacupuncture positively influence the method of delivery compared to the conventional standard of care treatment alone?

Results: The method of delivery for the conventional standard of care treatment plus electroacupuncture was positive with a 5.6% cesarean birth rate compared to conventional standard of care treatment alone with a 16.7% cesarean birth rate.

Discussion

The process of recruitment was largely dependent on provider and office staff engagement. As an introductory study in the area of complementary therapy use in pregnant women, the ability to recruit and retain participants may be as important as the outcome results. The recruitment process took approximately 3 months. The researcher presented the research opportunity to 133 potential participants over the course of the study period with 36 participants recruited and completing the study. No significant statistical differences in the change in Bishop score between the categories of intervention were revealed. Conventional standard of care treatment plus electroacupuncture had a shortened delivery time ($p = 0.051$) and had fewer cesarean births (5.6%) compared to the conventional standard of care group (16.7%). Specific details and tables of the data were presented in the results section of Chapter 4.

Implications

The study findings have several important implications for clinical practice, education and research. Nurses and providers should be aware of the study implications to be an informed advocate for the patients and their families.

Clinical Implications

This study provided a greater understanding regarding the feasibility of conducting a larger study in the future. When meeting with patients at 38 completed weeks of gestation the interest regarding the use of electroacupuncture was higher than expected (see Figure 4). The total number of patient meetings at 38 weeks was 107. Forty-two patients declined to participate in the study for the following reasons: (a) I do not like needles (11), (b) I do not have the time to fit in acupuncture treatments (9), (c) I would like to have acupuncture and do not want to risk getting the control group (14), and (d) I do not want to take part in a study (8).

At the completion of 39 weeks, the researcher met with 51 patients who still met criteria. Fifteen patients declined to participate for the following reasons: (a) I am not interested (5), (b) my partner is concerned about the study (5), (c) I do not like needles (2), (d) I would like to have

acupuncture (2), and (e) I travel 90 minutes to the office – too much travel for 5 acupuncture treatments (1).

Several options should be considered in recruitment of participants. Potential participants should understand that electroacupuncture does not always use needles. In future studies, patients who are averse to needles could be given the needless acupuncture option, which would offer patients an alternative treatment route. Another recruitment consideration is the location of the TCM provider. In this study, the TCM provider was located in the downtown area. Using space in provider offices would enable participants to receive treatment at the same time as their weekly physician appointment. Additional locations would be beneficial for two reasons: (a) receiving acupuncture at the same time as their weekly appointment and in the same office is more convenient for the patient and (b) patients may be more receptive to acupuncture treatment that is offered within a trusted environment.

Another implication for clinical practice relates to the practice of electroacupuncture. For this study, specific, consistent acupoints were used for all patients. Eastern medicine in its' truest sense utilizes differential diagnostics, similar to Western medicine. For example, in current Western medicine practice, if patients have a similar problem or disease process, providers can individualize treatment based on differential diagnosis. In this study, TCM providers were not able to individualize the treatment because of the study protocol. In future studies, it would be more patient-centered if the TCM provider were able to adjust acupoints or Hz of electroacupuncture based on patients' needs.

Educational Implications

Educating women about risks and benefits of labor induction are essential to enable pregnant women to make informed choices. Educational resources should include information regarding the physiological benefits of a full-term pregnancy for both the mother and the infant. ACOG advises women against scheduling elective, non-medically indicated inductions of labor between 39 and 41 weeks unless the cervix is deemed favorable (ACOG, 2013). Gestational age,

pelvic adequacy, fetal size, fetal presentation, and cervical status should also be assessed before labor induction (Simpson, 2013). When cervical ripening is medically necessary, educating women about the complementary option for cervical ripening with acupuncture could potentially decrease the rate and severity of complications associated with labor induction. The use of acupuncture for cervical ripening and labor induction requires that pregnant women and their healthcare providers be well informed regarding this type of intervention, and its risks and benefits.

Research Implications

An important implication from this study is the need for additional research in the area of electroacupuncture. The researcher noted a gap in the literature using electroacupuncture for cervical ripening; especially, in the area of a comparative analysis of conventional treatment, traditional acupuncture, and electroacupuncture. Another gap noted is most studies also used fixed acupoints. Future study interventions should include the development of a treatment manual allowing for differential diagnoses in TCM to determine acupoints in pregnant women for cervical ripening. However, all studies should abide by the STRICTA guidelines. Conducting studies of adequate power is important so generalizations may be made to other like populations. Finally, grants should be sought to support additional studies through the National Institute of Health (NIH), the National Center for Complementary and Integrative Health (NCCAM), or third party insurers as acupuncture may reduce healthcare cost and increase patient satisfaction rates.

Limitations

The primary limitation of the study was the small sample size limiting the ability to use more robust analyses, which made it difficult to generalize results. Another limitation was multiple examiners documenting Bishop scores (Bishop, 1964) making inter-rater reliability difficult to achieve. For example, aspects of the Bishop score could be subjective, thus differences in the scoring could occur. A third limitation of the study was participants were not blinded to the intervention. While participants were requested to keep their treatment method

confidential, it was not fully known if that request was upheld. Finally, the use of set acupoints was a limitation. It would be beneficial in future studies to develop a framework/reference manual that would allow for individualized treatment by the TCM provider.

