

**Registry-Based, Randomized Controlled Trial Comparing Intra-  
operative Urinary Catheter vs. no Catheter for Laparoscopic  
Inguinal Hernia Repair**

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## **INTRODUCTION**

An inguinal hernia repair is a common outpatient procedure with a low rate of morbidity. One well-recognized complication of this operation is post-operative urinary retention (PUR), which is a failure of spontaneous voiding requiring catheterization[1]. The reported incidence of PUR ranges between 0.4 and 3% of open tension-free repairs. For laparoscopic inguinal hernia repairs that range is between 1 and 22 %[2]. At our institution there is no consensus when it comes to using intraoperative catheters. Among the surgeons who routinely use the catheters the incidence of urinary retention is reported to be 1-5%. Since no randomized controlled trials have evaluated PUR as the primary outcome exist in literature, there is no consensus on whether catheter use aids in minimizing post-operative urinary retention. Routine use of intraoperative catheterization increases the risk of urethral trauma, catheter-associated infections and bladder damage leading to increased cost of care and potential patient morbidity[3]. On the other hand, PUR is associated with additional procedures, such as catheterization, which may delay hospital discharge or increase the length of stay and cause patient discomfort [1]. This work aims to study the effect of intraoperative catheters on PUR and whether the aforementioned risks associated with this procedure are justified.

We hypothesize that the use of intra-operative urinary catheter reduces the incidence of postoperative urinary retention after laparoscopic inguinal hernia repair, thus justifying the potential complications associated with intra-operative catheter insertion.

Specific Aim #1: To determine if the use of intra-operative urinary catheter reduces the incidence of postoperative urinary retention after laparoscopic inguinal hernia repair.

Specific Aim #2: To determine if there is a difference in the rates of intraoperative bladder injuries between the study groups.

Specific Aim #3: To determine the rate of urinary tract complications after insertion of the intra-operative urinary catheter for the control group.

Specific Aim #4: To determine the rate of urinary tract complications after insertion of a urinary catheter for patients who develop PUR.

## **STUDY DESIGN**

This trial will follow the same methodology of data collection employed in previous randomized controlled trials (RCTs) performed by the Cleveland Clinic Hernia Center. The Americas Hernia Society Quality Collaborative (AHSQC) registry will serve as the main platform for data collection. Registry-based trials use data available in a preexisting database to increase the efficiency of performing RCTs, decreasing the high cost and logistical challenges associated with operationalizing this type of research.

This will be a multi-institution study, performed at the Cleveland Clinic Foundation (CCF) hospitals in Ohio and Florida. Enrollment and surgeries are anticipated to occur at Cleveland Clinic Hernia Center located at Main Campus, Fairview Hospital, Hillcrest Hospital and CCF Weston in Florida. Additionally, enrollments and surgeries may also occur in Strongsville, Twinsburg and Beachwood Family Health and Surgery Centers.

Specific patient inclusion criteria include all patients aged 18 years or older presenting for an elective unilateral or bilateral inguinal hernia repair, who are able to tolerate general anesthesia and who are considered eligible to have a hernia repair through a laparoscopic approach. Patients presenting with primary or recurrent inguinal hernias, previously repaired in an

open fashion, will be considered eligible to be enrolled in this study. Exclusion criteria include patients who cannot tolerate general anesthesia and patients who are not able to understand and sign a written consent form. The intervention will be no intraoperative urinary catheter for the entirety of the case. If surgeons determine the need for an intraoperative catheter for the no catheter group, the patient will remain in the intervention group and will be treated as intention to treat which will be recorded in RedCap. Patients will be randomized to urinary catheter versus no catheter after anesthesia induction and stratified based on unilateral versus bilateral repair. No other intraoperative or postoperative differences will occur between the two groups.

Post-operative urinary retention will be defined as post-operative failure to void requiring straight catheterization, placement of an indwelling catheter or return to the emergency department due to failure to void after discharge from the hospital[4,5]. Bladder scanning, its timing and specific criteria for placement of urinary catheter will be determined by the standard policies of each institution and surgeon.

Baseline information, operative details, and 30-day outcomes are already captured within the AHSQC database, allowing for follow-up, and data capture with decreased effort outside of routine care. Randomization data will be captured and stored in RedCAP®.

Baseline patient demographics will be obtained at initial patient recruitment, and baseline AHSQC questionnaires will be completed following patient recruitment. All operative details are already routinely collected and stored in the AHSQC database. Patient-reported quality of life will also be assessed at baseline and at 30 days using the EuraHS Quality Of Life survey tool[6], which is collected for all patients entered into the AHSQC as part of the AHSQC Inguinal Hernia Postoperative Assessment. Patients will be required to complete these forms at each clinic visit, or via telephone contact, as this is standard procedure for all patients entered into the AHSQC. At

the time of the one-month follow-up clinic visits, a routine physical examination will be performed on all patients. The patients will be blinded to which arm they were randomized until the first 30-day follow up visit.

