STU#: STU00211845

PROTOCOL TITLE: The effect of decreased uterine filling pressure in hysteroscopy, a double-blind randomized control trial

PRINCIPAL INVESTIGATOR:
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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	N/A
IND / IDE / HDE #	N/A
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	68
Funding Source	None
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☐ No

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OBJECTIVES:
The aim of the study is to compare the outcomes of patients undergoing hysteroscopy with a Myosure device with a pressure of 60 mmHg to those using the standard of 80 mmHg.

BACKGROUND:
The current standard of practice at Northwestern Medicine is to use a pressure of 80mmHg for adequate visualization during hysteroscopy procedures. This pressure can involve patient discomfort post-operatively due to intravascular fluid overload. There have been studies looking at the effect of lower pressures in hysteroscopy in hopes of reducing post-operative discomfort. The finding of Haggag et al. (2017) demonstrated that a pressurization of 60mmHg did not impact the number of surgeries completed. The findings of Shadhid et al (2014) found that in a double-blind randomized trial that 70mmHg and 100mmHg had similar visualization in hysteroscopy but did not present with decreased pain. The aim of this trial will be to determine the efficacy of a lower pressurization of hysteroscopy for visualization as well as other patient outcomes such as amount of fluid used, operative time, weight of sample collected, and surgeon satisfaction.

STUDY ENDPOINTS:
The primary endpoint is the amount of pressure used in hysteroscopy procedure with the Myosure device, the standard for this surgical procedure. The experimental group will be set at a pressure of 60 mmHg. The control group will have the device set at the standard of care of 80mmHg.

The outcome variables will be procedure time, specimen weight per minute, volume of normal saline used, fluid deficit, surgeon rating of satisfaction, surgeon rating of adequacy of visualization, any changes in pressure needed during the surgery, and whether the patient required Lasix post-operatively.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):
60 mmHg Myosure pressurization for hysteroscopy compared to the standard of care, which is 80mmHg. The rationale for this determination is that the pressurization can result in excess fluid being absorbed by the patient without a substantial benefit to surgical outcome. Minimizing the pressure used during this procedure may optimize outcome without compromising visualization of the surgeon. The research procedure will take place in the operating room of the minimally invasive gynecologic surgery department.

PROCEDURES INVOLVED:
An a priori sample size calculation was completed. To achieve 80% power and an alpha of .05, we needed a sample size of 68 total with 34 participants in each group.
The study will be a double-blind randomized control trial. Patients will be recruited based on surgery type (hysteroscopy) and consented using a written consent by the research coordinator with sufficient time to ensure patient comprehension and allow for any questions. The consent process will happen in the pre-operative appointment.

Participants will then be randomized to either the standard of care of 80mmHg or the experimental pressure of 60 mmHg for uterine filling pressure via an automated randomization program. The physician performing the surgery and the patient will not know what group they are assigned to.

The procedure involved in the study will be hysteroscopy. Hysteroscopy is a procedure that is used to diagnose and sometimes treat intrauterine pathologies. In order to visualize the uterus, pressurized saline is

used to distend the uterus. In this study, the specific hysteroscopic procedure will involve the removal of uterine fibroids with a Myosure device. These tissues will be collected and sent to Pathology to be weighed. During the surgery, the surgeon will be able to request an adjustment pressure if they feel that visualization is not adequate.

Physicians will start with a pressure of 80mmHg. Once physician is ready to introduce the myosure hysteroscopy device, they will then be randomized.

During the procedure, monitoring will be done by anesthesia through the use of pulse oximetry and measurement of vitals during the Monitored Anesthesia Care. There is also real-time monitoring of hysteroscopic fluid deficit via the fluid management system that is attached to the hysteroscopic pump. Fluid deficit can also be confirmed by the nurse who manually counts the amount of fluid used during the procedure. Per policy, once a 2500mL deficit is reached, the procedure is terminated.

After the surgery, the surgeon will fill out a questionnaire that measures the outcomes of surgeon satisfaction and visualization.

The other end points of procedure time, specimen weight, volume of normal saline used, any changes in pressure needed during the surgery, and whether the patient required Lasix post-operatively will also be collected at this time.

Procedures list below in order of occurrence:

1. Patient will be approached by the study coordinator to discuss study during patient's pre-operative appointment with the Principal Investigator.
2. Patient and study coordinator will review the consent form.
3. If patient consents, the coordinator will make a copy for the participant to take home and then file the original consent appropriately. Coordinator will also track participants via StudyTracker.