Conclusion

Cervical ripening and labor induction utilizing pharmacological agents continue to be a concern in the United States today. The data presented in this dissertation study suggest that the use of electroacupuncture may be beneficial in the area of cervical ripening and spontaneous labor, as well as the reduction in the use of pharmacologic agents, the reduction of time in labor, and a reduction in cesarean births. Future study interventions in this population are needed and should include securing funding to allow for a large study. The development of a treatment manual allowing for differential diagnoses in TCM to determine acupoints in pregnant women for cervical ripening, and a change in the timing of electroacupuncture treatment from 39 completed weeks of gestation to 38 completed weeks of gestation would also be a consideration for future study.

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Appendix A

RESEARCH STUDY: VOLUNTEERS NEEDED!!!

WHO: Pregnant women who have completed 39 weeks of pregnancy and the cervix has not softened or thinned out.

WHAT: The Use of Electroacupuncture for Cervical Ripening

- Cervical Ripening is the process of causing physical softening, thinning and dilating of the cervix in preparation for labor.
- Electroacupuncture is electrical stimulation of acupoints exclusively through acupuncture needles.
- Acupuncture needles are very thin. Five or six acupuncture needles could fit into the needle used for shots.
- Acupoints used are located on the hand, side of the lower leg, ankle, lower back and shoulder. (6 points)

WHEN: You may enroll in the research study at the completion of 39 weeks gestation with the permission of your physician if you meet the study criteria.

(continued on back)

Potential Benefits:

- **Enhanced cervical softening, thinning and dilation.**
- **No Charge for Acupuncture treatments if you are assigned to that group.**
- **May be no direct benefit for you; however, your participation may help further the understanding of the labor process.**

Potential Risks:

- **Slight risk of discomfort or redness at the needle insertion site.**
- **Slight risk of headache and fatigue.**
- **RARE side effects may include swelling, bruising or infection.**

What Next:

At your 39 week appointment, ask your physician if you qualify for the study. If your physician approves, the Primary Investigator for the study (Becky) will explain the study to you and will obtain your written consent. (A sample consent form is attached so you can review it over the next week). There are two potential study groups: a conventional treatment group (which means you will continue with your weekly appointments with your physician) or a conventional study plus electroacupuncture group (which means you will continue with your appointments with your physician as well as receive electroacupuncture treatments - three the first week and two the second week). Since the selection is randomized, you have a 50/50 chance (flip of a coin) of receiving the electroacupuncture group.

07-31-2015

Appendix B - Research Informed Consent Form

Study Title: The Use of Electroacupuncture for Cervical Ripening: A Feasibility Study

Principal Investigator: Becky Nauta, MSN, RN, CNML; PhD Student
Diane Brage Hudson, PhD, RN; Faculty Advisor

Study Sponsor: University of Nebraska Medical Center; College of Nursing
Nellie House Craven Scholarship

1. Introduction

You are being asked to participate in a clinical research study. Clinical research is the study of human diseases in an attempt to improve diagnosis and treatment. In order to decide whether or not you should agree to be part of this research study, you should receive enough information about its risks and benefits to make a judgment. This process is called informed consent.

This consent form gives detailed information about the research study which will be discussed with you. If you wish to participate in this study you will be asked to sign this form.

2. Purpose of This Research Study

You are being asked to be part of this study because you are pregnant, have completed 39 weeks gestation, and have an infant in the head down position. The purpose of this study is to compare cervical ripening (cervix thinning) outcomes of pregnant women receiving conventional standard of care with those receiving conventional standard of care plus electroacupuncture (small electric current is passed between pairs of acupuncture needles) treatment. Cervical status is the most important factor in predicting the success of labor as well as labor induction. For pregnant women with an unfavorable cervix where the cervix has not started thinning, and dilation has not yet occurred (Bishop score of 6 or less) there is an increase in the risk of cesarean birth. Pregnant women who agree to participate will be randomly selected to receive conventional standard of care or conventional standard of care plus electroacupuncture. The electroacupuncture treatments will take place at the Wege Institute located at Mercy Health Saint Mary's. A Licensed Traditional Chinese Medicine (TCM) Provider (an acupuncturist) will provide the treatments according to the requirements established for this study.

Pregnant women eligible for the study must have completed 39 weeks gestation, have a single pregnancy, have a Bishop score of 6 or less at 39 weeks, be able to read and speak English, are 21 years of age or older, and have an infant in the head down position (cephalic presentation).

3. Length of Your Participation

The expected length of your participation in this study is approximately 2 weeks. Your participation will begin at the time of informed consent and will conclude after the delivery of the infant.

09-28-15

Page 1 of 7

Pt. Initials _____

4. Where the Study is Being Done and Number of People Participating

The study will be conducted through Mercy Health-Saint Mary's in Grand Rapids, Michigan. Participants receiving conventional standard of care will continue to receive care at their providers' office. Participants receiving conventional standard of care and electroacupuncture will continue to be seen in their provider's office and will be requested to be seen at Mercy Health Saint Mary's Wege Institute for the electroacupuncture treatments. The Institute is located at 300 Lafayette, across from Mercy Health Saint Mary's. The minimum number of treatments is 1; the maximum number of treatments is 5. A total number of 36 participants will be recruited for this study with 18 participants randomized to the conventional standard of care treatment only group and 18 participants randomized to the conventional treatment plus electroacupuncture group.

5. Study Procedure

After you agree to be part of the study and sign this form you will be randomly assigned to a group. (You will have a 50/50 chance, similar to the flip of a coin, of being in the electroacupuncture group). Only you and the principal investigator will know your group assignment. You are asked to keep this information private and not share it with provider/office staff so as not to influence the outcome of the study. You will also be given a lab order to have a Complete Blood Count drawn at no charge to you.

