

Use of Ultrasound Guidance to Assist with Labor Epidural Placement in Patients with a BMI ≥ 40

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Research Protocol Abstract:

Placement of labor epidurals is a very common daily practice in obstetrical anesthesia. Currently, these epidurals are placed based upon palpation of landmarks to determine midline and the correct spinal level for placement. Palpation of these landmarks can be difficult, however, particularly in morbidly obese patients who have significant amounts of soft tissue overlying these landmarks which can contribute to an increased number of attempts needed for placement, increased time required to complete the procedure, increased likelihood for complications, and decreased patient satisfaction. In recent years, ultrasound guidance has been increasing in popularity as a way to help visualize the spine and offset these challenges, though there is a lack of data comparing its practical application for daily use against the current standard of a palpation based only technique.

Objectives:

The objective of this study is to determine if ultrasound guidance can be utilized in morbidly obese patients to improve the total time required for epidural placement, decrease the number of attempts needed, increase the success rate in the first attempt, decrease the complication rate, and lead to improved patient comfort and satisfaction levels.

Study Design:

Prospective, multicenter (MWH and West Penn Hospital) randomized controlled trial

Setting/Participants:

This study will be limited to inpatient laboring patients presenting to Magee Women's Hospital of UPMC and to West Penn Hospital and desiring epidural anesthesia for anticipated vaginal delivery. Inclusion criteria include BMI ≥ 40 , Age ≥ 18 , and ASA classification score of 3. Exclusion criteria include contraindications to neuraxial blockade, previous lumbar surgery, intrauterine fetal demise, non-viable fetus, or known scoliosis.

Study Interventions and Measures:

The major intervention in this study is the use of ultrasound (US) guidance to assess for correct spinal location prior to epidural placement. This differs from the current standard of care which is to use palpation only to assess for correct spinal location. The outcome measures that will be assessed and evaluated include:

- Total time required for epidural placement*
- Epidural procedure time**
- Number of epidural attempts needed
- Success rate in the first attempt
- Complication rate including incidence of PDPH and paresthesias
- Incidence of failed epidurals needing to be replaced
- Verbalized patient anxiety and satisfaction levels based on a 1-10 scale
- Modified Woman's Views of Birth Labour Satisfaction Questionnaire (WOMBLSQ) scores

*Procedure time plus the time needed to locate the puncture site using either palpation or ultrasound guidance, begins when hands or ultrasound probe are applied to the patient

**Time from insertion of the epidural needle to removal of the epidural needle

Describe the availability of resources and the adequacy of the facilities to conduct this study:

* The facilities and resources as they currently exist are perfectly adequate for this study. This study involves performing epidurals on laboring inpatients at Magee Women's Hospital which is already routinely done many times every day. All of the supplies and resources necessary are already present. The study also involves using an ultrasound machine to evaluate the patient's spine prior to performing the epidural. Such an ultrasound machine is already owned by the anesthesia department and resides on the labor and delivery floor to be used to help with epidurals and other various procedures. We have every ability to use this machine for this study at no additional costs to the patients, anesthesia department, or hospital. Everything we need, we already own and are able to use. No additional resources, expenses, or charges will be needed as a result of this study.

Objective: What is the overall purpose of this research study? (Limit response to 1-2 sentences.)

The objectives of this study are to assess if using ultrasound imaging to identify the epidural space prior to epidural placement in morbidly obese patients improves results over a palpation based technique alone in regards to:

- Epidural procedure time
- Total time
- Number of attempts
- Success rate in the first attempt
- Number of failed epidurals
- Complications including post dural puncture headache (PDPH) or paresthesias
- Patient anxiety and satisfaction levels

Specific Aims: List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).

Primary Objective (or Aim)

The primary objective of this study is to determine if using ultrasound guidance for epidural catheter placement is associated with a reduction in the total time required in epidural catheter placement.

