Protocol Title: Does Ultrasound-guided CSE Technique Improve Midline Placement of Epidural Needle Thereby Helping Junior Residents With Correct Placement of the Catheter Compared to the Placement Using With Anatomical Landmarks?
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Mount Sinai Beth Israel Mount Sinai St. Luke's Mount Sinai Roosevelt	Protocol Name:	Does Ultrasound-Guided CSE (Combined Spinal Epidural) Improve Midline Placement of Epidural Needle with Positive CSF Flow Through the Spinal Needle, Compared to Catheter Placement using Palpation of Anatomical Landmarks: A Comparative Study Done in Junior Residents Rotating for the First Time on the Labor and Delivery Floor
	Principal Investigator:	Barbara Orlando, MD.
	Primary Contact Name/Contact Info:	Barbara Orlando, MD.
	Date Revised:	January 25, 2017
	Study Number:	IRB 15-0031 / HSM# 15-00583/IF# 1780780

HRP-503 PROTOCOL TEMPLATE

- *Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. Provide information if and when applicable, and in cases where an entire section is not applicable, indicate this by marking the section "N/A". Do not delete any sections.*
- *This document refers to Checklists: these can be found here: http://icahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/researchers-palette/pphs-form-and-document-kiosk*
- *This protocol template may be used for submissions to the Mount Sinai Beth Israel IRB or the Mount Sinai SLRHC IRB. If the research is only occurring at one site within the Mount Sinai Health Care System, you may delete references to the other sites as appropriate.*
- ***For any items below that are already described in the sponsor's protocol, the investigator's protocol, the grant application, or other source documents, you may simply reference the title and page numbers of these documents in the sections below, rather than cutting and pasting into this document.. Do NOT refer to any derived documents, such as the Sample Consent document, or other internal documents required with the submission.***
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Brief Summary of Research (250-400 words):

Epidurals provide superior labor analgesia and anesthesia compared to other modalities. Unfortunately, failure of the epidural is a frequent problem (up to 27% in some studies). These include insufficient analgesia, catheter dislodgement and conversion to general anesthesia and may result from technical difficulties, insufficiency of local anesthetics, epidural septum or midline adhesions, and misplacement of the epidural catheter (half of the failures). The combined spinal epidural technique (CSE) technique is widely utilized by obstetric anesthesiologists. The epidural space is located with a larger bore needle, a smaller spinal needle is used to deliver local anesthetic then an epidural catheter is placed. With CSE, pain relief is rapid and profound due to the spinal injection and the epidural catheter can be used for labor after the spinal doses wears off or if there is a need for cesarean delivery. CSE provides comparable/decreased failure rates for labor analgesia and surgical anesthesia, compared to epidural. Positive CSF flow in the spinal needle confirms correct epidural needle placement in the epidural space and in the **midline** position. This should minimize lateralized placement of the catheter with less unilateral analgesia.

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The practice of CSE relies on the palpation of anatomical landmarks not always easy to feel. For junior resident, it can be challenging to identify those landmarks on a patient in pain with higher average weight due to the pregnancy. Therefore, the epidural needle may be placed "off midline" with failure to pierce the dura with the spinal needle. The spinal dose will not be possible and this could result in an increased "failed" or suboptimal epidural analgesia.
Ultrasound (US) has recently been utilized to facilitate placement of lumbar epidurals and spinals by imaging the lumbar spine in different scanning planes to identify the epidural space. The two acoustic windows used are the transverse and the longitudinal paramedian plans to identify the correct interspace, depth and midline position.
A previous study done by our team, comparing "blind" vs US guidance technique, did not show any significant difference in term of success rate or complications. However, the study was done by 4 trained physicians with lot of practice. We thought about doing this study with junior residents rotating for the first time on the floor, to see if there is any difference in their learning curve using the US versus the "blind" technique.

1) Objectives

Research Question:

To determine if the junior resident learning curve is improved using the US technique.

Background

The objective of this study is to determine if US guided CSE technique will improve, in the junior residents' population rotating for the first time on the labor and delivery floor, the placement of the epidural needle in the midline position, thereby increasing the incidence of positive CSF flow in the spinal needle and correct placement of the catheter. By randomly assigning patients to one or the other technique for the same junior resident throughout his rotation, it will be possible to determine if ultrasound guided CSE technique more accurately places the epidural needle in the midline position compared to epidural needle placement via palpation of anatomical landmarks, and if the learning curve and success rate is better with the US technique compared to the anatomical landmark technique.