You will continue with conventional standard of care treatment. Conventional treatments will be the standard of care office visits to document progress and assess fetal well-being. Conventional treatment may even include non-stress tests (tests scheduled in the office or at the hospital to document fetal well-being if required by your provider). The conventional standard of care visits usually include monitoring your blood pressure, heart rate, urine tests for protein, fetal heart rate and possibly a vaginal examination to assess for cervical thinning and dilation.

If you are assigned to the conventional standard of care and electroacupuncture group you will also receive:

- An initial admission assessment by the Traditional Chinese Medicine provider (acupuncturist) including the first treatment (initial time usually takes 90 minutes) and
- Four follow-up electroacupuncture treatments taking place over a period of 2 weeks. Each follow-up treatment takes approximately 40-60 minutes. You are asked not to share your cervical ripening information with the acupuncturist provider as if you do it may influence the outcome.

When receiving electroacupuncture, the fetal heart rate will be taken prior to and after treatment.

A total of six acupuncture sites will be utilized including the hand, lower leg, ankle, shoulder, and two sites on the lower back. You may feel some tenderness at the site of needle insertion, a tingling sensation when receiving the treatment and increased fetal movement after the treatment. After delivery for all study participants, the investigator will review and combine the healthcare provider office data and the acupuncture data from the patient medical records and will assess the results.

6. What Will Happen When You Complete the Study

After the delivery of your baby, your study participation is complete. You will no longer be able to access electroacupuncture treatments as part of this study. You will continue receiving conventional standard of care treatment.

7. Possible Risks or Side Effects of Taking Part in this Study

There is a slight risk of discomfort at the site of needle insertion when electroacupuncture is utilized. It is possible that some participants may experience enhanced sensation when electroacupuncture is utilized. Other side effects may include fatigue, headache, and insertion site redness or tenderness. Rare side effects may include swelling, bruising, or infection. The Traditional Chinese Medicine provider (acupuncturist) is actively involved in the care and will work with the participants to resolve their discomfort, staying within study protocols. There is no documented risk to the fetus.

There is a risk of a loss of confidentiality; however, every effort will be made to ensure participant information is secure.

8. Costs for Taking Part in this Study

You will not be charged for the electroacupuncture treatments that you receive for being part of the study. You are responsible for the conventional standard of care treatment costs per your previous arrangement with your provider.

If you are injured as a result of your participation in this research project, Mercy Health will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance including deductibles, will be your responsibility. Mercy Health's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact Becky Nauta at 616-258-9449 with any questions or to report an injury.

9. Payment for Taking Part in this Study

You will not be paid for being part of this study.

10. Possible Benefits to You for Taking Part in the Study

You may directly benefit from this study through enhancement of the cervical ripening process utilizing electroacupuncture if you are assigned to that group. You may not directly benefit from your participation in the study. However, your participation in this study may contribute to the understanding of the cervical ripening process as it relates to conventional standard of care treatment and the use of electroacupuncture.

11. About Participating in this Study

Before entering this study, or at any time during the research, you may ask for a second opinion about your care from a doctor who is not associated with this research study. You will be responsible for any costs associated with obtaining a second opinion.

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the investigator.

Your doctor, the investigator and/or the Sponsor (University of Nebraska Medical Center) may stop your participation in the study at any time if they decide that it is in your best interest. They may also do this if you do not follow instructions. If you have other medical problems or side effects, the doctor in consultation with the investigator will decide if you may continue in the research study.

If you wish to take part in this study, we expect that you will:

- Keep your study appointments. If you cannot keep an appointment, contact the investigator or research study staff to reschedule as soon as you know that you will miss the appointment.
- Tell the investigator or research study staff about any side effects, doctor visits, or hospitalization that you may have whether or not you think they are related to the study therapy.

If you decide to leave the research study, please contact the investigator so that the investigator can document the reason for leaving as part of the study.

12. Compensation for Injury

If you are injured as a result of your participation in this research project, medical care and/or hospitalization will be provided, if necessary. If you have health insurance, your insurance carrier will be billed in the ordinary manner. As with any health insurance, any costs that are not covered or are in excess of what is paid by your insurance, including deductibles, will be your responsibility. No funds have been set aside to pay you in the event of a study related injury.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

13. Confidentiality of Study Records and Medical Records

Information collected for this study is confidential. However, the investigator, delegated representatives of Mercy Health and Mercy Health Institutional Review Board (IRB), the University of Nebraska Medical Center Institutional Review Board (IRB), and other government agencies involved in keeping research safe for people may look at your medical records when necessary, either in person, by mail, fax or electronically.

After informed consent is obtained, participants will be randomized through a computer-generated system. A consecutively numbered, sealed manila envelope containing the study arm assignments will be opened by the primary investigator for each participant. All patient records will be de-identified utilizing pre-assigned codes included in each envelope. The patient name and assigned codes will be kept in a file separate from other documentation.

All data will be secured and maintained utilizing REDCap (a secure electronic data capture system) to assure the confidentiality of data. All paper files will be kept locked in a fireproof cabinet in a locked environment by the primary investigator. The primary care providers and TCM (acupuncture) provider keep separate patient files and are held to the same high standards of Mercy Health.

14. Release of Personal Information

We will do our best to ensure that your personal information is kept confidential and private to the maximum extent required by law. We cannot guarantee absolute confidentiality and privacy. Your personal information may be disclosed if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

15. Financial Conflict of Interest

The investigator involved in this study has not disclosed any financial interests that may be a conflict with the planned study activity.

16. HIPAA Authorization

As part of this research study you are being asked to release your health information. The Health Insurance Portability and Accountability Act (HIPAA) permits a hospital or doctor's office to use or release protected health information (PHI) for the purposes of treatment, payment or health care operations. A HIPAA authorization gives permission from you to use or release PHI for research purposes, and is in addition to your consent to participate in this research study. In working with the sponsor (UNMC), the investigator, **Becky Nauta**, will use and share personal health information about you. This is information about your health that may also include your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results. Some of these tests may have been done as part of your regular care. The investigator will use this information about you to complete this research.

The investigator will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor (University of Nebraska Medical Center) and its representative may review or copy your personal health information at the study site. Regulatory authorities and the Mercy Health's Institutional Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Authorization, you allow the investigator to use your personal health information to carry out and evaluate this study. You also allow the investigator to share your personal health information with:

- The sponsor (University of Nebraska Medical Center) and its representatives
- The Mercy Health Regional Institutional Review Board
- Other regulatory agencies - e.g. National Institutes of Health (NIH) and Department of Health and Human Services (DHHS)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health confidential.

You have the right to see and get a copy of your records related to the study for as long as the investigator has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the investigator in writing. Send your written withdrawal notice to **Becky Nauta; Mercy Health Saint Mary's Research Department; 200 Jefferson S.E.; Grand Rapids, MI 49503. Please mark confidential.** If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical records may be reviewed. All information that has already been collected for study purposes and any new information about an adverse event to the study will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

This authorization does not have an expiration date.

If you do not sign this Authorization, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

17. Names of Contacts for Questions about the Study:

If you have any questions about taking part in this study, or in the event of a research related illness or injury, contact Becky Nauta; 616-258-9449. If you have any questions about your rights as a research participant, you may contact:

Brenda Hoffman, Mercy Health Regional Institutional Review Board (IRB) Chairperson
200 Jefferson Ave. SE – Grand Rapids, MI 49503
Telephone: 616-685-6198

or

University of Nebraska Medical Center
Kevin Epperson, Institutional Review Board (IRB) Chairperson
987830 Nebraska Medical Center
Omaha, NE 68198-7830
Telephone: 402-559-2587

DOCUMENTATION OF INFORMED CONSENT

By signing this consent form and HIPAA authorization and by initialing each page, you certify you have read this form, you have had the opportunity to ask questions about this study and this form, and you have received answers that fully satisfy those questions. You are voluntarily signing this consent form and HIPAA authorization as evidence of your decision to participate in this research study and you are giving authorization for release of all your protected health information relative to this research.

You are aware you may withdraw your consent and HIPAA authorization in writing at any time without harming your future medical care or losing any benefits to which you might be otherwise entitled. You have been advised that the investigator in charge of this study may discontinue your participation in this study if it is felt to be in your best interest, if you do not follow the study requirements or if the study is stopped.

You will receive a signed copy of this Research Informed Consent Form and HIPAA Authorization.

By signing this consent form, you have not waived any of your legal rights or released the parties involved in this study from liability for negligence.

Signature of Study Participant

Date

Printed Name of Study Participant

Signature of Person Obtaining Consent

Date

Signature of Principal Investigator

Date

09-28-15

Appendix C – Complete Blood Count (CBC) order

Mercy Health Laboratory
 Saint Mary's
 200 Jefferson SE • Grand Rapids, Michigan 49503
 616-685-6595

Client: OB RESEARCH STUDY IRB 15-0803-01

Name: _____ **DOB:** _____

Diagnosis: Not needed guarantor acct.

BILLING to GUARANTOR

*GOBRESEARCHSTUDYIRB,
 CPI##17540646

Pt. Address: Leave pt. address in Health Quest

Ordering Provider: _____
 (print last name, first name)

LAB Print Location: GAHC

Check Test(s) Ordered:

CBC (no diff)

This copy-Saint Mary's Laboratory
 Questions: OB Research Becky Nauta 258-9449 Saint Mary's Sue 685-6232,

rev. 6/9/16

Appendix D – Physician Letter



OB/GYN East Beltline
 1471 East Beltline, Suite 101
 Grand Rapids, MI 49525
 616.685.8600 Phone
 616.365.0057 Fax
MercyHealthPhysicianPartners.com

July 27, 2015

Becky Nauta, MSN, RN
 University of Nebraska Medical Center
 College of Nursing
 c/o 4931 36th Avenue
 Hudsonville, MI 49426

Dear Ms. Nauta,

I enthusiastically support your research study entitled "The Use of Electroacupuncture for Cervical Ripening". The use of Electroacupuncture for Cervical Ripening will offer pregnant women with a low Bishop score a minimally invasive option to enhance cervical ripening and potentially reduce or eliminate the need for pharmacologic induction.

As an OB physician, I grant you permission to recruit subjects at the Mercy Health OB physician partners East Beltline Practice. Recruitment can proceed following approval from the Institutional Review Board.

I look forward to working with you on this project.

