

**Registry Based, Randomized Controlled Trial Comparing Telescopic dissection vs. Balloon**

**Dissection for Laparoscopic Totally Extraperitoneal Inguinal Hernia Repair (TEP)**

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## INTRODUCTION

Minimally invasive approaches have been successfully incorporated into the surgical armamentarium of inguinal hernia repair, with proven benefits for decreased postoperative pain and earlier return to work [1]. Laparoscopic inguinal hernia repair is more commonly performed through the transabdominal preperitoneal (TAPP) approach or the totally extraperitoneal (TEP) approach. The TEP approach has been proven to have equivalent recurrence rates, decreased postoperative pain, earlier ambulation and return to work when compared to the open, tension-free repairs. [1,2] Additionally, when compared to TAPP, the TEP approach has also been associated with decreased postoperative pain, shorter operative times and equivalent rates of postoperative complications and hernia recurrence [3].

A key step in the TEP procedure is the creation of the extraperitoneal space, which can be performed using either telescopic dissection or with a balloon dissector.[1-4] Telescopic dissection is the creation of the extraperitoneal space with blunt dissection performed with the laparoscopic probe. Telescopic dissection was initially described in the original paper describing the TEP procedure, in 1992 by Ferzli et al. [5]. To date, telescopic dissection is still used in many centers around the globe [4]. In order to facilitate the creation of the initial working space, disposable dissection balloons have been developed and are commercially available. Balloon dissection is now the most commonly used method for creation of the extraperitoneal space for TEP procedure in the United States [4]. A randomized, prospective multicenter study conducted between 1994 and 1997 and published in 2001 by Bingham and colleagues [6] has compared operative times, conversion rates, postoperative morbidity and time to return to work between patients in which the TEP procedure was performed with or without the balloon dissector. In this study, the use of

the balloon was associated with lower conversion rates and statistically, but perhaps not clinically, significantly shorter operative times (9 minutes difference). No difference was seen in postoperative morbidity, recurrence rates or time to return to work between the groups. Of note, the surgeons performing these procedures were still at an early point of their learning curve for the TEP procedure, which might have influenced the results, especially for the group without the balloon.

Low-cost alternatives have been proposed to substitute the commercially available balloon dissector, especially in developing countries where the access to the balloon dissector is restricted. Despite the fact that the TEP procedure has become more popular in the last 15 years, with surgeons being each time more proficient in this operation, there is a paucity of data comparing cost and surgical outcomes among telescopic and balloon dissection.

Furthermore, according to current consensus, the use of a balloon dissector is especially recommended during the learning period when surgeons are still unfamiliar with the preperitoneal anatomy.[5] Especially for expert surgeons, delineation of the inguinal area and dissection in the creation of extraperitoneal space can be performed as safe and efficient with telescopic dissection.[3,4]

The TEP procedure for inguinal hernia repair is performed on a regular basis by numerous surgeons at our institution, both with and without the use of a balloon dissector, according to each surgeon's expertise and preference. At our institution, the commercially available disposable balloon dissector (SpaceMaker™, Medtronic, Minneapolis, MN) costs around US\$ 600, increasing the direct cost of the procedure. Therefore, the regular use of the balloon dissector is associated with a significant expenditure to the institution. Nevertheless, if the use of the balloon dissector

confers a significant decrease in operative times reflecting a decrease in the total costs of the procedure, its use would still be economically advantageous.

One of the co-investigators (Dr. Kalman Bencsath) listed in this protocol, has been performing his TEP procedures consistently using telescopic dissection, with equivalent results and safety profiles when compared to balloon dissection. Our institution has in its staff, three expert surgeons, with a robust experience in the TEP procedure, performed either with and without the balloon dissector. To help determine if the use of the balloon dissector is associated with a significant decrease in operative times when compared to telescopic dissection, we aim to conduct a randomized controlled trial using the Americas Hernia Society Quality Collaborative (AHSQC) registry. The AHSQC is a nationwide registry designed to improve the value of hernia care using real-time continuous quality improvement principles[7]. Data pertaining to baseline and intraoperative variables, short and long term outcomes are collected prospectively for quality improvement purposes. The information collected in the AHSQC offers a natural repository of information that can be used for research, in addition to its quality improvement purpose.

