Defining Novel Pharyngeal Pressure Metrics to Predict Dysphagia Treatment Outcomes and Clinical Prognosis Using High-resolution Manometry

NCT04569097

April 21, 2023

Participant Name: _____ Date:_____

Title of Study: Defining novel pharyngeal pressure metrics to predict dysphagia treatment outcomes and clinical prognosis using high-resolution manometry

Madison Site Investigator: Jill Zielinski MS CCC-SLP **VA Facility:** William S. Middleton Memorial Veterans Hospital

Principal Investigator Multisite Study: Timothy McCulloch, M.D.; William S. Middleton Memorial Veterans Hospital

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by VA Research & Development (RR&D). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We are inviting you to participate in this study because you have a swallowing disorder. By doing this study, we hope to see if a new technique called high resolution manometry (HRM) can help measure the effects of swallowing treatment in people with a swallowing disorder. To do this, we will be using HRM along with a commonly used technique which doctors use to evaluate how you swallow, called a modified barium swallow study (MBSS). Your participation in will last about 2 months. There will be three study visits and each will take about 2-3 hours.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Your participation in the study may benefit other people in the future by helping us learn more about swallowing disorders.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There are several risks associated with participation in this study to include but not limited to discomfort when the catheter passes through the nose. Potential risks include gagging, choking, and fainting. The likelihood that these risks would occur is small, and can be further reduced by resting between trials.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the overall study is Timothy McCulloch, MD at William S. Middleton Memorial Veterans Hospital. Each site also has a Local Study Investigator in charge of the study at their site. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Local Site Investigator

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project we hope to learn if HRM can help identify the progress in treatment for patients with swallowing disorders compared to healthy controls. We are doing this research to find out if using HRM, along with MBSS, can help measure the effects of swallowing treatment and help physicians decide which swallow treatments may be most effective for a particular patient.

This study is being done at the Otolaryngology and Speech Pathology clinics or in a suite in the Radiology department at the William S. Middleton Memorial Veterans Hospital. A total of 200 people will participate in this study; 150 will have a swallowing disorder and 50 will not have a swallowing disorder.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years. Your individual participation in the project will take 2 months. The study will involve three visits: 1) baseline; 2) 4 weeks; and 3) 8 weeks. Each visit will take about 2-3 hours.

We will ask you not to eat anything for 4 hours or drink anything for 2 hours before each scheduled visit. We will repeat these tests at each study visit.

If you have a swallowing disorder, you will have a MBSS as part of your regular care at each visit, and the research team will use the results of that test for this study. The other tests are for research purposes only.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to participate in this research study, the researchers will ask you to sign this consent form and you will be asked questions about your experiences swallowing and if you have any problems swallowing, as well as questions about your general medical history. We will also ask you if you are allergic to topical anesthesia (such as lidocaine) or nasal sprays. This should take about 20 minutes. You may skip any questions on questionnaires and/or during the interviews that you do not wish to answer. If you are a female who could become pregnant, you will also need a urine pregnancy test to make sure you are not pregnant.

Next, we will take some measurements of the pressures in your mouth during swallowing. You will be asked to place a small, air-filled pressure sensor in your mouth, directly behind your front teeth. With the pressure sensor in your mouth, you will be asked to swallow your saliva 10 times, and to press your tongue against the roof of your mouth as hard a possible 10 times. You will also be asked to perform a series of squeezes on a dynamometer, a device that measures force or power, by squeezing a handgrip. This test gives us a general measurement of your muscle strength. This will take about 10 minutes.

The next part of the experiment is the HRM, which involves inserting a small tube, called a catheter, into your nose and down into your throat. Before the catheter is inserted, some topical anesthetic (numbing medicine) will be sprayed into your nose to numb the surrounding area. This will not have any negative effect on your breathing. After the anesthetic has had an effect, a trained speech language pathologist will insert the catheter with pressure sensors into your nostril and guide it to the back of your throat.

For some participants, we may have difficulty ensuring that the catheter is in the correct position. If that happens, we may insert a flexible scope about the same size of the catheter in through your other nostril. This will help us to visualize your voice box (larynx) and throat (pharynx) to make sure that the catheter gets placed in the correct position. We will not record any images or video of your throat. Once we can confirm the correct position of the catheter, we will remove the scope. You are free to not allow us to insert the scope, if you wish.