## **OUTCOMES TO BE INVESTIGATED**

Each outcome to be investigated is based on the specific aims of the study and they are listed below:

- *Specific Aim #1: To determine if the use of intra-operative urinary catheter reduces the incidence of postoperative urinary retention after laparoscopic inguinal hernia repair.*

This will be assessed by comparing the PUR rates between the two study groups.

- *Specific Aim #2: To determine if there is a difference in the rates of intraoperative bladder injuries between the study groups.*

This will be determined by comparing the rates of intraoperative bladder injuries between the two study groups. The events will be captured on RedCap.

- *Specific Aim #3: To determine the rate of urinary tract complications after insertion of the intra-operative urinary catheter for the control group.*

This will be accomplished by analyzing the rates of urinary tract injury, infections and bladder injuries due to intraoperative catheter placement. The events will be captured on RedCap.

- *Specific Aim #4: To determine the rate of urinary tract complications after insertion of a urinary catheter for patients who develop PUR.*

This will be accomplished by analyzing the rates of urinary tract injury, or infections and bladder injuries due to catheter placement after patients develop PUR. The events will be captured on RedCap.

## **SURGICAL PROCEDURE**

Patient preparation common for both groups

All patients will be asked to void in the pre-operative area prior to going into the operating room. Patients will be operated in the supine, and slight Trendelenburg position (15° degrees), with arms tucked along the body. The procedure will be performed under general anesthesia. Antibiotic prophylaxis will be performed according to institutional protocol. Pharmacological prophylaxis of venous thromboembolic events is usually not necessary for general laparoscopic inguinal hernia repair. Although, if deemed necessary, this will be performed per Surgical Care Improvement Project (SCIP) protocol and will not be considered a protocol deviation. Skin preparation and hair removal will be performed per SCIP protocol. All necessary materials, including the urine catheterization kit, will be available in the operative room before the start of the procedure.

After induction of anesthesia, randomization will occur. It will be performed according to a computer-generated block randomization scheme, which will take place in RedCAP. The randomization will be stratified for unilateral or bilateral hernias based on the surgeon's report.

The operating room nurse will call a designated phone number where he or she will be able to speak to the research coordinator who will perform the randomization in RedCAP. After confirming with the surgeon whether the hernia is unilateral or bilateral, he or she will inform the surgeon regarding the group that the patient has been assigned. In case there is an incidental hernia discovered on the contralateral side upon dissection, and after randomization has occurred, the patient will remain in the original arm with an intention to treat.

- **For the intraoperative urinary catheter group**

A standard catheterization kit available at the institution where the surgery is being performed will be used to place the catheter using standard sterile technique.

- **For the no intraoperative urinary catheter group**

No catheter will be inserted.

### **Common operative steps for both groups**

Inguinal hernia repairs will be performed using the transabdominal preperitoneal (TAPP) or total extraperitoneal (TEP) techniques based on surgeon preference and expertise. These techniques have been described in detail in the literature.

### **ANTICIPATED TIME FRAME**

Estimated patient accrual time is two years with data collection to occur throughout the year up to 30 days from the last surgery. Data analysis and manuscript production will occur within six months of completion of data collection.

### **PATIENT RISKS AND DISCOMFORTS**

As with any surgical procedure, there are some associated risks, and these will be discussed in a separate surgical consent form. The subjects may experience some pain, bleeding, and discomfort; however, this may occur with any surgical operation. Common events following hernia repair include seroma or hematoma around the hernia repair, inflammation, or infection. Patients will be made aware of the risk for conversion to an open approach if considered necessary by the attending surgeon. Additionally, the risk of injuries to the bladder, iliac vessels, epigastric vessels, cord structures, and vas deferens during preperitoneal space or hernia dissection are always discussed prior to any inguinal hernia repair. The risk of postoperative chronic pain and hernia recurrence will be discussed in detail during the preoperative visit, as it is usual for every inguinal hernia repair. This will occur independently of patient participation in this study.

### **PATIENT BENEFITS**

There are no direct benefits to subjects for participating in this study. Subject participation will help to improve the general knowledge of the use of urinary catheters during minimally invasive inguinal hernia repair.

### **COSTS TO THE SUBJECTS**

There are no extra costs to the subjects associated with the research. Procedures related to the preoperative evaluation and the hernia surgery are considered standard of care and will be the responsibility of the subject and the subject's insurance company.

