

Title: Esophageal Manometry During Recovery from Anesthesia: Pilot Study

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# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

## CONSENT TO PARTICIPATE IN A RESEARCH STUDY

### Study Title: Esophageal Manometry during Anesthesia: Pilot Study

This is a medical research study. Your study doctor(s), John P. Cello, M.D., Rachel McKay, M.D., and Stanley J. Rogers, MD from the UCSF Departments of Medicine, Anesthesia, and Surgery, will explain this study to you. Dr. J.P. Cello is one of the attending doctors for your procedure already scheduled.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask one of the study doctors.

You are being asked to take part in this study because you are already scheduled to undergo a surgical procedure under general anesthesia.

### Why is this study being done?

Esophageal manometry is a procedure where a small tube (1/8 inch in thickness and 12 inches in length) is passed through the nose into the esophagus (swallowing tube). It measures the pressures at 1-inch intervals (spacing). Most of these procedures are done when a patient is awake or receiving light sedation. Although the esophageal manometer is a device that has been approved by the Federal Drug Administration (FDA), this device is not FDA approved for the performance of manometry under general anesthesia. Ability to swallow is a vital protective reflex, allowing humans to protect their lungs from aspiration of secretions from the mouth or gastrointestinal tract. It is known that anesthesia and heavy sedation impair swallowing ability temporarily.



The purpose of this study is to obtain a greater understanding the time at which normal swallowing ability returns after surgery, during awakening from general anesthesia. The performance of manometry (measurement of pressure in swallowing tube) is not currently a routine part of anesthesia care. An accurate determination of the return of normal swallowing function may alert the clinician to the point at which swallowing ability has recovered, thereby providing safer conditions for removal of the endotracheal (breathing) tube. We are proposing a research study to document pressure readings from the esophagus and pharynx, using standard high-resolution manometry, in ten patients who are recovering from general anesthesia. We propose to document the return of normal esophageal and swallowing function in coordination with the standard verbal commands to initiate swallowing.

### How many people will take part in this study?

### **What will happen if I take part in this research study?**

- (1) Following your surgical procedure when the endotracheal tube (breathing tube) is still in place in the airway (about 10 minutes from removal), a standard esophageal pressure tube, esophageal manometry catheter, will be placed through the nose into the upper portion of the esophagus. This esophageal manometry catheter is about the size of a standard nasogastric tube (tube that passes from nose to stomach). The placement of the esophageal manometry catheter is not routine for surgical procedures.
- (2) After the manometer is placed, your anesthesia you have been receiving during your surgery will be turned off so that you may awaken. While you still have the endotracheal tube (airway breathing tube) in place, the esophageal manometry will test the return of normal esophageal function in coordination with the swallowing commands: “swallow, swallow, swallow,” “take a deep breath, open your eyes, swallow”, “squeeze my fingers, squeeze my fingers, swallow, swallow, take a deep breath”. Regardless of whether you choose to participate in this study, it is standard practice to remove the breathing tube only after you awaken and follow a specific command (most commonly “open your eyes” or “squeeze my hand”) to demonstrate that you are awake.
- (3) At the conclusion of anesthesia, as you awaken, we will both 1/ issue statements routinely made during emergence (“open your eyes” and “squeeze my hand”), and 2/ monitor the return of normal coordinated swallowing including the movement of the tongue, the relaxation of the upper sphincter of the esophagus and the return of normal contraction of the esophagus.
- (4) We will document the return of normal functioning swallowing mechanism at the time of the removal of the breathing tube.
- (5) Five minutes after removal of the breathing tube the esophageal pressure (manometry tube) catheter will be removed.

Study location: All study procedures will be done in the operating suite or the endoscopy center at San Francisco General Hospital.

### **How long will I be in the study?**

Participation in the study will take a total of about 40 to 60 minutes. It includes a 30-minute interview prior to the proposed procedure, and passage and monitoring of the manometry device during the last 15 minutes of the recovery process from general anesthesia. No extra additional anesthesia or operating room (OR) time will be associated with this study.

### **Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation in the study safely.

The study doctor may stop you from taking part in this study at any time if he or she believes it is not in your best interests to continue participating, if you do not follow the study rules, or if the study is stopped.

## **What side effects or risks can I expect from being in the study?**

### **RISKS OF Passage of the Manometry Catheter:**

#### **Likely**

- Nasal irritation (5%)
- Nasal bleeding (5%) If there is any bleeding with the passage of the catheter, the study procedure will be stopped.

#### **Less Likely**

- Aspiration (fluid entering lungs following vomiting) of gastric contents in lungs (1:100,000)
- Irritation and stimulation of vomiting which can lead to aspiration after removal of endotracheal tube (1:100,000)

#### **Rare but serious**

- Perforation (causing a hole) of nasal passageways or esophagus needing urgent surgery (1:1,000,000)
- Passage of catheter into windpipe without knowing (1:100,000)
- For more information about risks and side effects, ask your study doctor.

## **Are there benefits to taking part in the study?**

There will be no direct benefit to you from taking part in this study, but the recording of esophageal motor function during the process of removing the breathing tube may reveal a delayed return of normal swallowing mechanism that the anesthesia doctors are unaware of and they may decide to leave the breathing tube in place for a while longer..

## **What other choices do I have if I do not take part in this study?**

- You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, you can still get your care from the institution the way you usually do.
- Your planned procedure will proceed as planned.

Please talk to your doctor about your choices before deciding if you will take part in this study.

## **Will my medical information be kept private?**

We will do our best to make sure that the personal information in your medical record is kept private. Information regarding anyone participating in the study is coded and saved on a protected network.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research and data analysis include:

- The University of California
- The National Cancer Institute (NCI) and other government agencies, e.g., the Food and Drug Administration (FDA), involved in keeping research safe for people.

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Only UCSF researchers involved in the study protocol and your doctors will have access to specimens and data collected during the study. Information regarding results of the study (enzyme analysis, endoscopy) will be stored in a password-protected database.

### **What are the costs of taking part in this study?**

You will not be charged for any of the study activities.

### **Will I be paid for taking part in this study?**

You will not be paid for taking part in this study.

### **What happens if I am injured because I took part in this study?**

It is important that you tell your study doctor, Dr. John Cello, Dr. Rachel McKay or Dr. Stanley Rogers, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them at 415-206-4767 or 415-514-3131. You may also speak directly with the research coordinator, Mr. Alex Rodas, at 415-206-4746.

**Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical cost, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

### **What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

## Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study.  
Contact your study doctor(s)

Dr. Cello: 415-206-4767

Dr. McKay: 415-502-1715

Dr. Rogers 415-514-3131

You may also call Mr. Alex Rodas, study coordinator, at 415-206-4746.

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.

**If you have any comments or concerns about participation in this study, you should first talk with the investigator. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the committee office between 8:00 and 5:00, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco/San Francisco, CA 94143.**

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## CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent