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Official Title of the Study

Intrapartum epidural catheter displacement: Comparison of three dressing methods in morbidly obese parturients

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Protocol Title: *Intrapartum epidural catheter displacement: Comparison of three dressing methods in morbidly obese parturients*

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1. Objectives

Purpose, specific aims, and hypothesis:
Purpose: We propose this study to prospectively evaluate the efficacy of the three types of epidural catheter dressings that we currently use in our Labor and Delivery unit, in terms of catheter migration, taking into consideration the influence of body mass index on this variable.
Primary aim: We will evaluate the efficacy of three different epidural catheter dressing systems in laboring patients.
Secondary aims: To compare the effect of different degrees of obesity measured by BMI, on epidural catheter migration and quality and failure of epidural labor analgesia. To evaluate the effect of time an indwelling catheter remains in place, level of insertion and patient's height on epidural catheter migration.
Hypothesis: The use of dressing with transparent Tegaderm™ plus SorbaView SHIELD® dressing is superior to the dressing with Tegaderm™ plus Steri-Strip™ bands in addition to a catheter support pad, and to a dressing with Tegaderm™ only, for epidural catheter fixation in laboring obese and morbidly obese patients, in terms of catheter migration. epidural quality and failure and epidural catheter replacement in the labor analgesia setting.

2. Background

Background and rationale for the study:
Failure of labor epidural is a well-recognized situation in obstetric anesthesia practice. Incidence of epidural failure was shown to be 12% in a retrospective analysis of 19.259 deliveries (1). Epidural migration has been documented in both the obstetric and non-obstetric settings (2,3). It has been argued that prevention of epidural displacement is a potential remedy to at least part of the incomplete or failed epidurals in obstetrics (4,5). Motamed et al showed that 45% of epidural failures in major abdominal surgery could be attributable to catheter migration (6). Phillips et al studied epidural catheter migration in labor finding an incidence of 54% (7). Migration was 2 cm on average and tended to be directed inward. Crosby et al found a similar incidence of catheter migration but in an outward direction (8).

Factors influencing catheter migration include weight, body mass index, depth of the epidural space and patient positioning (9,10). Bishton et al documented inward migration in 13% and outward displacement of one or more centimeters in 22% of patients in a cohort of 153 laboring patients (10). They also found that all cases of failed epidural occurred in patients with outward migration greater than 2,5 cm (10). Hamilton et al showed an association between patient position change and movement of epidural catheters, when the patient is sitting with a straight back and when placed on lateral decubitus position (11). The authors found that the magnitude of epidural catheter movement was more pronounced in patients with BMI >30 kg/m2. It has been hypothesized that the epidural catheter might be fixed to the ligamentum flavum after it is threaded, as the maximum pressure found during catheter placement corresponds to this anatomical structure (12). When the patient changes position after taping the catheter, especially in the case of a parturient with high BMI, the new anchor point theoretically moves to the skin, facilitating outward migration of the epidural catheter (9).

Some authors have evaluated the influence of different dressing methods on epidural catheter migration. Burns et al compared TegadermTM dressing, TegadermTM plus filter-shoulder fixation and Niko Epi-Fix dressing in 113 patients in labor (2), finding that TegadermTM plus filter-shoulder was superior in terms of minimization of epidural catheter displacement. Their study doesn't mention weight or BMI of patients included in the study. Odor et al evaluated the efficacy of Epi-FixTM, Lockit Plus® and TegadermTM for dressing of intrapartum catheters, finding superiority of the Lockit Plus® system to decrease catheter migration and epidural analgesic failure (13). The authors didn't evaluate the effect of BMI on the outcomes and even excluded patients with BMI >50 kg/m2. Similar results were reported by Clark et al in a cohort of 102 patients having epidural catheters for major non-obstetric procedures (14).

The obstetric population treated at the Labor and Delivery Unit at Augusta University Medical Center is characterized by a high incidence of obesity and morbid obesity. This situation makes insertion and management of epidural labor analgesia catheters particularly challenging. Although the influence of BMI on catheter migration has been suggested; to our knowledge, no study to date has evaluated epidural catheter migration in a high BMI obstetric population. Evaluating these type of association is clinically relevant as epidural failure is a situation that might potentially compromise patient safety. It may increase the rate of epidural replacement with the concomitant technical difficulties and the potential need to use general anesthesia in cases of unplanned cesarean section in a patient with an indwelling epidural catheter. This latter situation is particularly hazardous, knowing the increased incidence of difficult airway in both obstetric and obese patients (15). We propose this study to compare the effect of three different epidural catheter dressing systems in patients with BMI >30 kg/m2 on epidural catheter migration and epidural quality and failure in the labor analgesia setting.

