Title: Validation Of Cardiac Output Using Pulse Decomposition Analysis In Post-Cardiac Surgery Patients In The ICU
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School of Medicine

Informed Consent

Department/Section of *Anesthesiology/Critical Care Medicine*

VALIDATION OF CARDIAC OUTPUT USING PULSE DECOMPOSITION ANALYSIS IN POST-CARDIAC SURGERY PATIENTS IN THE ICU

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

Ashish Khanna, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research study is to evaluate a wrist device called the Caretaker, a novel monitoring device that measures vital signs after cardiac surgery in patients in the intensive care unit. You had this particular monitoring device placed after your surgery when you arrived in the intensive care unit. We are now asking for permission to use the information obtained from the Caretaker device, as well as to perform a review of your medical record to obtain information about your surgery and your treatment in the cardiac intensive care unit.

Participation in this study will involve providing consent to allow us to retrieve your medical information about your care during and after surgery. The Caretaker device was placed on you after you arrived in the cardiac intensive care unit after your surgery. This device works just by being attached to your wrist, similar to a smart watch, with a finger cuff that wirelessly measures your blood pressure, heart rate, and your breathing rate. We are then going to be comparing this information to the information that is in your medical record that was obtained using standard monitoring after heart surgery. You do not have to take any tests or do anything special to be in the study, only allow permission for the study team to retrieve your medical information.

All research studies involve some risks. There will not be direct benefit to you from your participation. Your participation in this study is voluntary. You do not have to allow us to review your medical record if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Ashish Khanna, one of the cardiac intensive care unit medical providers. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact Dr. Khanna at akhanna@wakehealth.edu or [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you had cardiac surgery, were in the intensive care unit after your surgery, and you had this device placed after your arrival in the intensive care unit. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare the results of the Caretaker device to the standard monitoring devices that are normally used after cardiac surgery. The Caretaker device has been approved by the US Food and Drug Administration (FDA) to be used in this manner.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

At Wake Forest Baptist Medical Center, we plan to include up to 50 patients in this research study.

WHAT IS INVOLVED IN THE STUDY?

On the day of your surgery, your surgical procedure proceeded as planned and you were taken to the cardiac intensive care unit to begin your recovery. After you arrived in the cardiac intensive care unit, a member of the research staff evaluated you to determine if you met the criteria to be in this research study. If you did, they then placed the Caretaker device on your wrist. This research device stayed on as long as you had your invasive blood pressure monitor called the arterial line in your wrist. The arterial line is an IV (a small plastic catheter) that was placed in your wrist in an artery that measures your blood pressure. This is because we are comparing the arterial line vital signs to the Caretaker.

If you agree to participate, as part of the data collection for this study, your electronic medical record will be reviewed and information about your hospital stay will be retrieved. This will include demographic information, information about your surgical procedure and your stay in the cardiac intensive care unit, and medications that you received. The information will also be retrieved from the Caretaker device. All information that is collected will be de-identified and a unique subject identifier used to maintain confidentiality.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for the length of time you were in the cardiac intensive care unit and required an invasive hemodynamic monitor to track your vital signs. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. There is a slight risk of a breach of confidentiality. We will do our best to

protect your confidential information. There also may be other risks that we cannot predict. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

The Caretaker device is non-invasive and just straps to your wrist like a watch band. The cuff that wraps around your finger uses Velcro to hold itself in place. Information from this device is downloaded wirelessly to a research computer but is de-identified.

Reproductive Risks and other Issues to Participating in Research

Pregnant women are excluded from participation in this study. If you are a sexually active woman of childbearing potential and have not been using a reliable method of birth control, a negative urine pregnancy test will be required prior to starting treatment.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will not be a direct benefit to you. We hope the information learned from this study will benefit other people in the future. Our aim is to show that the Caretaker device works just as well as the invasive monitors that are normally used as standard monitoring for cardiac surgery.
The information retrieved from the data using this device will not be used in your care as it is under investigation.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: not allowing research personnel to review your medical record to retrieve information about your surgery and recovery.

WHAT ARE THE COSTS?

Costs for your regular medical care, which are not related to this study, will be your own responsibility. You and/or your insurance company will not be billed for the cost of the use of the Caretaker device.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Caretaker Medical. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Ashish Khanna at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes information about your hospitalization and the treatments you received during this hospitalization. If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations. We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password-protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research (Caretaker Medical); the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any

publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you for this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information collected specifically for the study will be destroyed.
You can tell Dr. Khanna that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Ashish Khanna, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study. If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you were enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 Web site at any time. Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, or your condition worsened. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Ashish Khanna at akhanna@wakehealth.edu or by phone at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

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Person Obtaining Consent:_____ Date:_____ Time:_____ am pm