2) Setting of the Human Research

The study will take place at the Roosevelt site on the Labor and Delivery Floor.

3) Resources Available to Conduct the Human Research

The Mount Sinai Roosevelt's Labor and Delivery floor is a busy unit with an average of 7000 deliveries per year. Enrolling 48 patients should be feasible in a year period. The idea is to have this study repeated every month with each new junior resident coming to rotate for the first time, for at least 6 months to see if there is a pattern. In addition, we have a team of OB anesthesia trained attending and fellow who will be involved in this study and keeping track of the results.

4) Study Design

a) Recruitment Methods

The objective of this study is to determine if US guided CSE technique will improve, in the junior residents' population rotating for the first time on the labor and delivery floor, the placement of the epidural needle in the midline position, thereby increasing the incidence of positive CSF flow in the spinal needle and correct placement of the catheter. By randomly assigning patients to one or the other technique for the same junior resident throughout his rotation, it will be possible to determine if ultrasound guided CSE technique more accurately places the epidural needle in the midline position compared to epidural needle placement via palpation of anatomical landmarks, and if the learning curve and success rate is better with the US technique compared to the anatomical landmark technique. The resident will be his/her own control since he will alternately do the procedure with one or the other technique, in a randomly assign process. A consent to participate in the study will be given to the resident prior to including him/her in the study. This will give them the right to "decline participation" without any repercussion on their training. The resident's decision about whether or not to participate in this study and their performance in the study will in no way affect their standing with the residency at Mt. Sinai and their future employment.

Group 1: Ultrasound group
Woman requests epidural for pain relief
Ultrasound guided CSE placed
Continuous epidural infusion started
Infusion 12 ml/hr of 0.0625% Bupivacaine and Fentanyl 2mcg/ml

Group 2: Palpation of anatomical landmarks
Woman requests epidural for pain relief
CSE placed using palpation of anatomical landmarks
Continuous epidural infusion started

Infusion 12 ml/hr of 0.0625% Bupivacaine and Fentanyl 2mcg/ml

As part of the recruitment methods, we will place recruitment flyers with study information in OB clinics, OB physician offices and have them posted at prenatal visits for parents planning delivery at the hospital. The investigator will present this study at OB department meeting such as OB Grand Rounds so the study can be described to the OB physicians. The OB physicians can be asked to post the flyer in their offices and asked if their patients can be recruited for this study. This information flyer will describe this study and provide a contact number for the PI or a member of the study team. This is so that patients can contact the study team to get more information about the study. If contacted potential subjects can receive the consent form in the mail to review and discuss with the investigators prior to presenting in the labor ward and providing consent there. This will give patients enough time to ask any questions they may have about the study before they sign the consent form. If the patient did not inquire about the study prior, upon admission to labor and delivery, further information will be provided, questions answered, and consent will be obtained by co-investigators.
All potential participants will be given the option to be approached by the research team or not. If they agree to it, the research team will get in contact with the patient. Participants will be randomized to either Group 1 or Group 2 for our junior resident. After obtaining informed consent during early labor, the patients will have the midline identified and marked with a surgical marker either by ultrasound or midline palpation. Prior to be included in the study, the junior resident will be given a permission note with an option to "decline participation" without any repercussion on their training. The resident's decision about whether or not to participate in this study and their performance in the study will in no way affect their standing with the residency at Mt. Sinai and their future employment. If they agree to conduct the study, they will be briefly trained to the use of US or to the landmark technique by one of our OB anesthesia attending participating in the study. Thereafter, the junior resident will attempt to perform a CSE. Positive or negative CSF flow in the spinal needle will be recorded. In addition, the number of attempts and adjustments will be recorded. Each group will receive the same intrathecal dose of fentanyl and local anesthetic and started on the same epidural infusion. After 2 hours, participant's dermatome and analgesia levels will be assessed using temperature and sensation.

b) Inclusion and Exclusion Criteria

Inclusion Criteria:

a. Term (>37 weeks gestation)
b. Vertex presentation
c. Singleton gestation

d. Ability to provide informed consent
e. Request for analgesia for labor pain
f. Maternal age 18 years or greater

Exclusion Criteria:

a. Preterm (< 37 weeks gestation)
b. Presentation other than vertex (breech, transverse)
c. Active drug/alcohol dependence
d. Previous spinal surgeries
e. Known spinal deformities
f. 9 cm and greater dilation

c) Number of Subjects

The study design is a prospective randomized study. The statistics involved require 48 patients per resident who rotates for a month on Labor and Delivery. The anticipated duration of the study is one year. This will allow for a power analysis of 80%.