3. Inclusion and Exclusion Criteria

Inclusion criteria will be the following:

1) *Patients admitted to the Labor and delivery Unit at Augusta University Medical Center who request epidural analgesia.*
2) *BMI >30 kg/m^2.*
3) *Age older than 18 years old.*

Exclusion criteria are the following:

1) *Allergy to adhesive tape or to the components of the dressings used in the study.*
2) *Preexisting sensory neurologic deficits affecting lower extremities.*
3) *Patients taken to the operating room for cesarean section during the study period.*
4) *Chronic pain conditions.*
5) *Patients with intrathecal catheters.*

4. Number of Subjects/Records/Samples Collected

Total number of subjects to be accrued/records reviewed/samples collected:

Based on previous experiences for a measurable difference of 0,5 cm, we will include 35 patients in each group to have a power of 90% and a statistical significance level of 0,05.

5. Recruitment Methods

Recruitment methods:

Patients who request labor epidural and fulfill inclusion criteria will be included in the study and randomly assigned to one of the three study groups.

6. Procedures Involved

a. *Procedures involved to include those procedures that are standard evaluation and/or care and those that are solely for research purposes:*

After approval by the Institutional Review Board, we will obtain consent from the participant patients Patients will be randomized using a random number table to be allocated to one of three groups with sealed envelopes, based on the type of dressing to be used to secure the epidural catheter after its insertion:

1) Tegaderm™ plus SorbaView SHIELD® dressing
2) Dressing with Tegaderm™ plus Steri-Strip™ bands in addition to a catheter support pad (All included in the epidural kit)
3) dressing with Tegaderm™ only

Patients will have an epidural catheter placed for labor. We will use the standard epidural kit (Smiths Medical ASD Inc. Keene, NH. USA). The technique will consist of the use of a 17G Tuohy needle using a midline

approach with the patient in the sitting position. Localization of the epidural space will take place using loss of resistance to air or saline per anesthesiologist's preference. A 20G epidural catheter will be inserted to leave 5 cm into the epidural space (distal to the tip of the Tuohy needle). After the Tuohy needle is removed and the catheter is considered to be at an adequate depth, the patients will be asked to sit up straight. Then, a test dose with 3 mL of Lidocaine 1,5% with epinephrine 1:200.000 will be injected through the catheter into the epidural space, and a dressing varying depending on the assigned group will be applied. The rest of the catheter will be secured longitudinally along the patient's back over the shoulder.

b. *Study design:*

This is a randomized controlled clinical trial.

c. *Procedures performed to lessen the probability or magnitude of risks:*

The application of the three types of epidural dressings analyzed in this study are part of our current standard clinical practice. There is no additional risk due to our intervention. We will protect the rights of the patient maintaining confidentiality (records will be de-identified and assigned a study number) and patients can revoke their consent to participate at any moment during the study. Visual evaluation of the site of insertion of the epidural catheter will be inspected during the study period and any signs of topical or allergic reactions to any of the components used for dressing will be identified and treated accordingly should it happen.

d. *Duration of an individual subject's participation in the study and the time involved:*

The patients will be participating in the study for as long as the epidural catheter remains in place for clinical indications. The expected time will be between 6 and 12 hours.

7. Data and Specimen Management

a. *Data analysis plan:* ☐ N/A

Sample size: Based on previous experiences for a measurable difference of 0,5 cm, we will include 35 patients in each group to have a power of 90% and a statistical significance level of 0,05. Data will be analyzed using analysis of variance, Student's t test, chi-square test and Pearson's correlation coefficients where appropriate.

b. *Power analysis:* ☐ N/A

See above

c. *Data handling:* ☐ N/A

i. *Information included in the data*

Following dressing application, demographic variables of each patient will be recorded including (age, gravity, parity, weeks of gestation, weight, height, BMI). Other recorded variables include time of insertion, distance from catheter tip to skin in centimeters. One hour after delivery, immediately before catheter removal, time, duration of catheter presence, centimeters from skin to catheter tip and dressing integrity will be recorded. Dermatomal level and symmetry of the block will be recorded every two hours or every time the patients requires a top-up dose. We will also record number of top up doses and rate of epidural infusion as well as the need for catheter replacement during the observation period.