Secondary Objectives (or Aim)

The secondary objectives are to further determine if using ultrasound guidance for epidural placement:

- Decreases the number of attempts
- Increases the success rate in the first attempt
- Decreases the number of failed epidurals
- Leads to fewer complications including PDPH or paresthesias
- Improves patient satisfaction and anxiety levels

Background: Briefly describe previous findings or observations that provide the background leading to this proposal.

Placement of labor epidurals is a very common daily practice in obstetrical anesthesia. Currently, these epidurals are placed based upon palpation of landmarks to determine midline and the correct spinal level for placement. Palpation of these landmarks can be difficult, however, particularly in morbidly obese patients who have significant amounts of soft tissue overlying these landmarks which can contribute to an increased number of attempts needed for placement, increased time required to complete the procedure, increased likelihood for complications, and decreased patient satisfaction. In recent years, ultrasound guidance has been increasing in popularity as a way to help visualize the spine and offset these challenges.

Ultrasound guidance is already used in multiple patient populations to assist with many different procedures including neuraxial and peripheral nerve blocks. With regards to peripheral nerve blocks, it is now considered standard of care to use ultrasound guidance to provide visualization when performing nearly any procedure including interscalene blocks, supraclavicular blocks, infraclavicular blocks, axillary blocks, femoral nerve blocks, sciatic nerve blocks, adductor canal blocks, quadratus lumborum blocks, transversus abdominus plane blocks, and others. It is also standard in anesthesiology to use ultrasound guidance to assist with central line placement such as internal jugular or femoral vein central lines. Multiple centers have also begun using it for neuraxial placement such as with epidurals, spinals, or combined spinal epidurals (CSEs). Several researchers such as Carvalho, Vallejo, Chin, Balki, Ansari, and others have explored the use of ultrasound guidance in obstetric patients and found it useful in several ways such as estimating the distance to and more easily locating the epidural space. We hope to continue to expand the current research in this area.

There have been no attempts to date at West Penn Hospital to begin enrolling patients for this study. This was due to the PI (myself) no longer being available at that facility to conduct the research. The PI at that location has since been changed to Tracey Vogel and they intend to begin data collection within the next month.

Significance: Why is it important that this research be conducted? What gaps in existing information or knowledge is this research intended to fill?

Several studies have looked into the use of ultrasound guidance to assist with placing labor epidurals. It has been demonstrated that ultrasound guidance can help to identify the depth from the surface of the skin to the epidural space thus aiding in epidural placement. Further studies have demonstrated the use of ultrasound guidance in identifying the correct spinal level for epidural placement and in helping to provide more reliable landmarks for placement of the epidural needle. Studies have also been conducted on the use of ultrasound in patients with easily palpable spines and reports of using it in patients that are known to be difficult. Ultrasound use has even been shown to improve complications such as decreasing the failed labor epidural rate in resident trainees.

Despite these studies demonstrating clinical benefits to the use of ultrasound guidance, there have been no studies directly comparing the two methods with a focus on the practical aspects of overall time to perform the procedure, complication rate, and patient satisfaction in morbidly obese parturients. By comparing the use of ultrasound guidance to the current standard of palpation only, we hope to provide evidence that the use of ultrasound in morbidly obese patients provides not just an experimental but also practical advantage over palpation alone, which can then be used to promote the more routine use of ultrasound guidance in this patient population.

Will screening procedures (i.e., procedures to determine research subject eligibility) be performed specifically for the purpose of this research study?

* Yes

List the screening procedures that will be performed for the purpose of this research study.

Obese patients will have their medical records screened for eligibility. Additional information for screening will be obtained by history and physical examination which is a routine part of clinical anesthesia care on the labor and delivery unit. Information to be gleaned include BMI and any relevant associated medical conditions which may be a contraindication to epidural placement. After this initial conversation, should the patient be eligible, the study will be introduced in its entirety as explained elsewhere in this protocol.

Provide a detailed description of all research activities (e.g., all drugs or devices; psychosocial interventions or measures) that will be performed for the purpose of this research study.

