A RANDOMIZED COMPARISON OF PERCUTANEOUS CLOSURE TO MANUAL COMPRESSION FOR HEMOSTASIS OF MULTIPLE VENOUS ACCESS SITES AMONG PATIENTS UNDERGOING CATHETER ABLATION FOR ATRIAL FIBRILLATION

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 130 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question: Does using a small internal suture (or "stitch") facilitate faster times to hemostasis (stopping bleeding) after removing intravenous sheaths (special IVs that are used for ablation procedures) after an atrial fibrillation ablation procedure? You are being asked to be in this research study because you are scheduled for an atrial fibrillation ablation.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for the duration of your atrial fibrillation ablation and through 30 days afterwards. The researchers will ask you to do the following: 1) Potentially have your IV sheath access sites closed with the stitch device after your atrial fibrillation ablation; 2) Potentially attempt to get up from bedrest soon than is typical; 3) Answer some questions including a questionnaire about groin pain after the procedure; and 4) Respond to questions for follow-up at 30 days after your procedure. ALL of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. You may need to spend less time in the post-procedure area and you may be able to walk sooner after your procedure if you are in this study but you may not.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The device that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include development of a blood clot in the leg, bleeding, or a large bruise called a hematoma at the IV

site. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
The alternative to participating in this study is to choose not to participate. You do not have to be in this study to be treated for your arrhythmia.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance. This includes the stitch device. You will have to pay for your treatment outside of the study procedures including your treatment for atrial fibrillation.

The study team can help you work out how much you might have to pay.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: A randomized comparison of percutaneous closure to manual compression for hemostasis of multiple venous access sites among patients undergoing catheter ablation for atrial fibrillation.

Principal Investigator: Dr. Michael S Lloyd

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?

The purpose of this study is to determine if using a small internal suture (or "stitch") facilitates faster times to hemostasis (stopping bleeding) after removing intravenous sheaths (special IVs that are used for ablation procedures) after an atrial fibrillation ablation procedure. The device used to place the stitch is PerClose Proglide™ and is an already FDA-approved technology for closing these IV sites. The study will also determine if it is safe to get up and walk sooner than what is considered typical after closing these IV sites with the PerClose device. You are having an atrial fibrillation ablation procedure because you have this arrhythmia and have decided with your medical team that an ablation procedure would help reduced your burden of atrial fibrillation. This study does not change the ablation strategy or any other treatment you would receive for atrial fibrillation.

"Hemostasis" is a term that means to stop bleeding from happening. After an ablation procedure, the large IVs (a.k.a. "sheaths") that are used to gain access to your veins in the leg are removed and your treatment team will achieve hemostasis. This can be done in a variety of ways including holding pressure for a period of time, use of an external stitch, a compression device, or the use of a closure device (which stops the bleeding from inside the body, underneath the skin), or some combination of these. Afterwards, you will have to lie flat (a.k.a. "bedrest") for a period of time (usually 2-4 hours). The goal of this study is to see if using a closure device helps achieve hemostasis faster and allows patients to get up from bedrest sooner.

What will I be asked to do?

If you volunteer to participate in this study, we will ask you to allow:

1. Potentially have your IV sheath access sites closed with the percutaneous closure device after your atrial fibrillation ablation.
2. Potentially attempt to get up from bedrest sooner than is typical.
3. Answer some questions including a questionnaire about groin pain after the procedure.

This would be done at the end of the ablation procedure and would not change how you are treated for your atrial fibrillation or any of your follow up afterwards. We would continue to collect information related to you IV access sites for up to 30 days to evaluate for any complications, regardless of whether your IV access sites were closed with the percutaneous closure device or other methods. This information would be gathered during your routine post-procedure care and follow ups and would not otherwise change your treatment or follow up plan for your atrial fibrillation.

Who owns my study information?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that was already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time that are uncommon.
The most common risks and discomforts expected in this study are rare but possible: development of a blood clot in the leg (less than 1%), bleeding (less than 1%) or a large bruise called a hematoma at the IV site (less than 1%).

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

If you are a woman: to protect against possible side effects of the study device, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. You may need to spend less time in the post-procedure area and you may be able to walk sooner after your procedure if you are in this study but you may not. This study is designed to learn more about the use of percutaneous closure with the PerClose Proglide™ after atrial fibrillation ablation. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

The alternative to participating in this study is to choose not to participate. You do not have to be in this study to be treated for your arrhythmia.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory and Saint Joseph's Hospital or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Medical Record

If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory places may not become part of your Emory and Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should [redacted] You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you to get medical treatment. Neither Emory and Saint Joseph's Hospital nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and Saint Joseph's Hospital and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Saint Joseph's Hospital, the only

exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information and Release of Medical Records

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study .
- Emory and Saint Joseph's Hospital may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
[redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

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Signature of Person Conducting Informed Consent Discussion **Date** **Time**