Sincerely,

Sajal Bennett
 OB Physician
 Mercy Health Physician Partners

Appendix E – Data Collection Tools

Patient Name: _____

Nauta - 1

Nauta – Research Protocol – Data Collection

Assigned ID Number: _____ Assigned Group: _____

Birthdate: _____ Provider Office: _____

EDC: _____ Age in Weeks Gestation: _____

Parity: _____ Ethnicity: _____

Initial Bishop Score Documentation - Date: _____ Score: _____

(Circle Elements)

| Bishop Scoring System | | | | | |
|-----------------------|---------------|----------------|---------|-------------|--------------------|
| Factor | | | | | |
| Score | Dilation (cm) | Effacement (%) | Station | Consistency | Position of Cervix |
| 0 | Closed | 0-30 | -3 | Firm | Posterior |
| 1 | 1-2 | 40-50 | -2 | Medium | Midposition |
| 2 | 3-4 | 60-70 | -1, 0 | Soft | Anterior |
| 3 | ≥5 | ≥ 80 | +1, +2 | — | — |

From: "Pelvic scoring for elective induction." By E. H. Bishop. Obstetrics and Gynecology, 24, p.267. Copyright 1964 by American College of Obstetricians and Gynecologists.

08-13-15

Patient Name: _____

Nauta - 2

Nauta – Research Protocol – Data Collection

Assigned ID Number: _____ Assigned Group: _____

Birthdate: _____ Provider Office: _____

EDC: _____ Age in Weeks Gestation: _____

Parity: _____ Ethnicity: _____

Second Bishop Score Documentation - Date: _____ Score: _____

(Circle Elements)

| Bishop Scoring System | | | | | |
|-----------------------|---------------|----------------|---------|-------------|--------------------|
| Factor | | | | | |
| Score | Dilation (cm) | Effacement (%) | Station | Consistency | Position of Cervix |
| 0 | Closed | 0-30 | -3 | Firm | Posterior |
| 1 | 1-2 | 40-50 | -2 | Medium | Midposition |
| 2 | 3-4 | 60-70 | -1, 0 | Soft | Anterior |
| 3 | ≥5 | ≥ 80 | +1, +2 | — | — |

From: "Pelvic scoring for elective induction." By E. H. Bishop. Obstetrics and Gynecology, 24, p.267. Copyright 1964 by American College of Obstetricians and Gynecologists.

PLEASE BRING WITH YOU TO LABOR AND DELIVERY

Patient Name: _____ Birthdate _____

Final Bishop Score Documentation: Date: _____ Score: _____

(Circle Elements)

| Bishop Scoring System | | | | | |
|-----------------------|---------------|----------------|---------|-------------|--------------------|
| Factor | | | | | |
| Score | Dilation (cm) | Effacement (%) | Station | Consistency | Position of Cervix |
| 0 | Closed | 0-30 | -3 | Firm | Posterior |
| 1 | 1-2 | 40-50 | -2 | Medium | Midposition |
| 2 | 3-4 | 60-70 | -1, 0 | Soft | Anterior |
| 3 | ≥5 | ≥ 80 | +1, +2 | — | — |

From: "Pelvic scoring for elective induction." By E. H. Bishop. Obstetrics and Gynecology, 24, p.267. Copyright 1964 by American College of Obstetricians and Gynecologists.

08-13-15

Patient Name: _____

Nauta – 4 (08-13-15)

Physician Office Visits

| Date of Visit | Gestational Age | Findings | Concerns |
|---------------|-----------------|----------|----------|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Patient Name: _____ DOB: _____

Acupuncturist Visits

CBC Date Completed: _____ Platelet Count: _____

| Date of Visit | Gestational Age | Fetal Heart Rate and Quadrant Heard | Completed Treatment | Concerns/Points TCM provider would have added if individualized treatment |
|---------------|-----------------|-------------------------------------|---------------------|---|
| | | Before: After: | | |
| | | Before: After: | | |
| | | Before: After: | | |
| | | Before: After: | | |
| | | Before: After: | | |

ID Number: _____

Nauta – 4

Delivery Information

Date of Delivery: _____

Time of Delivery: _____

Type of Delivery: _____

Active Labor: Start Time: _____ End Time: _____

Infant Apgars: 1 minute _____ 5 minute _____ 10 minute _____

Induction Methods Utilized: (Pharmacological method/Mechanical method/amt/time)

Comments

Appendix F – Mercy Health IRB Approval



MercyHealth.com
Page 1 of 2

NOTICE OF IRB NEW APPROVAL

To: Becky Nauta, MSN, RN, CNML
4931 36th Avenue
Hudsonville, MI 49426

Re: IRB# 15-0803-01
The Use of Electroacupuncture for Cervical Ripening

Date: September 30, 2015

Thank you for your re-submission of the protocol, informed consent form, and patient brochure in response to the IRB's request dated 09/24/2015.

This is to inform you that the Mercy Health Regional Institutional Review Board (IRB) has approved the above research study. This also includes approval for:

Protocol, Version 09-28-2015
Research Informed Consent Form, Version 09-28-15
Data Collection Tool, Version 08-13-15
Patient Education Booklet, Version 09-28-15
Recruitment Flyer, Version 07-31-15

The approval period is from September 30, 2015 to September 21, 2016. Your study number is 15-0803-01. Please be sure to reference this number and/or your study title in any correspondence with the IRB.

Your responsibilities to the IRB do not end with this approval. You will be required to submit a continuing review report by the date indicated on the second page of this letter or, upon completion of the study, a notification of study closure form and a report of the study's findings. **Failure to properly renew or close out your study may jeopardize future IRB approvals.**

Continued approval is conditional upon your compliance with the following requirements:

- A copy of the Informed Consent Form(s), which includes HIPAA authorization, approved as of September 30, 2015, is enclosed. No other consent form(s) may be used. The consent form(s) must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject must be given a copy of the signed consent form(s).