This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.

At a minimum the description should include:

all research activities

personnel (by role) performing the procedures

location of procedures

duration of procedures

timeline of study procedures

This study is to be a prospective, randomized, controlled trial of morbidly obese parturients presenting to either West Penn Hospital or Magee Women's Hospital for delivery and desiring epidural anesthesia. Patients will be screened for participation in the study during the standard pre-anesthesia assessment that is already conducted by anesthesia staff on all patients presenting to Labor and Delivery. Screening will include an evaluation of the patient's medical history and BMI. The study will then be explained to patients who satisfy the inclusion and exclusion criteria and informed consent obtained should they choose to participate. A waiting period of 5-30 minutes will elapse between introduction of the study to the participant's consent to participate. At the time the patient is ready to receive their epidural, an opaque, sealed, numeric envelope labeled only with a study number will be opened containing the data collection sheet and randomly assigned group for that participant. These envelopes will be prepared prior to beginning the study by a healthcare provider not involved in the study. An online randomizer (Randomization.org) will be used to generate a random order for assignment to either the ultrasound guidance group (experimental group) or the palpation only group (control group) which will be revealed to the experimenters only upon opening the envelope at the time of epidural request. These envelopes will be distributed in equal numbers to each facility participating in the study at the onset of the study.

Once the patient has progressed in their labor to the point where they request placement of labor epidural analgesia, the primary investigator for that site (Thomas Vernon at Magee, and Tracey Vogel and West Penn) will be the one to open the envelope revealing which group the patient has been assigned to. This will occur during the same hospitalization as the screening visit and in many cases within just a matter of minutes to hours after the initial screening and consent process. This same person will then position the patient in

their labor and delivery room appropriately for their epidural and then use either the ultrasound machine (experimental group) or palpation (control group) to mark with a marking pen the desired location for epidural placement. Thomas Vernon and Tracy Vogel will be the only providers to mark the patients. Every attempt will be made for them to be available for study patients, but if they cannot be (they are caring for another patient or are no longer in the hospital at the time the epidural is requested) then the patient may have to be dropped from the study. Once the patient has been marked, a second anesthesia provider who will be performing the epidural will come into the room. This second provider will be blinded to whether the marks on the patient were made based upon ultrasound guidance or palpation (the patient will not be blinded). This second provider who will perform the epidural can be any type of experienced provider (attending, fellow, resident, or CRNA) who has already completed at least 40 epidurals in the past. They will then perform the epidural in the standard fashion, using the previously marked site as their initial entry point. If entering at the already marked site does not result in success, the provider performing the procedure may reassess and redirect at their discretion. During epidural placement, the primary investigator (Thomas Vernon or Tracy Vogel) will be responsible for timing the procedure and recording the number of attempts required to succeed. Epidurals are typically placed successfully within 5-10 minutes depending on patient anatomy and provider experience.

Following the epidural placement and achievement of pain relief, the patient will be asked to rate their satisfaction and anxiety levels during the procedure. No extra interventions or monitoring specific to this study (i.e. outside of what is already normally performed) will be required.

Patients will be followed up on in their hospital room within 24 hours of their delivery to assess for any complications related to their epidural placement and to administer the modified WOMBLSQ questionnaire. If a complication is detected, treatment will be given as clinically warranted. Following that visit no further participation from the patient will be necessary. This study is projected to take about 6 months to complete.

Will follow-up procedures be performed specifically for research purposes?

Follow-up procedures may include phone calls, interviews, biomedical tests or other monitoring procedures.

* Yes

Detailed procedures listed in the textbox below:

Following the epidural placement the patient will be asked to rate their satisfaction and anxiety levels during the procedure. The patient will again be followed up with in their hospital room within 24 hours of their delivery to assess for any complications related to their epidural placement and to administer the modified WOMBLSQ questionnaire. Following that visit no further participation from the patient is anticipated. Should they present afterwards with an epidural-related complication, that information will be collected and included in the study.