### **ALTERNATIVES TO PARTICIPATION**

Patients are under no obligation to participate in this study. A member of the research will discuss all available surgical options to the patients. Declining to participate in this study will not impact any patient's ability to receive care or to undergo inguinal hernia repair at the Cleveland Clinic Foundation.

### **PAYMENTS TO THE SUBJECTS**

Subjects will not receive payment for their participation or any activity related to this proposed study.

### **PLAN FOR OBTAINING INFORMED CONSENT**

For each subject, written informed consent will be obtained prior to any protocol-related activities. As part of this procedure, the principal investigator, surgeon co-investigator, or one of the approved study coordinators must explain orally and in writing the nature, duration, and purpose of the study in such a manner that the subject is aware of the potential risks, inconveniences, or adverse effects that may occur. The subjects will be informed that they may withdraw from the study at any time. Subjects will receive all information that is required by federal regulations.

Once a potential study patient is identified, the investigator or one of the approved study coordinators will be responsible for instituting the informed consent process in a face-to-face manner. Before starting any study procedures, the investigator will discuss the proposed research study in detail with the potential subject during the office visit to discuss treatment options. The subject will be allowed ample time to read and review the informed consent document and ask

questions. The informed consent document will be reviewed with the subject in depth by the participating investigator or designated member of the research team to ensure that the potential participant has a good understanding of the study protocol, what is required of the study participants, the potential risks and benefits of study participation, and his or her rights as a study participant. The investigators will be available by phone or office visit to answer any questions that the participant may have. After consideration, the subject may return if necessary for another appointment with the investigator to discuss the study, ask questions, and sign the informed consent document to participate in this study.

After the subject has read and reviewed the informed consent document and has agreed to participate, he or she will be asked to sign and date the document. The study member obtaining consent will also sign and date the form, and documentation of the informed consent process will be included in the research file (i.e., the person who obtained consent, where and when consent was obtained, and who was present during the process). A copy of the consent form will be given to the subject for their records.

### **PROVISIONS FOR SUBJECTS FROM VULNERABLE POPULATIONS**

The population to be studied includes adults 18 years of age or over, so children are therefore excluded. Decisionally-impaired and cognitively-impaired persons will not be approached to participate in this study as we are seeking subjects who have the capacity to understand and actively consent to the procedure independently. Pregnant women will be excluded from participating in this study.

Staff and employees at the participating institutions are considered a part of the vulnerable population. Staff and employees may be eligible to participate in this study. Since subjects may or may not benefit from this study, we do not want to exclude this population. If an employee is a potential candidate for this study, the subject will be informed during the consent process that his or her participation or refusal to participate will in no way influence grades, employment, or subsequent recommendations. Every effort will be made to prevent coercion during this initial process and throughout study participation. According to IRB policy, students and house staff cannot be asked to participate in research conducted while under the direct supervision of the investigator, so those subjects will not be enrolled.

In those instances where potential participants cannot read the consent form because they do not speak English, we will work with the IRB to develop a language-appropriate consent form. In addition, a qualified translator will be present to assist with obtaining the informed consent of the participant and throughout the duration of the patient's participation in the study. In addition, in the unusual situation where a subject cannot read a consent form due to illiteracy or blindness, a member of the research study staff will read and explain the consent form to the participant or to the participant's legally authorized representative. A witness, who will sign and date the consent form, must also be present during this oral presentation.

## **SUBJECT PRIVACY AND DATA CONFIDENTIALITY**

Anonymity and confidentiality of subjects participating in this study will be maintained. The only potential identifiers on any study documents submitted to the sponsor or designee will be subject study numbers, dates of birth, and dates of procedures. Every effort will be made to maintain the confidentiality of documents that identify the subject by name (e.g., signed informed consent documents, clinic charts), except to the extent necessary to allow monitoring by the Office of Research Compliance at the Cleveland Clinic or other regulatory authorities.

All information collected, such as name or medical record number, will be stored in the AHSQC database. Randomization will occur with the use of a customized Research Electronic Data Capture (REDCap®) database program. This is in a secure network/firewall protected electronic database to which only the investigator and the designated members of the study team will have access using an individual assigned login and password. Only approved study members listed on the IRB protocol will have access to the separately-stored master list. This list will be stored on a CCF computer and a secured drive. Only the Principal Investigator, Lead Research Coordinators, and Biostatisticians will be granted access to retrieve patient data for routine data quality assessments and data analyses. All electronic records pertaining to the clinical study will be password-protected and only approved study members listed on the IRB protocol will have password access.