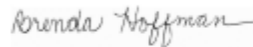
Institutional Review Board - 200 Jefferson Ave. SE – Grand Rapids, MI 49503 - P: 616.685.6198

- All protocol modifications to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate risks to the study subjects.
- Significant changes to the study site and significant deviations from the research protocol that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research must be promptly reported to the IRB.
- All forms of advertising (including but not limited to: television, radio, internet, flyers, brochures, posters) must be submitted to the IRB and must not be implemented until approved by the IRB.
- Unanticipated problems, adverse events and safety reports must be reported to the IRB if, in the opinion of the local investigator, the event is *unexpected, probably related* to the study article, *and* places subjects or others at *greater risk* than was previously known. (See IRB SOP# RR404 – <http://www.mercyhealth.com/irbsops>). EXCEPTION: If there is the *death* of a participant *at your site*, we request this information be submitted to the IRB.
- Please complete and submit reports to the IRB as follows:

Renewal of the study - complete and return the Continuing Review Report/Request for Renewal by August 1, 2016. The study cannot continue after September 21, 2016 until re-approved by the IRB.

Closure of the study – complete and return the Notification of Study Closure form.

Please call me if you have any questions about the terms of this approval.



Brenda Hoffman
IRB Chairperson

Copy: File

Enclosures: Informed Consent Form(s) approved September 30, 2015

Appendix G – UNMC IRB approval



NEBRASKA'S HEALTH SCIENCE CENTER

Office of Regulatory Affairs (ORA)
Institutional Review Board (IRB)

November 23, 2015

Becky A. Nauta, MSN, RN
College of Nursing
UNMC - 5330IRB # **744-15-ET**TITLE OF PROTOCOL: **The Use of Electroacupuncture for Cervical Ripening**DATE OF REVIEW: **November 19, 2015**DATE OF FINAL ACCEPTANCE: **November 19, 2015**VALID UNTIL: **November 19, 2020**

The UNMC IRB has completed its review of the above-titled external research protocol. Please be advised that the UNMC IRB has accepted approval from the Mercy Health Regional Institutional Review Board (IRB) under the provisions of 45 CFR 46.114.

It is understood that the Mercy Health Regional IRB is responsible for oversight of the above-titled research project in accordance with HHS regulations at 45 CFR 46 and FDA regulations at 21 CFR 50, 56 as applicable. Such oversight includes: 1) continuing review no less often than annually, 2) approval of any protocol amendments, 3) reporting to the Office for Human Research Protections (OHRP), and FDA as applicable, 4) unanticipated problems involving risk to subjects or others, and 5) serious and continuing non-compliance, as well as suspensions. Should any reports be filed with OHRP and/or FDA, the UNMC IRB should be provided with copies of such correspondence.

Finally, please be advised that acceptance by the UNMC IRB of the Mercy Health Regional IRB approval is valid for a period of **five years** from the initial date of review. If the study continues beyond the five year period, the project must be resubmitted in order to maintain an active status.

On behalf of the IRB,

Signed on: 2015-11-23 11:41:00.000

Kevin J. Epperson, CIP
IRB Administrator III
Office of Regulatory Affairscc: Bruce G. Gordon M.D.
IRB Executive Chair

Academic and Research Services Building 3000 / 987830 Nebraska Medical Center / Omaha, NE 68198-7830
402-559-6463 / FAX: 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

Research Study Opportunity:
The Use of
Electroacupuncture for
Cervical Ripening

WELCOME
baby!

Primary Investigator:
Becky Nauta, MSN, RN, CNML
University of Nebraska Medical Center – College of Nursing

09-28-15

Why is this study important?

The purpose of this research study is to determine if the use of electroacupuncture is as effective as medications for ripening the cervix.

Key Definitions:

Cervical Ripening: is the process of causing physical softening, thinning and dilating of the cervix in preparation for labor.

Electroacupuncture: Electrical stimulation of acupoints exclusively through acupuncture needles.

Deqi: a sensation that is felt after placement and rotation of the acupuncture needles.

Key Questions:

How does acupuncture work?

Acupuncture involves stimulating specific points in the body in order to treat a specific condition or regain body balance.

Who does the acupuncture treatment?

Electroacupuncture treatments will be performed by a licensed Traditional Chinese Medicine provider at the Wege Institute for Mind, Body and Spirit located at Mercy Health Saint Mary's.

Are acupuncture needles like the needles used for shots?

No. Acupuncture needles are very thin. Five or six acupuncture needles could actually fit into the needle used for shots.

What does acupuncture feel like?

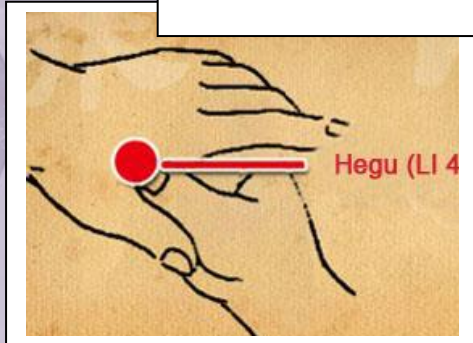
The needles are inserted quickly and usually there is minimal discomfort, often described as less than a pin prick.

After needle insertion, it is slightly rotated until deqi is obtained. Deqi may feel like a strange sensation around the needle or a feeling of heaviness or slight aching in the lower back area.

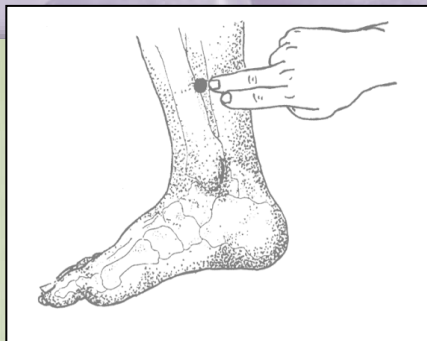
The low voltage (2Hz) electrostimulation will be applied for 20 minutes, allowing the opportunity for continuous stimulation instead of manually turning the needle every 10-20 minutes.

