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Epidural Catheter Thread Between Two Different Vendors

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A head-to-head comparison of catheter thread between two epidural kit vendors.

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Abbreviated Title: Epidural Catheter Thread

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BACKGROUND

Identification of the epidural space involves recognition of a change in pressure from one tissue plane to another. This drop of pressure, called "loss of resistance" (LOR), across a band of connective tissue into the epidural space is detected using a needle-syringe apparatus. The operator applies pressure to the plunger of the syringe until the drop in pressure is identified when the plunger collapses. The epidural catheter, a small tube that is inserted into the epidural space to give the medication, is then advanced using the needle as a guide. Confidence in locating the epidural space is based on clarity of the loss of resistance and the ease of threading the epidural catheter.

When there is difficulty in advancing the epidural catheter after the epidural space has been identified, several maneuvers are performed in order to correct the problem. These include: injecting saline through the needle to "expand" the epidural space, advancing the needle tip 1-2 mm, inserting a new flexible epidural catheter, inserting a new non-flexible epidural catheter, rotating the needle bevel, changing a patient's posture, pulling the needle back to re-engage the *ligamentum flavum* and then preforming a second LOR technique, and removing the needle entirely and preforming a new placement at the same or different interspace (1). Each time a new maneuver is preformed, this is considered a new attempt at threading the epidural catheter into the epidural space. Not succeeding on threading the epidural catheter correctly into the epidural space on the very first try is considered a "failure to thread," however these maneuvers are performed until adequate labor analgesia is established in all patients. Establishing labor analgesia on the first epidural catheter threading attempt reduces the amount of time between when the epidural is requested and when pain relief is administered. A "more successful"

epidural threading attempt is related to a decrease in the time required to thread the epidural and adequately relieve labor pain.

Difficulty to thread an epidural catheter is distinct from a far more serious complication, epidural failure (2). Epidural failure is when the epidural fails to provide adequate pain management. Per internal data review, there is no statistically significant difference between epidural failure rates in literature (2) and the epidural failure rate on the Labor and Delivery floor (9^{th} floor) of the University of Michigan von Voitlander Women's Hospital.

Two different epidural catheter kits, Arrow FlexTip Plus® Epidural Catheterization Kit (Arrow® International, Cleveland, OH) and Perifix® FX Springwound Epidural Catheter Kit (B.Braun Medical Inc., Bethlem, PA) are currently in use on the Labor and Delivery floor (9^{th} floor) of the University of Michigan von Voitlander Women's Hospital. Both kits are standard of care and are routinely used to place epidurals at von Voitlander.

OBJECTIVES

The aim of the study is to assess if there is a difference in ability to thread the epidural catheter (measured in time to thread) from two different pain management kits: Arrow® and B.Braun®. In order to improve patient care at U of M, if there is a difference in the time to thread epidurals with one kit over the other (i.e. one epidural catheter threads more easily than the other), we would like to use the kit with decreased time to thread in the future. We would like to make this comparison based on data.

Our hypothesis is that there is no difference in the average time required for clinicians to thread the epidural catheters from the Arrow® and B.Braun® pain management kits.

The primary outcome is to compare the number of epidural threading attempts between the Arrow® and B.Braun® pain management kits.

Secondary objectives of this study are to compare the difference in average time required to advance the epidural catheter, the number of epidural needle manipulations once the epidural space has been established, the incidence of unintended dural punctures, the incidence of paresthesia, and the incidence of epidural intravascular cannulations between the two different kit vendors.

Our findings may not be generalizable to other facilities due to local practices (presence or absence of trainees, training level of the residents, obesity of patients, etc.) but data will be made publically available. This project is primarily intended to improve patient care at U of M via scientific level analysis.

METHODS

Type of Study

Comparative effectiveness study via an open label alternate treatment design with randomized scheduling.

Inclusion Criteria

The Arrow® and B.Braun® epidural kits available in labor and delivery.

All patients requesting or requiring epidurals on the 9th floor (Labor and Delivery) of the University of Michigan von Voigtlander Women's Hospital.

Exclusion Criteria

Epidural kit not available at the moment of the study.