After the catheter is in place, you will swallow liquids of different thicknesses. While you are swallowing, a study team member will be recording pressure measurements using the HRM catheter. The swallowing tasks will take about 30 minutes and the entire process should take about one hour. The catheter will be removed at the end. If you require a nasal spray anesthetic, you may continue to feel a slight numbness in your nose for up to 30 minutes after the exam.

Next we will do a modified barium swallow study (MBSS), which takes x-rays while you swallow liquids of different thicknesses so we can watch the liquids pass through your throat. The MBSS will be performed in the same visit or maximum 1 week apart from the HRM exam. Because you have problems swallowing, this part of the visit is part of your standard care. The MBSS takes about 30 minutes and we will record it for the research study.

After the first visit, we will ask you to return for two additional study visits: at 4 weeks and at 8 weeks. We will ask you not to eat anything for 4 hours or drink anything for 2 hours before each

scheduled visit. We will repeat all of the same tests described above at each study visit. Because you have a swallowing disorder, the MBSS as part of your regular care, and the research team will use the results of that test for this study. The other tests are for research purposes only.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant or might have gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.

Subjects will be informed of any findings with known clinical significance. If the physician sees anything during the HRM test and the swallow study that is important to your health, he will tell you about it.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- Fasting for 4 hours before each study visit is not expected to have any risks. However, if you are diabetic or have low blood sugar, take precautions needed to maintain your blood sugar.
- Potential risks include gagging, choking, and fainting. The likelihood that these risks would occur is small, and can be reduced by resting between trials. If you know you have difficulty with certain foods or liquids (for example, you know that you have difficulty with larger sips of water, you can let us know and we will not perform that particular trial). If you feel uncomfortable at any point during this experiment, please tell us and you can take a break.
- You may also experience discomfort when the catheter is passed through your nose. If you feel discomfort, please tell us and we will apply topical anesthetic with a nasal spray. There is a very small risk of an allergic reaction to neck numbing medicine (anesthetic) that includes reddening and irritation of the skin, rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

- As with any scientific study, there is a risk that your information could become known to someone not involved in this study. We will protect your information by using a code on study data instead of your name and storing study information securely.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions.

If the physician sees anything during the HRM test study that is important to your health, he will tell you about it.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at the VA hospital or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

If you do choose to leave the study, your standard of care treatment will continue as usual.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely, in locations that are locked in secure spaces or in password protected databases on secure servers. Study data will be coded to protect your identity and study data will only be accessible to approved research team members. Only

coded data will be shared between sites in this study, and the key will be kept in a secure location separate from the data.

Once the study data been deidentified, the information could be used for future research studies without additional informed consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Identifiers might be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

The following information from research procedures will NOT go in your medical records: HRM exams, the questionnaire, data collected from the dynamometer and data collected from the air-filled sensor that is placed in your mouth.

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

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I RECEIVE PAYMENT FOR PARTICIPATING IN THE STUDY?

You will be compensated $75 at the baseline and final study time points and $150 for the midpoint visit, for a total of up to $300. You will be reimbursed by direct deposit. You will be asked to provide your SSN in order to receive the electronic payments, and that will generate an IRS 1099 tax form.

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WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

There is no additional compensation available should an injury occur. However, by signing this form you are not giving up any legal rights or releasing the VA from any liability.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, please contact:

DURING THE DAY: Local Site Investigator

AFTER HOURS: Contact the William S. Middleton Memorial Veterans Hospital, (608) 256-1901.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled.

If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. You may discontinue taking part at any time without any penalty or loss of benefits. If applicable, you may withdraw and still receive the same standard of care that you would otherwise have received.

There are no consequences if you choose to withdraw from this study. Data collected prior to withdrawing from the study will be used but we will not collect any further information from your medical record.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

You may also be withdrawn from the study by the PI due to changes in medical status, an unanticipated problem making continuing in the study contrary to the your wellbeing, or a situation

occurs such that continued participation in the study would not be in your best interest. These decisions will be documented in your study chart.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, complaints, and concerns about this research please contact Local Site Investigator

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers.

This is what will happen with your banked data:

- We will use the data in future research projects about swallowing disorders. We may also use them for other types of research.
- The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data will be deidentified.
- When we give your data to other investigators for research projects, they will not be able to figure out which data are yours.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Local Site Investigator, Clinical Speech Language Pathologist or Clinical Research Coordinator has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **04/21/2023**

LSI Approval Date: **N/A**

LSI Verification Date: **05/10/23**