TITLE: Traditional loss-of-resistance technique vs Compuflo-aided technology for placement of a thoracic epidural catheter: a randomized trial of the effect on the success rate

NCT Number: 03826186

Principle Investigator: Yatish Siddapura Ranganath, MD

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INFORMED CONSENT DOCUMENT

Project Title: **Traditional loss-of-resistance technique vs Compuflo-aided technology for placement of a thoracic epidural catheter: a randomized trial of the effect on the success rate**

Principal Investigator: **Yatish Siddapura Ranganath**
[redacted]

Research Team Contact: [redacted]

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult who will be receiving a thoracic epidural to help with your pain management.

This research study involves thoracic epidural catheter placement. Traditionally, loss-of-resistance (LOR) to air or saline with a special ground-glass syringe is the technique used to identify epidural space, but there is a certain failure rate that has been reported using this technique for thoracic epidural placement. This failure rate has sparked the search for newer techniques to improve the success rate for placement. The CompuFlo epidural system is a device that provides anesthesiologists and other healthcare providers the ability to quantitatively determine and document the pressure at the needle tip in real time. The device is currently FDA approved for use with Lumbar epidurals, but not for Thoracic epidurals, therefore the use of the CompuFlo epidural system for Thoracic epidurals is considered investigational.

The purpose this research study is to compare the success rate of the two different approaches (e.g. traditional method v/s CompuFlo assisted) to thoracic epidural placement. No changes will be made to the nerve block procedure we routinely perform. We will collect information and share our findings. Your personal and medical information will be kept confidential.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 133 people will take part in this study conducted by investigators at the University of Iowa

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will start while we place the thoracic epidural. After we place the epidural catheter in an appropriate area on your back, we routinely administer a ‘test

dose' of lidocaine through the catheter to confirm correct placement.

Your involvement will last for about 20 minutes during which we test the area every 5 minutes up to 20 minutes. In addition, we will collect data related to your pain management from your electronic medical record. There is no follow up required for this study.

WHAT WILL HAPPEN DURING THIS STUDY?

- If you agree to participate in this study, you will be randomly assigned to receive thoracic epidural either by the 'traditional technique' or by the investigational method 'CompuFlo assisted technique'. This means that whichever approach to 'thoracic epidural' you receive will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving thoracic epidural by either of the approaches. You will only be assigned to 1 technique method.

- We can give you a sedative medicine to help you relax, if needed. For the procedure, you may feel a quick pinching sensation in your back followed by a burning sensation when we inject the numbing medication to numb the area, where the epidural needle is inserted. Following this, you may feel some pressure in your back when we position the epidural needle in the correct space. After identification of the epidural space, we thread the epidural catheter into the space. We then evaluate the epidural by injecting a 'test dose' through it. The volume of the 'test dose will be split. You will receive part of the volume initially and the remaining volume will be given 5 minutes later. You may notice a cold solution going into your back at this time. The catheter is then secured to your back with a fixative device and some clear tape.

- We want to find out when you can no longer feel "cold sensation" on the chest/abdomen depending on the site of epidural catheter insertion, to a cold stimulus after administration of a 'test dose'.

- We test both sides of chest or abdomen. We will place the cold stimulus (copper tube filled with ice) on a part of your body not likely to be affected by the epidural; so that you can compare the 'cold' feeling between your chest or abdomen and the other unaffected part of your body. This makes it easier to detect any difference in sensation.

- We want to know when you can't feel the "cold sensation". Every 10 minutes, a cold stimulus will be held lightly against the test spots for about a second. You will be asked, "Does this feel cold?" You should answer with "Yes", "No", or "I can't tell."

- We do these tests every -10 minutes until you can't feel the cold sensation any more on both sides of your body or up to 20 minutes.

- After the testing, when both you and your surgeon are ready for surgery, your medical procedure will be conducted as it would be even if you were not participating in this study.

- We will collect information and share our findings. Your personal and medical information will be kept confidential.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to

these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The risks of the study are the same for typical patients getting a nerve block for ambulatory surgery. Most commonly there are no complications. We safely perform over 3000 nerve blocks per year. If any of these problems happen, we are there to give you medical attention. The risks are the same for either of the randomized groups receiving the block by two different approaches.

Likely (more than 35%)

- A very brief pinch-like sensation when we insert the numbing needle and pressure sensation in the back with the epidural needle.
- A "charley horse like" sensation as the epidural catheter is inserted through the needle
- Light "cold sensation" from testing for nerve block

Less Likely / Less Common (10% - 35%)

- Block failure

Rare (less than 0.05%)

- Hematoma, or a blood clot around the spinal
- Infection – Meningitis or epidural abscess
- Seizure
- Nerve damage
- Paralysis (loss of sensation)
- Paraplegia (loss of muscle power in lower limbs)
- Allergic reaction
- Heart rhythm disturbance
- Death

There is a risk of loss of confidentiality of subject data in this research. Measures in place to protect subject confidentiality are indicated in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that in the future other people may potentially benefit from the new knowledge generated by having an 'epidural technique' with a better success rate. Choosing the technique with the higher success rate will help in better management of pain for patients in future.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could just receive the thoracic epidural for pain control without being a part of the study. In case you decide not to have a thoracic epidural we can use Intravenous and/or oral pain medications for pain control

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The UIHC Department of Anesthesia is funding this study. The University and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University of Iowa employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Federal government regulatory agencies, The Food and Drug Administration
- Auditing departments of the University of Iowa
- Milestone Scientific, the manufacturer of the Compuflo device.
- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies)
- Statisticians from the Anesthesia and Biostatistics departments.
- Other members of the Department of Anesthesia who will review the safety of the study.

To help protect your confidentiality, we keep the information from the study secured so only authorized people working on this study can obtain. The data is ID coded in a way that would make it extremely difficult for anyone to know it was you even if they did see the collected data. Paper data is kept in a locked drawer in a locked office. Electronic data (spreadsheet with number or a database) is password protected and stored in a locked office on a password protected computer. If we write a report or article about this study or share the study data (not your personal information) set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health

condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to **Dr.** [redacted]. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: [redacted]. If you experience a research-related injury, please contact: [redacted] If study involves significant risks, **please call hospital operator 800-777-8442** ask **for the anesthesia research resident/fellow on call and to tell operator you are a research subject of** [redacted] **Compuflo Study.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the **Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu.** General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)