Randomization Procedure

Epidural kits are available for eligible patients on labor and delivery Von Voiglander 9th floor who are requesting labor analgesia. Approximately 30 epidural placements occur in the obstetric service during any given week. These epidural placements are consistently performed by residents, faculty, and fellows in a sharable and equitable number. No group of individuals are specifically targeted.

A prospective alternating intervention study design with randomized weekly scheduling will allow for equal use of the two epidural kits. In weeks randomized to Arrow®, only Arrow®

kits will be available. In weeks randomized to B.Braun®, only B.Braun® epidural kits will be available. In order to target a sample size of 240 epidural placements (n=120/group), and assuming that every week 30 epidurals will be performed, in 8 weeks we should be able to finish the study. However, if at the end of the 8 weeks we have not reached the target sample size per kit group, we will continue to randomize kit use in the following weeks in order to achieve sufficient sample size. The randomization of the kit to be exclusively used each week will be generated through a password-secure computer (www.randomization.com) by the research assistant. The two available kits are:

1) FlexTip Plus® Epidural Catheterization Kit (Arrow® International, Cleveland, OH).

OR

2) Multi-orifice epidural kit: Perifix® FX Springwound Epidural Catheter Kit (B.Braun Medical Inc., Bethlem, PA).

However, the alternate pain management kit will remain accessible during the study if it is deemed necessary for a particular patient.

This study design is in consideration of the fact that retrospective analyses of large databases or patient records are subject to unknown biases, thus causation is difficult to assign. (3) (4)

Prestudy Data Collection and Training

All anesthesiologists' level of expertise (post-graduate year or training) will be collected before starting the study as shown in Table 1. Patients' demographics will be collected and selected patient data will be recorded by the provider (see Table 2). This ensures that there are no

confounding factors in the difference in perceived ability to advance the epidural catheter among groups (i.e. morbid obesity or presence of known spinal deformities). This will be done in a coded manner, using a numerical code to be assigned to each individual study case. The master file will be kept in a locked filing cabinet in the principal investigator's office. All data will be analyzed in a coded fashion. Attention to strict confidentiality will be maintained; no attempts will be made to identify individual study subjects.

Equipment, Technique and Study Data Collection

There will be two epidural kits available for the study:

1) The FlexTip Plus® Epidural Catheterization Kit contains a 17 Gauge Tuohy needle, 8.9 cm long and a single open end hole FlexTip Plus® 19 Gauge flexible epidural catheter (Arrow International, Cleveland, OH).

2) The Perifix® FX Springwound Epidural Catheter Kit contains a 17 Gauge Espocan® Tuohy needle, 8.9 cm long and a closed tip multiport Perifix® FX Springwound 19 Gauge flexible epidural catheter (B.Braun Medical Inc., Bethlem, PA).

Both the Arrow® and B.Braun® epidural catheter kits are currently used at University of Michigan.

All patients will be in a sitting position. After standard sterile prep and drape, a wheal of local anesthetic will be applied to the interspace. An epidural Tuohy needle will be advanced through the *ligamentum flavum*. A syringe with saline will be attached to the epidural needle and

continuous or intermittent pressure will be applied to the syringe plunger until a drop in syringe pressure will be noticed (LOR).

Each time a skin wheal of local anesthetic is injected in patients' lumbar area, this will be counted as one epidural attempt. In addition, once loss of resistance has been established, if the epidural needle is withdrawn, redirected and re-advanced in order to get loss of resistance again because the clinician is not able to advance the epidural catheter, this will be considered as an additional epidural attempt.

Once, the epidural catheter has been threaded successfully, the clinician will apply negative pressure to the catheter through a syringe in order to rule out blood or cerebro-spinal fluid (CSF) aspiration. If aspiration of blood and CSF is negative, the patient will be given our standard medications consisting of 2 ml Lidocaine 1.5% with epinephrine 1:200,000 to rule out intrathecal catheter placement. Following 2 minutes, the patients will be given additional 3 ml from the lidocaine and epinephrine mixture in order to rule out intravascular cannulation. In addition, a standard loading bolus of bupivacaine 0.125% with fentanyl 3 mcg/ml will be administered in three fractionated doses of 5 ml each, through an epidural pump. All patients will be then connected to a programmed intermittent epidural bolus pump with the following settings: bupivacaine 0.125% with fentanyl 3 mcg/ml, programmed intermittent bolus 6 ml every 45 minutes. Patient's demand bolus 6 ml every 15 minutes, without baseline infusion.

