Official Title: A Randomized Controlled Single-Blinded Study Evaluating the Optimal Volume Voided for Passage of a Backfill-Assisted Voiding Trial Following Urogynecologic Surgery
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Wake Forest University
School of Medicine

RESEARCH INFORMED CONSENT FORM

Atrium Health Navicent Department of Obstetrics and Gynecology

A RANDOMIZED CONTROLLED SINGLE-BLINDED STUDY EVALUATING THE OPTIMAL VOLUME VOIDED FOR PASSAGE OF A BACKFILL-ASSISTED VOIDING TRIAL FOLLOWING UROGYNECOLOGIC SURGERY

Informed Consent Form to Participate in Research
David Lovejoy MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. This research aims to help establish a standard of care for backfill-assisted voiding trials. You are invited to participate in this study because a backfill-assisted voiding trial will be included in your standard post-operative care. Your participation in this research will involve 2-3 post-operative visits and will last about *six weeks.*

Participation in this study will involve you undergoing a backfill-assisted voiding trial after your surgery, which is performed after all of Dr. Lovejoy's surgeries; however, you will be randomized to 1 of 2 groups with different thresholds for passing the voiding trial. If you do not pass the voiding trial, you will go home with a foley in place and then follow up outpatient with Dr. Lovejoy for a repeat voiding trial; again, this is standard post-operative care after all procedures Dr. Lovejoy performs. All research studies involve some risks. A risk to this study that you should be aware of is the potential for breach of patient confidentiality. There is also a small risk of acute urinary retention after Urogyn procedures if the foley catheter is removed too early; this risk is similar for both voiding trial protocols that will be used. You may not benefit from participation in this study, but you will be helping to contribute more knowledge to the field of Urogynecology

Your participation in this study is voluntary. You do not have to participate in this study 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. If you have questions, suggestions, or concerns regarding this study or want to withdraw, please contact the Principal Investigator at [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 Wake Forest University Health Sciences Research Subject Advocate at [redacted]

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you have a procedure scheduled that includes a back-filled voiding trial as part of your standard post-operative care. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the staff to explain any words or information in this informed consent document you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

This research study aims to help establish a standard of care for backfill-assisted voiding trials.

A voiding trial following gynecologic and urogynecologic surgery is a common practice, and how these voiding trials are conducted is usually a provider preference. Voiding trials can be completed by either spontaneous voiding or backfill-assisted voiding. A spontaneous voiding trial is where the patient spontaneously voids in a set time period after removing the foley catheter with a set postvoid residual to determine a passing voiding trial. A backfill-assisted voiding trial is completed by backfilling the patient's foley with a determined amount of sterile fluid (usually ~300mL OR as much as the patient can tolerate if unable to tolerate 300mL); the patient then has a set period of time (usually ~30 minutes) to void either 2/3 of the backfilled volume or greater OR more than 1/2 of the backfilled volume or greater. Few studies indicate which measurement to use, either 2/3 volume voided vs. 1/2 volume voided, as a passing volume in backfill-assisted voiding trials. The majority of studies on voiding trials compare spontaneous voiding with backfill-assisted voiding using two-thirds volume voided as a passed voiding trial. Though some trials and studies use half of the volume voided, the majority use two-thirds. This clinical trial aims to determine the optimal volume voided after a backfill-assisted voiding trial following urogynecologic surgery.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 100 people will take part in this study at this research site.
In order to identify the 100 subjects needed, we may need to screen as many as 150-200 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups. The study groups only differ in the volume of liquid that must be voided to pass the voiding trial. One group will be required to void 2/3 of the volume backfilled into the bladder, and the other group will be required to void 1/2 of the volume backfilled into the bladder in order to pass the voiding trial. Randomization means that you are put into a group by chance. It is like flipping a coin. You will not know which study group you will be placed in. This is done so that a fair evaluation of results can be made. This

information is available to the researchers.

After your procedure, you will participate in a backfill-assisted voiding trial. A nurse will insert 300ml of sterile water (or as much as you can tolerate if you are unable to tolerate the entire 300mL) into your bladder using your foley catheter. They will then remove the foley catheter, and you will be given 30 minutes to void this liquid. This test is part of normal post-operative care following your procedure. One trial group will be required to void 2/3 of the backfilled volume to pass. The other trial group will be required to void 1/2 of the backfilled volume to pass. The amount of liquid you void will be measured by a nurse and told to your doctor. If you fail the voiding trial, you will have a foley reinserted, follow up with Dr. Lovejoy outpatient in 48hr and undergo another voiding trial, this time with 2/3 of backfilled volume required to pass the voiding trial. You will then follow up with Dr. Lovejoy two weeks after your procedure for a virtual visit and six weeks after the procedure in person to discuss your progress and assess your healing after your surgery. The six-week postoperative visit will mark the end of your participation in this study.

