Protocol: Comparison of Loss of Resistance Technique with Air versus Saline to Identify Epidural Space for Combined Spinal Epidural Labor Analgesia

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Background and Significance:

Combined spinal epidural labor analgesia is a common form of labor pain relief method that provides rapid onset of labor pain relief with the first dose of medicine and also an epidural catheter is inserted for continuous administration of epidural medication throughout the duration of labor. In combined spinal epidural labor analgesia technique, an epidural is inserted first after numbing the skin with local anesthetic. When the epidural space is identified by the epidural needle, then a spinal needle is inserted through the epidural needle into the spinal fluid space. When a drop of clear spinal fluid return through the spinal needle, the spinal space is identified and then the first dose of medicine is administered through the spinal needle, after which, the spinal needle is removed and an epidural catheter is inserted into the epidural space for additional medication as needed. When the epidural needle is inserted initially to identify the epidural space, anesthesiologists typically attach to the epidural needle a syringe with 2-3 mL of air or saline. The air or saline is used to help identifying the epidural space. Both air and saline are commonly used and it is not clear and debatable which is a better method to identify the epidural space when the combined spinal epidural labor analgesia is performed. Some clinicians believe air is a better choice because when a drop of clear fluid returned from the spinal needle during the combined spinal epidural technique, it would be clear that it is from the spinal fluid since no saline and only air has been used in the syringe, and the first dose of medicine can be administered via the spinal needle. However, other clinicians believe saline is better because it allows easier and more reliable identification of the epidural space and that the saline would not interfere with the spinal fluid return from the spinal space during combined spinal epidural labor analgesia. To date, no studies have compared the outcome and success of combined spinal labor analgesia between using saline versus air for identifying the epidural space. The goal of this study is to compare whether air or saline makes a difference in success and outcomes of the combined spinal epidural labor analgesia. The results of this study may provide information on better choice of technique for obtaining combined spinal labor analgesia. A total of 350 labor patients will be enrolled at Forsyth Medical Center.

Obese patients present significant challenges for the anesthesia care providers. Neuraxial anesthesia is preferred over general anesthesia for Cesarean Section. In obese patients placement of spinal or epidural anesthesia is complicated by diminished landmarks and increased depth of the epidural and subarachnoid space. The ability to identify the epidural or subarachnoid space is more likely due to misdirection than inadequate needle length. In spinal anesthesia, a short introducer needle is used first and a spinal needle is inserted via the introducer to locate the subarachnoid space. In combined spinal epidural anesthesia technique, an epidural needle (longer than the standard introducer used in spinal anesthesia) is inserted first, and the spinal needle is inserted into the subarachnoid space via the epidural needle after epidural space is identified by the epidural needle. Both spinal and combined spinal epidural techniques are commonly used for cesarean section anesthesia. Many experienced anesthesia care providers

may have difficulty locating the spinal space with a standard short introducer and a small gauge spinal needle in obese patients and find that misdirection and time for placement of anesthesia is less when an epidural needle is used to identify tissue plans. The use of an epidural needle also allows the threading of an epidural catheter after spinal anesthesia is administered using a combined spinal epidural technique. This catheter provides additional security to the patient in the event of a prolonged operation or postoperative bleeding. To date, no studies have compared the time and success for placement of spinal anesthesia via standard spinal versus combined spinal epidural (CSE) technique in obese patients scheduled for Cesarean deliveries. The results of this study may provide anesthesia provider information on better choice of technique for obtaining subarachnoid anesthesia in obese patients undergoing cesaraean deliveries.

Purpose:

The purpose of this study is to document the success rate and outcomes of combined spinal epidural labor analgesia when saline or air is used to identify the epidural space during the combined spinal epidural labor analgesia. Additional objectives of this study are to quantify the any complications and pain relief and satisfaction assessed by pain scores via randomized visual and verbal analog scores.

Hypothesis:

Use of saline in combined spinal epidural labor analgesia during identification of epidural space does not increase the failure rate of combined spinal epidural labor analgesia when compared to the use of air.

Patient Population:

The patient population will consist of 350 women aged 18 years or older, weighing less than or equal to 250 lbs, and request neuraxial labor analgesia. **Emancipated minors may also be enrolled in this protocol**. Exclusion criteria will be American Society of Anesthesiologists physical status greater than II.