If the epidural catheter cannot be sufficiently advanced into the epidural space, one or more of the following maneuvers will be adopted: additional saline will be administered through the Tuohy needle; alternatively, a new flexible epidural catheter can be inserted; if the catheter advances following one of these afore-mentioned maneuvers, the thread will be considered successful with minor adjustments. Conversely, if the needle is rotated, re-angled, redrawn and

re-advanced or advanced blindly, these will all be considered as major needle manipulations and recorded as failure of that attempt to advance the epidural catheter. Further attempts are made until proper epidural analgesia is established.

Establishment of successful labor analgesia will be defined at a verbal analogue score equal to or less than 10 on a 100-point scale within 30 min from the standard epidural medication administration. All data related to the technical aspects of the epidural placement will be collected in the form shown in the appendix. The goal of both study groups is the management of labor pain.

Waiver of consent justification

A waiver of consent is requested as this study is no more than minimal risk to the study population.

When a patient requests an epidural, written consent is required in order for the provider to place the epidural. Thus, this study only involves patients who have consented to receive a standard of care epidural, as requested by the patient themselves. No patient will be asked to undergo an epidural placement procedure that they have not requested. Currently, this written consent to an epidural placement procedure at the University of Michigan von Voitlander Women's hospital implies a consent to have an epidural placed using either the Arrow® or B.Braun® pain management kit, depending on availability.

By changing to block randomization, this would not be a significant deviation from the provider's choice of pain management kits. The pain management kit available to place an epidural at a given time is subject to different influences that do not make it much different from

random. Most of the time, the provider uses whatever currently available is in the closet, whether the Arrow or BBraun kit.

There are logistical difficulties of obtaining informed consent from this vulnerable population (pregnant women in all stages of labor): (5)

(1) Patients in labor (particularly the later stages of labor) are temporarily incapacitated and unable to give true informed consent.
(2) Placing an epidural during labor (particularly the later stages of labor) occurs under time constraints where patient comfort is paramount to any research interests. We want to prevent any time delays in the anesthesiologist's administration of the requested epidural procedure.
(3) Approaching laboring patients and requesting that they participate in a research study has the potential to incur significant distress in this patient population, especially as many are temporarily incapacitated due to labor pain.

We request a waiver of consent only as we feel that all patients will have received an epidural placement procedure that upholds the current standard of care at Von Voigtlander, and that this study does not endanger patient safety. Furthermore, should the provider feel that participating in this study is not in a patient's best interest, the provider can proceed using whatever pain management kit they feel is best.

We also want to avoid bias. Recruitment sampling of patients in only the early stages of labor (rather than all stages of labor) would increase the risk of bias in the study. By sampling from all patients who request an epidural, our sample would be an ideal sample since women who want to get any form of neuraxial analgesia or anesthesia often decide when they are

experiencing pain during labor. (6) As labor advances and the laboring parturient experiences more pain, it becomes more difficult to place an epidural as the patient may:

- find it difficult to sit in the ideal position for threading an epidural
- find it difficult to remain still for the time required to place the epidural

We want to sample from an accurate representation of all the scenarios that an anesthesiologist provider is called on to administer an epidural, all which necessarily involve threading an epidural catheter into the epidural space.

Study Size

In order to determine the study size, we looked at 114 consecutive epidural placements as part of our routine quality assurance with the Arrow® Epidural Catheterization Kit at Von Voigtlander. We found that in 11% (n=12) of epidurals placed, the epidural catheter did not thread on the first attempt. In a separate quality assurance check we retrospectively reviewed 100 epidural placements finding out that in 1% (n=1) of epidurals placed, the epidural catheter did not thread on the first attempt. A sample-size analysis for the primary outcome shows that 107 epidural placements per group would provide a power of 80% to detect a difference in proportion between the two techniques of 0.10 at the 0.05 level. Considering an attrition of 10-20% for follow-up and data missing, a total number of 240 epidural placements will be collected. Power calculations were computed using PASS 14.