After the electroacupuncture treatment, you may feel energized or relaxed and slightly fatigued. You may also feel your baby move more right after the electroacupuncture treatment.

What acupoints will be used?



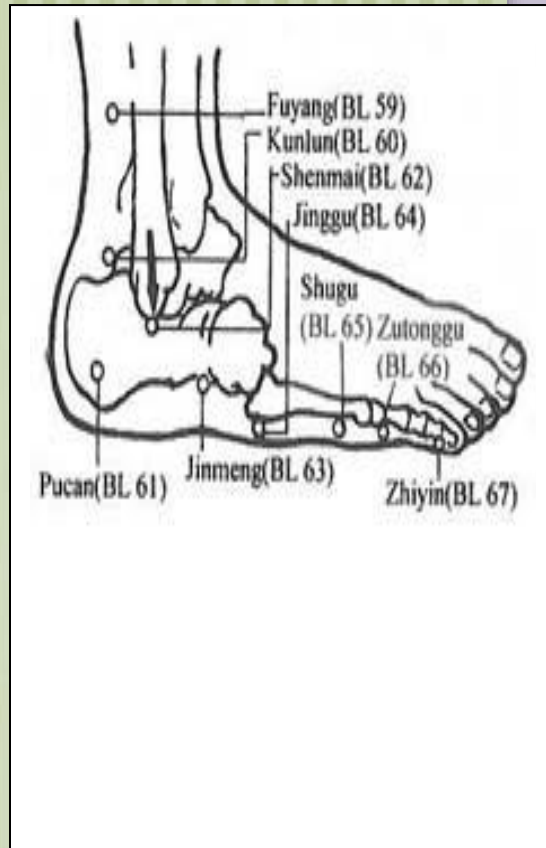
LI 4:
Located on
the hand



SP 6:
Located on the
side of the
lower leg

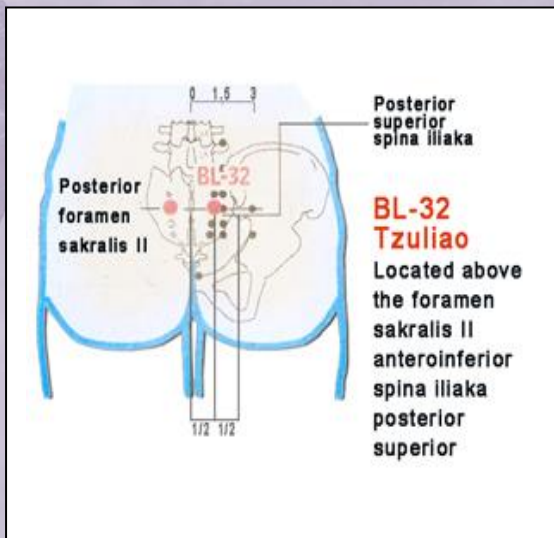
08-25-15

What acupoints will be used?

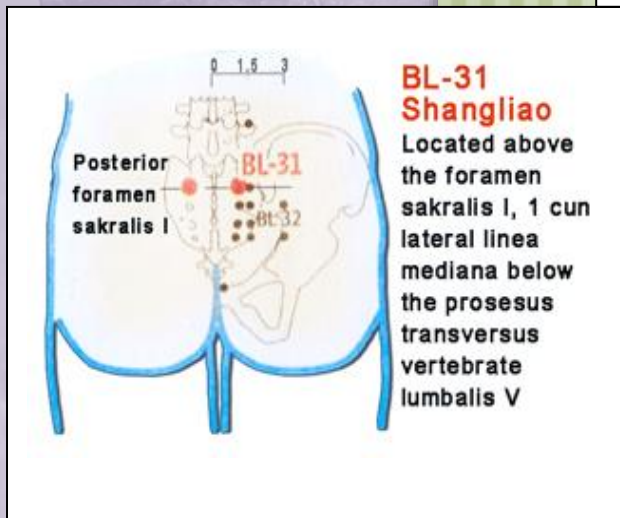


BL 60:
located
behind the
ankle joint

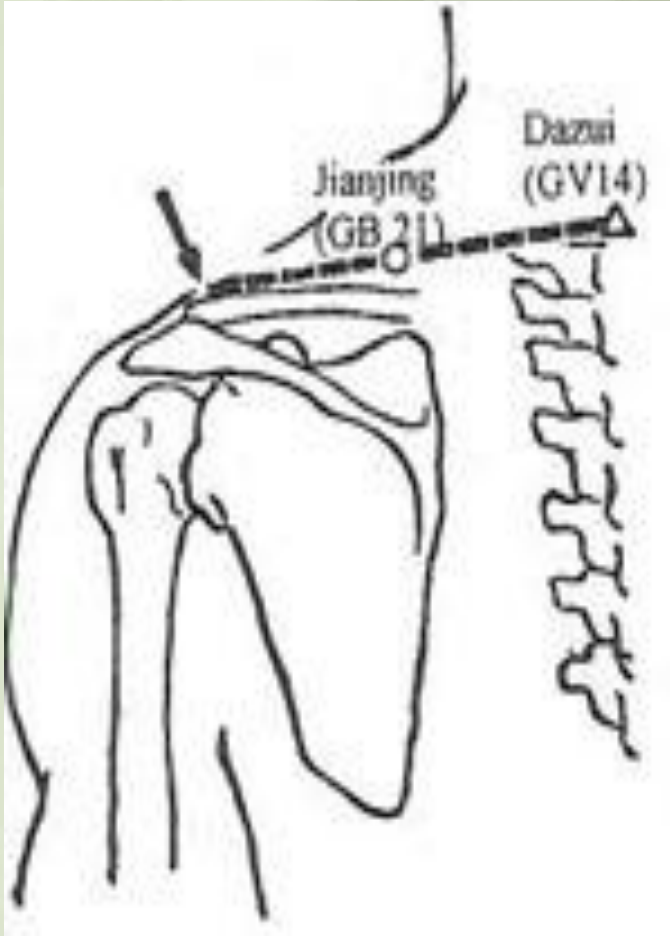
What acupoints will be used?