If you have any issues with urination requiring an ED/urgent care/office visit, please inform Dr. Lovejoy or his office staff either before or at your 6-week post-operative visit

If you take part in this study, you will have the following tests and procedures:
A backfill-assisted voiding trial, which is standard of care.

How Long Will I Be in the Study?

You will be in the study for about 6 weeks.

You can stop participating at any time. If you stop participating in the study, we encourage you to talk to the investigators or staff first

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. Risks and side effects related to the *procedures* we are studying include:

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.

Known potential risks include acute urinary retention, urinary tract infection, and pain/discomfort associated with foley catheter placement and maintenance. Acute urinary retention is a risk for both voiding trial methods; however, there is theoretically an increased risk in the voiding trial group with a more liberal (1/2 backfilled volume voided) voiding cutoff. Long-term risks of acute urinary retention include long-term voiding dysfunction. The risk of urinary tract infection and pain/discomfort associated with foley catheter placement and maintenance is also a risk for both voiding trial methods; however, there is a theoretical

decreased risk of infection and pain/discomfort associated with foley catheter placement/maintenance in the voiding trial with a more liberal voiding cutoff.

This study is comparing two approved methods for treating your condition. You will be randomly assigned to one of the two groups. It is possible that one treatment group may have a better response than the other. Therefore there is a risk that you may be assigned to a group that does not perform as well as its comparison.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins, and supplements you take and any medical conditions you have. This may help avoid side effects, interactions, and other risks to your health.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

Potential benefits of a more voiding volume cutoff may include: a decreased rate of patients discharged home with a foley catheter and thus decreased UTI rate and decreased patient burden due to continued catheterization, and decreased rates of patients discharged home with foley in place increase patient satisfaction rates

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There will be no additional costs to you by participating in this study besides your regular medical bills associated with your already scheduled procedure.

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 or permitted by law, or necessary to protect the safety of yourself or others.

Your 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.

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 Atrium Health Navicent. The sponsor is not providing money or other support to the researchers to help conduct this study. The Investigators have no conflicts

of financial interest

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

- Age of patient, BMI, race, highest level of education, menopausal status, HRT status, Last A1c, Diagnosis of Anxiety, Diagnosis of anxiety on medication, smoking status
- Type of surgery, indication for surgery, Number of procedures performed, type of sling, stage of pelvic organ prolapse, history of hysterectomy, history of previous prolapse surgery aside from hysterectomy, history of previous incontinence surgery, has patient ever had surgery in the past and had to perform CIC or went home with a catheter
- Operative time, the total volume of fluids given prior to performing voiding trial, estimated blood loss, amount of narcotic medication received prior to performing voiding trial, intraoperative complications
- Urodynamics study information: 1st sensation to void, bladder capacity, PVR
- Volume of fluid backfilled into the bladder, volume voided during voiding trial
- Passed or failed voiding trial and what group they were assigned to
- If they failed the voiding trial after surgery, did they pass the voiding trial after 48 hrs, if patient failed the outpatient voiding trial, how many days did they require to have a foley catheter in place
- If the patient required ED/urgent care/clinic visit for any complications or issues related to surgery between POD0 - 6-week postoperative visit
- Any issues or symptoms the patient had at the 6-week postoperative visit
- How satisfied were you with your voiding trial

We will take steps to keep your Protected Health Information private. We will store your Protected Health Information records in a locked office cabinet 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; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; 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, videotapes, audiotapes, or other recorded media which identify you unless we have your written authorization.

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 in 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 not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Lovejoy 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:

David A. Lovejoy, 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 Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are 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. Authorization to access this part of the medical record will only be available to people who need to know this information in order to perform their job-related duties. If you are not a patient of these healthcare facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available at 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 Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained 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, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped*. 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.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security

number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the study investigator David Lovejoy, MD, at the telephone number [redacted] after business hours

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 do not give up any legal rights as a research participant by signing this consent form.

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):_____

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