Statistical Analysis

Statistical analysis will be performed using SAS 9.3 (SAS Institute, Cary, NC). The

primary outcome will be the success rate of epidural catheter threaded with each epidural kit, which will be compared by group using a chi-square test or Fisher's exact test, as appropriate. The secondary outcomes will be analyzed as follows: the difference in number of epidural attempts will be compared using the Mann-Whitney test; the difference in time to perform the epidural start to finish defined as the time the epidural needle is inserted through the patient's skin to the end of the catheter thread will be compared using the Student's t-test; the difference in the incidence of epidural needle manipulations once the epidural space has been established will be compared using the Chi-Square or Fisher's exact test, as appropriate; the difference in incidence of unintended dural puncture, paresthesia, and intravascular cannulations will be compared using the chi-square or Fisher's exact test, as appropriate. In addition, the difference in unsatisfactory labor analgesia with Arrow® and B.Braun® kits will be compared through the chi-square or Fisher's exact test, as appropriate, by looking at the difference in percentages of patients who have a verbal analogue pain score equal or less than 10 (scale 0 to 100) at 30 minutes following epidural medication administration. A p-value of 0.05 throughout will be considered statistically significant.

All statistical analyses will be performed using SAS 9.3 (SAS Institute, Cary, NC).

Minimizing the Risk for Subjects

This project is a comparison of standardized epidural technique between two different epidural catheter kits that are currently in use in major academic institutions in the country and at the University of Michigan. There is no hypothesized difference in the ability to thread the

epidural catheter between the two kits. The research involves no risk to the patient subject beyond risk inherent to epidural placement.

Waiver of informed consent will not affect the rights, welfare, or pain management of the subject, given that in either scenario, they will receive a standard of care epidural.

No identifiable information will be collected and retained about the subjects after completion of the patient's vaginal or cesarean delivery. All data will be recorded using a numerical code to be assigned to each individual study case. The master file will be kept in a locked filing cabinet in the principal investigator's office. All data will be analyzed in a coded fashion. Attention to strict confidentiality will be maintained; no attempts will be made to identify individual study subjects.

Potential Risks of Participation

The risk of participation is the same as the risks of receiving an epidural catheter for analgesia if not enrolled in the study. This study design includes clinical procedures already being performed, with the risks the same as standard epidural placement regardless of which device is used or physician participation in the study. The overall goal for both study groups remains the same: adequate and timely management of labor pain.

For placement of epidural catheter for analgesia, risks include:

- Inadequate pain control; likely, but it is not serious as it can be managed with additional pain control interventions

- Persistent headache; infrequent, but it could be more serious and require follow up with anesthesiologist

- Infection; rare, and is serious, requiring additional care by physicians

- Temporary hip/leg discomfort; likely, but can be managed with additional pain control interventions and should go away on its own

- Low blood pressure; common, but can be treated with additional interventions

- Decrease in the baby's heart rate; infrequent, but it could be serious and require additional interventions

To minimize any risks, the research team will place epidural catheter according to standard clinical protocol including:

- Ask patients and monitor their pain control and clinical status, performing other interventions if needed

- Use aseptic technique

Additionally, there may be a loss to confidentiality and privacy. See *Minimizing the Risk for Subjects* for how the study team will minimize these risks.

As with any procedure, there may be additional risks that are unknown or unexpected but rare.

Equitable Selection of Subjects

All patients receiving epidural analgesia are candidates for this study. There are no patient factors that would be grounds for exclusion. No groups of persons based on gender, race, or any other distinction will be specifically targeted or excluded. Both epidural kits are current standard of care, thus there is no additional risk incurred due to participation in the study.

Costs

No additional cost will be incurred for the study.

Data and Safety Monitoring Plan

There are no plans for an independent data and safety monitoring board for this study. The principal investigator or the co-investigators will review analysis of all source data for each study subject when approximately half (n=120) of the epidural placements are completed. The principal investigator and the co-investigator will determine whether the research should be altered or stopped on an ongoing basis.

Adverse Event Reporting

The principal investigator will be responsible for reporting all adverse events according to the human research committee's guidelines.

Monitoring and Quality Assurance

The accuracy and completeness of all documents will be monitored on an on-going, weekly basis by the principal and co-investigator. All data will be collected at the time of each epidural placement, analyzed for completeness, and filed. The principal investigator and co-investigators will follow the validity and integrity of the data and adherence to the IRB approved protocol.

