Study Title: Does transesophageal echocardiography along with an orogastric tube improve the image quality intraoperatively?

NCT03454399

January 10, 2017

	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:
	PROJECT TITLE: **Does transesophageal echocardiography along with an orogastric tube improve the image quality intraoperatively?**	

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1. WHY IS THIS RESEARCH BEING DONE?

This research is attempting to show the effect of attaching orogarstric tube (OGT; suction tube which is placed routinely through the mouth after anesthesia induction to suction the stomach), to Transesophageal Echocardiography (TEE; a scope which is routinely placed through the mouth down to stomach to take a look at the heart) on the image quality. We will use the usual TEE probe and OGT. Traditionally, TEE and OGT are placed SEPARATELY, but in our research, they will be attached each other so that OGT will effectively suction the air/liquids around the TEE probe. We will leave the TEE probe and OGT until we decide they are not needed, as usual. We will need 40 subjects and the study will be conducted only at HFH.

You have been asked to take part in a research study because you have cardiac or liver disease which needs intraoperative TEE and OGT. The purpose of this research study is to assess the effect of attaching orogarstric tube (OGT) to Transesophageal Echocardiography (TEE) on the image quality.

There will be approximately 40 people in this research study at Henry Ford Health System (HFHS).

This study is not sponsored.

As part of this study, you will be exposed to TEE probe and OGT. These devices are approved by the FDA (Food and Drug Administration) and have been regularly used.

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Your participation in this study will last several hours during surgery, no extra surgery time anticipated.

Extra and experimental: We will attach OGT to TEE probe instead of placing separately. We will capture additional 2 more images with TEE (one is BEFORE suctioning, and the other AFTER suctioning).

Extra and not experimental: none

There will be no additional activity required.

3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now.
It is not expected that you will have any complications or discomforts from being in this study. There may be risks or discomforts that are not known at this time.

You should tell the person obtaining your consent about any other medical research studies you are involved in right now. While you are in the study, you are at risk for the following side effects:

New risks beyond the usual risks

- Less Likely: There is small chance that TEE and OGT can be detached accidentally in the stomach, and in which case, attaching thread can remain in the stomach. We will use silk thread, which has been used as a suture thread without reported complications.
- Rare but serious: nothing anticipated

There may be additional risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include: Possible better image quality which may lead to more precise information, which may facilitate anesthetic or surgical management. You may not be helped by participating in this study. However, others may be helped by what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study. Your other choices may include:

We will place TEE probe and OGT separately as usual.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:

- Your existing medical records.
- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).

- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

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.

7. WHAT IF I AM INJURED?

If you are injured as a result of being in this study, Henry Ford Health Systems will cover the costs of reasonable medical treatment necessary to diagnose and/or treat your injury. To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, Medicare insurance claim number and/or social security number. This is because the sponsor has to check to see if you receive Medicare, and, if you do, report the payment it makes to Medicare. The sponsor will not use this information for any other purpose. We do not pay these costs to the extent that your injury is caused by your own negligence or the natural progression of your disease. Financial compensation for such things as lost wages, disability, or discomfort due to the injury is not routinely available. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Yoshihisa Morita, MD, or his/her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Yoshihisa Morita at 313-970-1282. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.
These circumstances include, but not limited to, we decide that risks are higher than the benefits, or apparent procedure related complications noted.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

There will be no compensation to you for your participation in this study.

13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ _____ _____
Signature of Subject Date Time

_____
Print Name of Subject

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_____ _____ _____
Witness to Signature Date Time

_____
Print Name of Person Obtaining Consent

_____ _____ _____
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