Shangliao (BL 31) and Ciilian - Tzuliao (BL 32) located on the lower back



09-28-15



What are the potential benefits?

- You may benefit directly from this study through enhancement of the cervical ripening process if you are assigned to that group.
- There is no charge for acupuncture treatments if you are assigned to that group.
- You may not directly benefit from your participation in this study, however your participation may contribute to the understanding of the cervical ripening process.

What are the potential risks?

- There is a slight risk of discomfort at the site of needle insertion.
- You may feel tired.
- There is a slight risk of headache.
- There is a slight risk of redness or tenderness at the insertion site.
- Rare side effects may include swelling, bruising, or infection.
- There is no documented risk to the fetus.

What if I have questions?

- Contact Becky Nauta (the Primary Investigator) at 616-258-9449.

Steps in the study process:

1. If you have completed 39 weeks of pregnancy and your physician determines that your cervix has not started the thinning process and you meet guidelines established for this study, they will discuss this study option with you.
2. The primary investigator will meet with you and explain the study in detail and answer any questions that you may have. If you agree to be part of the study, you will be asked to sign a document called "Informed Consent".
3. Once you have agreed to take part in the study, the primary investigator will give you an envelope with your study assignment in it. There are two potential study groups: a conventional treatment group (which means you will continue with your regular appointments with your physician) or a conventional study plus electroacupuncture group (which means you will continue with your regular appointments with your physician as well as receive electroacupuncture treatments). Since the selection is randomized, you will have a 50/50 chance of receiving the electroacupuncture treatment.
4. A Complete Blood Count (CBC) will be drawn on all study participants at no charge to them 24 hours prior to the first intervention.
5. If you are in the electroacupuncture study group, you will be scheduled for an appointment with the Traditional Chinese Medicine Provider as soon as possible after acceptance into the study.
6. If you are in the electroacupuncture group, you will receive three electroacupuncture treatments within the first week of the involvement and two electroacupuncture treatment during the second week of involvement. The first treatment will take approximately 90 minutes with remaining treatments between 40-60 minutes. The maximum number of electroacupuncture treatments is five.
7. Participants in the study will not be charged for electroacupuncture treatments.
8. To evaluate if electroacupuncture treatment was effective, data will be collected from all study participants' medical records at the beginning of the study and after the delivery of the baby, noting the delivery date, time, length of time in labor as well as the type of delivery. All information is kept in a confidential file and will have all personal identifying information removed prior to data analysis. When the study is complete, the results will be available to you.

Questions?? If at any time you have questions or concerns, please contact **Becky Nauta, Primary Investigator for the study at 616-258-9449.**

Appendix I: Researcher Field Notes

Nauta – Field Notes

Name: _____

Date: _____

Elected to be part of the study: Yes: _____ No: _____

Why/Why not? _____

Conventional Treatment Group: What were your thoughts when you were randomized into the conventional treatment group?

Conventional Treatment plus Electroacupuncture Group: Where were your thoughts when you were randomized into the conventional treatment plus electroacupuncture group?

If part of the electroacupuncture group:

Was the timing of the acupuncture treatment convenient for you?

Would you recommend the acupuncture treatment to a friend?

If you could change anything, what would it be?

Appendix J: Letter of Submission to JOGNN

From: **JOGNN** em@editorialmanager.com
Subject: J16-235 JOGNN
Date: October 10, 2016 at 1:02 AM
To: Becky Ann Nauta, beckynauta@gmail.com

CC: dbrage@unmc.edu, slwilhel@unmc.edu, bcyates@unmc.edu

Dear Becky Nauta,

Your manuscript entitled "State of the Science on Acupuncture for Promoting Cervical Ripening and Labor Induction" by Becky Ann Nauta, MSN, RN; Diane Brage Hudson, RN, PhD; Susan L. Wilhelm, PhD, RNC; Bernice C Yates, PhD, RN has been successfully submitted to JOGNN and is now being reviewed by the JOGNN Editor. For future reference, your manuscript has been assigned the following number: J16-235. Reviewer commentaries will be forwarded to you as soon as possible, usually within four to six weeks.

Co-authors: Please contact the editorial office as soon as possible if you disagree with being listed as a co-author for this manuscript.

Please note that according to your copyright agreement with JOGNN, your manuscript, any part of your manuscript, and any research results may not have been previously published and may not be concurrently submitted to another publication or released through any media prior to publication in JOGNN.

You will be able to check on the progress of your manuscript by logging on to Editorial Manager as an author at <http://jognn.edmgr.com/>.

Thank you for submitting your work to JOGNN.

Kind regards,
Angela Hartley
Managing Editor