We hypothesize that at our institution, during TEP repairs, telescopic dissection will be associated with a 15-minute increase in total operative times for a unilateral inguinal hernia, when compared to the balloon dissection using the SpaceMaker™ balloon.

Specific Aim #1: To determine if the use of a balloon dissector by an experienced surgeon is associated with a significant decrease in total operative time compared to telescopic dissection for the creation of the extraperitoneal space during laparoscopic TEP inguinal hernia repair

Specific Aim #2: To perform a cost analysis for direct and total hospital costs among patients who have undergone laparoscopic TEP inguinal hernia repair performed either with telescopic dissection or balloon dissection

Specific Aim #3: To determine if there is a difference in postoperative pain scores at 1 day, 7 days and 30 days postoperatively between patients who have undergone laparoscopic TEP inguinal hernia repair performed either with telescopic dissection or balloon dissection.

Specific Aim #4: To determine if there is a difference in the rate of intraoperative complications and 30-day wound events between patients who have undergone laparoscopic TEP inguinal hernia repair with and without use of a balloon dissector

Specific Aim #5: To determine if 1-year hernia recurrence rates differ between patients who have undergone laparoscopic TEP inguinal hernia repair performed either with telescopic dissection or balloon dissection.

## 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, and the 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 single institution study, performed at the Cleveland Clinic Foundation in Cleveland, Ohio, with a total of 3 participating staff surgeons (Dr. Diya Aladeen, Dr. Kalman

Bencsath, and Dr. Steven Rosenblatt). Enrollment and surgeries are anticipated to occur at Cleveland Clinic Hernia Center located at Main Campus, Fairview Hospital, and Hillcrest Hospital. Additionally, enrollments and surgeries will occur in Strongsville and Beachwood Family Health and Surgery Centers.

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

Exclusion criteria include patients with bilateral inguinal hernias, recurrent hernias that have a prior preperitoneal mesh (which can include plug and patch, PHS, and laparoscopic inguinal hernia repairs), patients who cannot tolerate general anesthesia, patients who are not willing to undergo a mesh-based repair, and patients who are not able to understand and sign an written consent form. The intervention will be telescopic dissection alone for the creation of the extraperitoneal space. The control group will undergo preperitoneal dissection with the use of the SpaceMaker™ balloon dissector (Medtronic, Minneapolis, MN) for the creation of the extraperitoneal space. Patients will be randomized to balloon dissector group versus telescopic dissection alone at anesthesia induction. No other intraoperative or postoperative differences will occur between the two groups.

To confirm that the procedure technique will be standardized and performed consistently in the same manner among the three participating surgeons, one of the Co-Investigators (Dr. Kalman Bencsath) will record one of his procedures using telescopic dissection. This will be an educational video, to serve as a reference, and used to instruct and standardize the technique

among the other two participating surgeons (Dr. Diya Aladeen and Dr. Steven Rosenblatt). Dr. Bencsath will also be a source of reference and support for technical details regarding the performance of preperitoneal dissection using telescopic dissection. Dr. Bencsath has determined that three telescopic balloon dissection cases are required to overcome the learning curve in experienced surgeons hands, and thus all surgeons will document three cases prior to induction of the trial. Baseline information, operative details including the exposure variable (type of extraperitoneal space creation method), and outcomes of interest (operative time, 30-day wound morbidity, complications, and hernia recurrence) are already captured within the AHSQC database, allowing for follow-up, and data capture with decreased effort outside that of routine care. The only variables not captured in the AHSQC will be the postoperative pain scores and the costs related to the operation. This information 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 for baseline comparison. Exact total operative times will be abstracted from electronic medical records on EPIC and uploaded into REDCap. All operative details are already routinely collected and stored in the AHSQC database. Pain intensity at baseline, 1 day, 7 days and 30 days postoperatively will be assessed using the Numeric Pain Rating Scale (NRS-11). The NRS-11 is a simple, one-dimensional test, in which individuals are asked to score pain on a 0 (no pain) to 10 (worst pain imaginable) scale.[8]. Patient follow-up visits will occur in person at 4 weeks ( $\pm$  2 weeks) and 12 months ( $\pm$  3 months) postoperatively. In case patients are unable to attend their regular follow-ups, a telephone interview will also be performed. At baseline and at 30 days postoperatively, these assessments will be performed in person. Since most of the laparoscopic TEP procedures are performed on an outpatient basis, and patients are discharged on the same day of operation,