### **POWER CALCULATION**

Sample size and power calculation were performed according to post-operative urinary retention, the primary outcome measure. Previous publications have reported a urinary retention rate of 7.5% when no urinary catheters were used. We surveyed the CCF surgeons who routinely use intra-operative catheter and the average reported retention rate was 2%. Furthermore, we looked at the available AHSQC data only for the surgeons who reported routine use of catheters. After excluding patients with history of BPH, the rate of retention was 2%. In order to detect a 5.5 percentage-point decrease from the non-foley arm's 7.5% retention rate at 80% power while holding type I error at 5%, an estimated total sample size of 444 subjects (222 per arm) is required. Assuming a 10% loss to follow-up at 30 days, a total of 488 patients will be recruited for this study (244 patients per arm). Below is a plot of the study power for a range of possible event rates, to understand how the study power may change if the actual event rate in the non-foley arm is higher or lower. (Other parameters are held constant.)

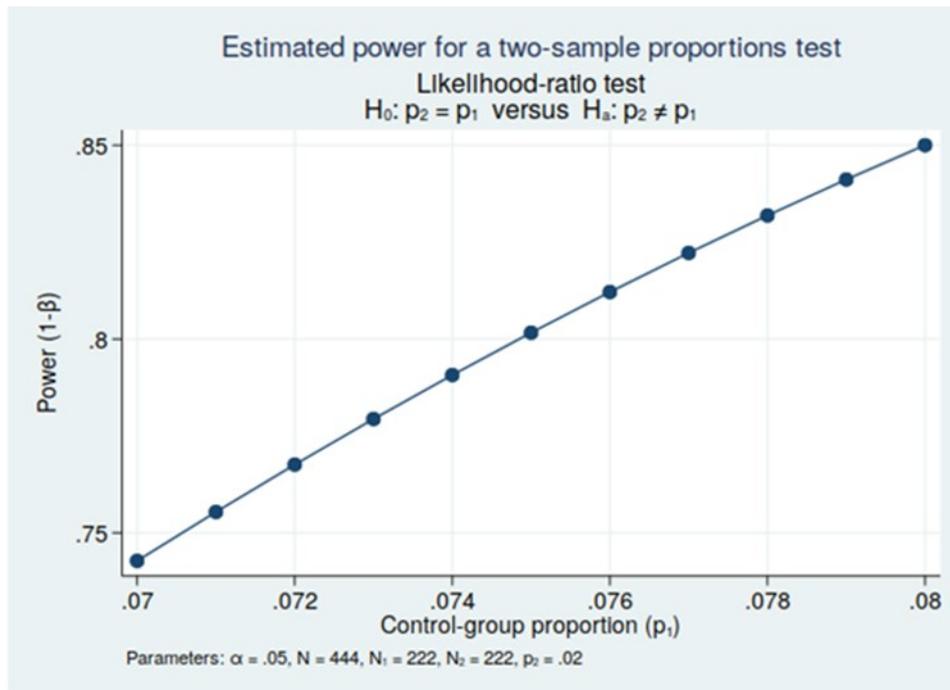


Figure 1: The plot of the estimated power for a two sample proportions test

## **STATISTICAL ANALYSIS**

The primary endpoint will be analyzed with a logistic regression model that includes treatment arm and covariates related to baseline disease severity. The primary aim will be tested with a likelihood ratio test of the treatment term in the regression model. As a sensitivity analysis, the unadjusted likelihood ratio test will be performed. Tests resulting in a p-value less than 0.05 will be considered significant.

Secondary endpoints will be analyzed in a similar fashion. Furthermore, tables of summary statistics of patient and hernia characteristics will be generated, summarizing continuous covariates with the median and IQR while summarizing categorical covariates with sample proportions. No hypothesis tests of baseline characteristics will be performed.

## **DATA SAFETY MONITORING BOARD**

A data safety monitoring board will not be required for this trial because both the intervention and the control are considered standard of care at CCF.

### **CLINICAL SIGNIFICANCE/INNOVATION**

Post-operative urinary retention is a well-recognized complication after minimally invasive inguinal repair. In the literature, there is a wide range (1-22%) of reported rates of retention. However, no studies looked at retention as a primary outcome. This will be the first randomized controlled trial that will determine if the use of intra-operative urinary catheter reduces the incidence of postoperative urinary retention after laparoscopic inguinal hernia repair.

As previously mentioned, this trial will be another registry-based randomized prospective study performed in the hernia disease space by our institution. We have an opportunity here to collect most of the data that will be analyzed at the end of the study on the AHSQC database, which will act as the central data storage platform for this trial. Registry-based clinical trials have been proposed as a way to achieve the scientific power of an RCT while minimizing the cumbersome nature associated with running such trials. In effect, the registry-based trial allows for faster accrual of patients and secure data storage with a reduced financial burden.

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