That is 24 participants in each group
24 in Group 1 (ultrasound group)
24 in Group 2 (palpation using anatomical landmarks)

d) Study Timelines

Each patient included in the study will be followed for 2 hours after placement of the CSE. Participant's dermatome and analgesia levels will be assessed using temperature and sensation. The need for replacing the CSE will be accounted for, as well as the incomplete/absent block after the spinal dose wears off.

This study should be completed within a year period after it starts.

e) Endpoints

Primary objective:

To determine if the junior resident learning curve is improved using the US technique.

Secondary objective:

We believe that ultrasound guided CSE technique will help junior resident rotating for the first time on the labor and delivery floor to place more accurately the epidural needle in the midline position as compared to placing the epidural needle via palpation of anatomical landmarks. This will result in increased ability to deliver the spinal dose with positive CSF in the spinal needle, to have correct midline placement of the epidural catheter, and to obtain adequate symmetrical labor analgesia/anesthesia.

Tertiary objective:

To determine if the ultrasound guided CSE technique will decrease the number of angle adjustments (redirections) of the epidural needle the ultrasound guided CSE technique and the number of attempts to locate the epidural space and midline position

f) Procedures Involved in the Human Research

All potential participants will be given the option to be approached by the research team or not. If they agree to it, the research team will get in contact with the patient. Participants will be randomized to either Group 1 or Group 2 for our junior resident. After obtaining informed consent during early labor, the patients will have the midline identified and marked with a surgical marker either by ultrasound or midline palpation by the junior resident. Once the junior resident has identified the insertion point by either technique, this same resident will then attempt to perform the CSE by using the mark made. Positive or negative CSF flow in the spinal needle will be recorded. In addition, the number of attempts and adjustments will be recorded. Each group will receive the same intrathecal dose of fentanyl and local anesthetic and started on the same epidural infusion. Each patient will be monitored per the ASA guidelines for monitoring in neuraxial analgesia placement (blood pressure cuff, pulse oximeter and fetal heart monitoring). Initially, the data recorded on a sheet made for the study, will include: number of insertion/redirection of epidural needle in the same epidural space, number of epidural space attempted, obtention of CSF. After 2 hours, participant's dermatoma and analgesia levels will be assessed using temperature and sensation. We will also record need to replace CSE, unilateral block, adequate pain relief.

g) Data Management and Confidentiality

Participants will be asked to sign an informed consent that is approved by the St. Luke's-Roosevelt IRB and will receive a copy of the approved consent. Original signed consents will be placed in the patient's permanent medical record. All the material obtained in the study will be used for research

purposes only. All data will be confidential and no patient identification will be part of the permanent data record. The data will be HIPPA compliant and will be stored in a locked file cabinet in the anesthesia office.

h) Provisions to Monitor the Data to Ensure the Safety of Subjects

There are no additional health risks to the participants in the study.

i) Withdrawal of Subjects

The patient's involvement in this study is completely voluntary and all subjects will be informed that they can withdraw at any time without loss of benefits to which they are otherwise entitled

5) Risks to Subjects

All the potential risks have been discussed. Potential benefit for the patients is a well-placed epidural catheter that provides symmetrical labor analgesia. The risks are reasonable in relation to the anticipated benefits that are expected to result.
There will be no exposure to radiation because of participating in this study

6) Provisions for Research Related Harm/Injury

The research does not involve more than minimal risk to subjects.

7) Potential Benefits to Subjects

The potential benefit is a well-placed epidural catheter in either branch of the study, which provides adequate symmetrical labor analgesia. The learning curve might be faster with the ultrasound technique.

8) Economic Impact on Subjects

Patients will not incur any additional financial expense as a consequence of being enrolled in this study.

9) Payments to Subjects

Patients will not be compensated for participation in this study.

10) Consent Process

Patients will be offered participation in the study after a standard preoperative evaluation is performed. The patient's involvement in this study is completely voluntary and all subjects will be informed that they can withdraw at any time without loss of benefits to which they are otherwise entitled.

11) Process to Document Consent in Writing

A written informed consent will be obtained from the patient before the epidural placement.

12) Vulnerable Populations

Include	*Exclude*	*Vulnerable Population Type*
	N	*Adults unable to consent*
	N	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	N	*Wards of the State (e.g. foster children)*
Y		*Pregnant women*
	N	*Prisoners*

US assisted not guided