Day of Surgery

4. A study team member will conduct the randomization.
5. A study team member will be present in the OR to perform the change in pressurization.
6. Once procedure is complete the study team member will ask the physician to complete a brief survey. This survey will inquire ratings regarding adequacy of visualization, listing any changes in pressure needed and overall satisfaction.
7. The final study endpoints will include:
    a. Physician survey
    b. Operative time
    c. Amount of fluid – volume of normal saline used
    d. Weight of specimen
8. Participant involvement in the study occurs only during the surgical procedure itself. Once the procedure is completed in the OR, the participant will have completed the study.

Data Analysis

9. Study team will collect the physician satisfaction survey and analyze the responses at the end of participant enrollment.
10. Surveys will be administered via paper and input into a spreadsheet by the study team. Survey will not contain any identifying information. Spreadsheet will contain participant ID number, specimen weight and physician survey response. Spreadsheet will be saved in the FSM resfiles and only accessed by the study team.

11. Data analysis will occur after recruitment and enrollment is complete.

DATA AND SPECIMEN BANKING
We will not be storing any tissue for this study. All collected tissue will be sent to Pathology to be weighed. We are only collecting the specimen weight.

All data collected will be de-identified. We are not collecting any demographic information or health data about the patient for our study.

SHARING RESULTS WITH PARTICIPANTS
During the consenting process, patients will be asked if they are interested in the results of the study.

STUDY TIMELINES
The individual's participation will be limited to time of written consent prior to surgery until they are discharged following surgery. Patient enrollment will occur over approximately 5 weeks (from time of consent during pre-operative appointment to their date of surgery).

Primary analysis will be completed within one year of study completion. We anticipate to complete this study within one year.

INCLUSION AND EXCLUSION CRITERIA
Inclusion:

- Patients electing for operative or diagnostic hysteroscopy procedures for management of polyps and fibroids
- Age $\geq$ 18 years
- Ability to understand and the willingness to sign a written informed consent. We will include non-English speaking patients in the study.

Exclusion:

- Patients electing for operative or diagnostic hysteroscopy procedures without polyps and fibroids
- Patients under the age of 18 years

RECRUITMENT METHODS
Patients who are scheduled for a hysteroscopy procedure will be approached and recruited during their pre-operative appointment. For non-English speaking patients, we will use the short-form consent in Spanish and will have a translator from Northwestern Medicine assist with informed consent and answering any questions from the participant.

Withdrawal from study: Patients can be taken off the study treatment and/or study at any time at their own request, or they may be withdrawn at the discretion of the investigator for safety, behavioral or administrative reasons. The reason(s) for discontinuation will be documented and may include:

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES
There will not be any compensation for participation in this research study.

RISKS TO PARTICIPANTS
There is no risk to patients compared to the standard of care for hysteroscopic procedures.

POTENTIAL BENEFITS TO PARTICIPANTS
There are no direct benefits.

DATA MANAGEMENT AND CONFIDENTIALITY
All collected date will be stored on a locked and secured Northwestern Memorial computer located in the Center for Comprehensive Gynecology and the secure FSM drive files on a Northwestern University computer. Only the study team will have access to the data. Only the study team will conduct data analysis.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS
Patients will be under close supervision by both the physician and nursing staff during surgery and post-operatively. All collected data will be de-identified. Once a patient consents to participate in this study, the study team will assign the patient an ID number. The study team will keep track of participant IDs and consents via StudyTracker.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS
All participants will have ample time to discuss any questions, concerns or comments about the study. Participants may also contact study coordinator after pre-operative visit if any other questions arise. Participant images will be de-identified and screening data will be secured on a locked Northwestern Memorial computer.

ECONOMIC BURDEN TO PARTICIPANTS
There is no cost to participate in the study.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)
Study team will only collect information to determine inclusion criteria as well as the study endpoints.

- Age
- Surgical procedure
- Date of surgery
- Procedure time
- Specimen weight per minute
- Volume of normal saline used
- Fluid deficit
- Whether the patient required Lasix post-operatively

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE
The Center for Comprehensive Gynecology sees a number of pre-operative patients presenting for gynecologic surgery. Both PI has extensive research and surgical experience. Entire study team is CITI Biomedical Research Trained. Study team collaborated on the study protocol and each member is well versed in the study procedures and their study duties.