Primary outcomes
Epidural catheter migration (ECM) in centimeters = Distance from tip to skin at insertion - Distance from tip to skin at removal. If the catheter moves inward, ECM will be negative and if it gets displaced outwardly, ECM will be positive.
Secondary outcomes

1) *Dermatomal sensory level measured with thermal discrimination*
2) *Incidence of asymmetric block*
3) *Rate of epidural catheter replacement*
4) *Total epidural dose (mL)*
5) *Number of top-up epidural boluses.*

ii. Data storage

Data derived from the study will be stored in a locked drawer in the office of the PI for the duration of the study. The de-identified information will be accessed by the research team and the statistician for analysis.

iii. Duration of data storage

For one year after study completion.

iv. Access to data

The PI and the research team.

v. Responsible for receipt or transmission of the data

The Principal Investigator

vi. Data transport

From the site of data collection to the PI office by the Principal Investigator.

8. Provisions to Monitor the Data to Ensure the Safety of Subjects

a. Data safety and delivery plan

The Principal Investigator (PI) will be responsible for the conduct of this study, including overseeing participant confidentiality, executing the Data and safety Monitoring (DSM) plan, and complying with all reporting requirements to local and federal authorities. This oversight will be accomplished through additional oversight from a Data and Safety Monitoring Committee at the Augusta University. We will conduct ongoing review of all serious adverse events (SAEs), unanticipated problems (UAPs) and reportable adverse events (AEs). Per the DSM Plan, SAEs, UAPs and reportable AEs will be reported to the institutional committee and IRB per study protocol. All SAEs, UAPs and reportable AEs are to be reported to the committee and IRB within 5 business days of receiving notification of the occurrence.

Audits will consist of a review of the regulatory documents, consent forms, and source data verification. Results and recommendations from audits will then need to be submitted by the PI to the IRB of record at the time of the continuing review.
b. *Data review.* *We will review the results for analysis at the end of data collection. The participants will be informed from the beginning of the study that any concerns related to the study be communicated directly to the PI, who will address them according to the DSM plan.*
c. *Collection of safety information* *Data will be de-identified right after collection and be kept as paper record in the PI office.*
d. *Frequency of data collection* *Data will be collected daily.*
e. *Responsible of data review.* *The research team (PI and 2 co-investigators) will collect and analyze data.*
f. *Frequency of data review* *Every week there will be a review of the cumulative data.*
g. *Conditions that trigger an immediate suspension of the research.* *N/A*

9. Withdrawal of Subjects ☐ N/A

a. *Anticipated circumstances under which subjects will be withdrawn from the research without their consent.* *Patients will be withdrawn from the study if she develops an allergic or topical reaction to dressing or if the dressing has to be replaced due to soiling or bleeding.*	☐ N/A
b. *Procedures for orderly termination.* *If during the preliminary data review one of the dressings is performing significantly better or worse than the others, or if one of the groups has higher incidence of catheter migration than that reported in the literature, the study will be terminated and the results analyzed up to that point.*	☐ N/A
c. *Procedures that will be followed when subjects withdraw from the research* *If there is withdrawal of consent or if a subject is withdrawn without consent for the circumstances cited above, those cases will be included in the analysis as "lost to follow-up" and reported in the results section.*	☐ N/A

10.Risks to Subjects

a. *Foreseeable risks.*
No risks additional to standard clinical care are foreseen. Topical or allergic reactions to the dressing materials would be managed by removal of the dressing and topical treatments.

b. *Costs that subjects may be responsible for because of participation in the research.* *N/A*	☐ N/A
c. *Risks to others who are not subjects.* *N/A*	☐ N/A

11. Potential Benefits to Subjects

There is no direct benefit to patients expected from their participation in this study. It is hoped the knowledge gained will be of benefit to other patients in the future.

12. Confidentiality

Procedures for maintenance of confidentiality.
See above

13. Consent Process

Before enrollment in the study, patients will be explained the purposes of the study, the risks and the procedures that will take place as part of the study. Time will be given to answer questions and PI contact information will be provided. Then, the patient will be given the opportunity to decide about participation in the study by signing the consent. The possibility of revoking the consent at any time during the study will also be explained (See consent form for details)..

14. Compensation for Research-Related Injury

This section is not required when research involves no more than Minimal Risk to subjects. ☒ **N/A**

a. *Describe the available compensation in the event of research related injury.*
N/A

15. Resources Available ☐ N/A

a. *Availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
N/A

b. Process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

The PI and the two co-investigators will collect and analyze date and are fully aware of the protocol as they participated in its construction. A statistician will assist with analysis and he will have access to tabulated de-identified information.

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