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5) Exceptions to the rule of informed consent for research with an intervention. Rebers S, Aaronson NK, van Leeuwen FE, Schmidt, MK. 2016 Feb; 17(9):1-11
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TABLES

Table 1 Inability to advance epidural catheters according to physician level of training

Physician level	Single-orifice Incidence	Multi-orifice Incidence	Statistics
First-year esident	x/X (x%)	x/X (x%)	p=
Second-year esident	x/X (x%)	x/X (x%)	p=
Third-year esident	x/X (x%)	x/X (x%)	p=
Fellow	x/X (x%)	x/X (x%)	p=
Attending	x/X (x%)	x/X (x%)	p=

Data are number (%).

Table 2 Demographic and Epidural data collection

Characteristics	Single-orifice N=125)	Multi-orifice N=125)	P-value
Demographics			
Age, years	XX ± X	XX ± X	X
Body Mass Index, kg/m^2	XX ± X	XX ± X	X
Gestational age, weeks	XX ± X	XX ± X	X
Pain relief within 30 minutes	X (x%)	X (x%)	X
Cervical dilation (cm)	XX ± X	XX ± X	X
Catheter failure to advance	X (x%)	X (x%)	X
Dural puncture epidural	X (x%)	X (x%)	X
Accidental dural puncture	X (x%)	X (x%)	X
Paresthesia	X (x%)	X (x%)	X
Intravascular cannulation	X (x%)	X (x%)	X
Time to catheter thread	X (x%)	X (x%)	X
Number of epidural attempts	X (x%)	X (x%)	X
Epidurals replaced	X (x%)	X (x%)	X

Table 3 Success rates and complications of corrective maneuvers performed

	Single-orifice		Multi-orifice		
Maneuver	Success (%)	Complications	Success (%)	Complications	Statistics
Saline injection	x/X (x%)	X	x/X (x%)	X	p=
Rotate needle bevel	x/X (x%)	X	x/X (x%)	X	p=
New placement	x/X (x%)	X	x/X (x%)	X	p=
Re-engage ligament, re-advance	x/X (x%)	X	x/X (x%)	X	p=
Advance needle	x/X (x%)	X	x/X (x%)	X	p=
Change needle angle	x/X (x%)	X	x/X (x%)	X	p=
New catheter	x/X (x%)	X	x/X (x%)	X	p=

Data are number (%).

SINGLE vs MULTI-ORIFICE CATHETER STUDY FORM

ANESTHESIOLOGIST CODE ____Date ____Time ____room ____

Anesthesiologist : Attending Fellow CA-3 CA-2 CA-1

Patient Description Age: __Gest Age: __ Ht/Wt: __ __ G __ P __

Cervical dilation ___ cm Estimated Level of placement: L _ - L _

Relevant patient's comorbidities: _____

EPIDURAL KIT: ARROW BBRAUN

Time: loss of resistance to Epidural needle removed following successful placement ____ minutes **:** _____seconds

Loss of Resistance Unable to get Loss Equivocal Loss Clear Loss

Dural Puncture epidural used ? YES NO
If Dural Puncture Epidural used, CSF in the spinal needle? YES NO
Dural Puncture Epidural used because of: ☐ Equivocal loss ☐ As part of technique
☐ Because catheter wouldn't thread and wanted to make sure I was midline

Ease of Threading the Epidural Catheter

☐ Easy thread without further maneuvers
☐ hydrodissection, then catheter: **Thread Did not thread**
☐ new catheter from the same brand, then catheter: **Thread Did not thread**
☐ Rotated the needle, then catheter: **Thread Did not thread**
☐ Changed needle angle, then catheter: **Thread Did not thread**
☐ Withdrawal and re-advanced the needle with an additional LOR (this count as an additional attempt), then catheter: **Thread Did not thread**
☐ Advanced the needle blindly, then catheter: **Thread Did not thread**
☐ Changed space

Patient Comfort at 30 minutes (VAS ≤ 10/100) YES NO

<u>Additional</u> Number of attempts after loss of resistance 0 1 2 3 4 5
Complications (circle all that applies)
Wet tap Paresthesias Intravascular Other (please explain)

Epidural analgesia failed and then epidural Replaced? YES NO
Delivery date _____ and **Time** _____