Procedures and Methods:

Demographic data including patient's age, height, weight, gestation, medications and history of previous epidurals or spinals will be recorded. Patients will be randomized into one of two treatment groups (Group Air or Group Saline) according to a table of random numbers. The patient will be placed in the sitting position and a midline approach will be used as in usual practice. Combined spinal epidural labor analgesia will be performed in the usual manner, with group Air using 3 mL of air and group Saline using 3mL of saline in the syringe for identifying the epidural space during the combined spinal epidural labor analgesia placement. After positive fluid return from the spinal needle, a standard of care acceptable usual dose of labor analgesic will be administered at the discretion of the anesthesiologist providing the care. Typically 10-20 mcg of fentanyl with or without bupivacine 1-2.5mg will be administered. The patients and data interpreters will be blinded to the treatment group; however, the anesthesiologist performing the procedure will not be blinded. Standard of care monitoring data will be recorded as usual, and level of pain relief will be obtained via pain scores by visual and verbal pain scores.

RANDOMIZATION AND TREATMENT: Patients will be randomized to have the anesthesiologist using saline or air for identifying epidural space during placement of the combined spinal epidural labor analgesia using standard loss of resistance technique. The chance of using air or saline is each 50%. The patients, data interpreters and analyzers will be blinded as to which group the patient is assigned to.

Confidentiality: All information obtained while you are in this study, as well as related hospital records, will be made available to the research staff and other regulatory authorities including the Food and Drug Administration (FDA). All information will be treated in a confidential manner and although the results of this research project may be presented at meetings or in publications, you will only referred to by number and your identity will not be disclosed in those presentations.

SAFETY MEASURES: Standard monitoring will be applied in the labor room as in usual clinical practice at Forsyth Medical Center. Unless other untowards effects are observed from the techniques, no additional monitoring will not be instituted.

OUTCOME MEASURES: The primary outcome measure will be the success or failure of the combined spinal epidural labor analgesia. Secondary outcome measures are any complication or side effects.

Benefits and Risks:

There may be no potential benefits from participating in this study other than more frequent assessment and observation. It is not known which technique actually provide the more favorable outcomes but both techniques are commonly used in clinical practice. The usual risks of combined spinal epidural labor analgesia include but not limited to : headache, failure of the spinal or epidural, intravenous catheter insertion and the extremely rare risks of bleeding, infection, nerve damage, paralysis, hypotension, high spinal block and even death rarely. All these risks are explained by the anesthesiologist participating or providing anesthetic care as part of the risk of neuraxial block.

Statistics and Data Analysis:

Data will be presented as mean (SD) or median as appropriate. Pain VAS scores will be examined, following tests for normality, by repeated measures two-way ANOVA in most study designs. Incidence data will be analyzed by Chi-Square or Fishers Exact Test. In the case of subject drop out, both intent to treat and completed treatment analyses will be performed. Continuous data will be compared by unpaired t-test and ANOVA. Assuming a difference in success rate of 95% versus 85% between the two groups, a sample size of 160/group is required to achieve a power of 0.8 and an alpha of 0.05. An estimate of 175/ groups or 350 total evaluable subjects will be enrolled in this study.

Human Subject

This study will be performed in the Sara Lee Women's Center at Forsyth Medical Center, which includes monitoring and resuscitation equipment and trained nursing support staff. All studies will be approved by the IRB and written informed consent obtained. The Project Investigators have all performed similar studies in patients. The purpose of the study and all risks will be discussed with each subject, and all questions will be answered prior to obtaining written informed consent. Risks to be discussed include discomfort with needle and catheter insertion, risk of postdural puncture headache and spinal needle insertion. The usual side effects and risks of spinal and combined spinal-epidural anesthesia apply. These include itching, nausea, hypotension, unilateral pain relief, small risk of spinal tap, headache, bleeding, infection, venous catheter, high block or inadequate block. All data acquired will remain confidential with no reference to individuals in publications.

Data Safety Monitoring Plan

These monitoring will be performed with a data safety monitoring board (Laura Dean, MD and David Merrill, PhD., MD), who are not involved in the study. Data and adverse events will be reported to these individuals, and reviewed on a regular basis. Adverse events will also be reported to the IRB. Serious adverse events will be reported to all of these groups and the data safety monitoring individuals within 24 hr and the trials halted until feedback is obtained from each.

References:

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