assessments at 1 day and 7 days postoperatively will be performed via telephone contact and this information will be uploaded into REDCap. Patient-reported quality of life will also be assessed at baseline and at 30 days using the EuraHS Quality of life score (European Registry of Abdominal Wall Hernias)[9], 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. Hernia recurrence will be assessed at 30-days and at one year postoperatively, using the Ventral Hernia Recurrence Inventory (VHRI) survey and by physical examination. The VHRI is a validated questionnaire that can be performed either in person or via email or phone correspondence and assesses patient perception of hernia recurrence symptoms.[10] At the time of the one-month and one-year follow-up clinic visits, a routine physical examination will be performed on all patients. At the completion of the study protocol, patients will be informed of their intervention arm.

A cost analysis will be performed. The direct cost and total hospital cost will be provided by the administration of the Digestive Disease and Surgery Institute.

#### OUTCOMES TO BE INVESTIGATED

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

- *Specific Aim #1: To determine if the use of a balloon dissector, in experienced hands, is associated with decreased total operative times compared to the*

*telescopic dissection, for the creation of the extraperitoneal space during laparoscopic TEP inguinal hernia repair.*

This will be assessed comparing mean total operative times between groups.

- *Specific Aim #2: Perform a cost comparison analysis accounting for direct costs and total hospital costs among patients who have undergone laparoscopic TEP inguinal hernia repair with the use of a balloon dissector or telescopic dissection for the creation of the extraperitoneal space.*

This analysis will ultimately determine if the hypothetical decrease in operative times related to the use of SpaceMaker™ balloon dissector (Medtronic, Minneapolis, MN) might overcome the direct cost of this device, for the laparoscopic TEP inguinal hernia repair.

- *Specific Aim #3: To determine if there is a difference in postoperative pain scores at, 1 day, 7 days and 30 days postoperatively between patients who have undergone laparoscopic TEP inguinal hernia repair with the use of a balloon dissector or telescopic dissection for the creation of the extraperitoneal space.*

This will be accomplished by comparing mean postoperative pain scores between the groups at each defined time point.

- *Specific Aim #4: To determine if there is a difference in the rate of 30-day wound morbidity and intraoperative complications among patients who have undergone laparoscopic TEP inguinal hernia repair with the use of a balloon dissector or telescopic dissection for the creation of the extraperitoneal space*

This will be accomplished comparing the rates of 30-day wound events.

Wound events are defined as surgical site infections (SSI), surgical site occurrences (SSO) and surgical site occurrences requiring procedural intervention (SSOPI). Intraoperative complications are defined as hemorrhage requiring transfusion, preperitoneal access injury, bowel injury, bladder injury, liver injury, gastric injury, major vascular injury requiring operative intervention, spermatic cord injury, and testicular injury. This information is already captured in the AHSQC and is also reported in electronic medical records.

SSIs will be reported and classified according to the Centers for Disease Control and Prevention (CDC) classification [11], as superficial, deep incisional and organ-space.

SSO include any SSI as well as wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch abscess, seroma, hematoma, infected or exposed mesh, or development of an enterocutaneous fistula.[12,13] SSOPI is defined as any SSO that requires wound opening, wound debridement, suture excision, percutaneous drainage, or partial or complete mesh removal.[12,13].

- *Specific Aim #5: : To determine if there is a difference in clinical hernia recurrence at one year postoperatively, among patients who have undergone laparoscopic TEP inguinal hernia repair with the use of a balloon dissector or telescopic dissection for the creation of the extraperitoneal space .*

This will be assessed through physical examination performed by a surgeon at the 1-year follow-up clinical encounter . Additionally, as it is customary for all patients in the AHSQC, subjects will answer the Ventral Hernia Recurrence Inventory Survey [10], which is part of AHSQC Inguinal

Hernia Postoperative Inguinal Hernia Assessment would make sure this can be performed by phone call too, so we limit lost to follow-up.

#### SURGICAL PROCEDURE

Patient preparation and initial operative steps, common for both groups

Patients will be operated in supine position, in a 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. Patients will receive a single dose of 2000mg of Cefazolin, within one hour of the incision. In case patients are allergic to this drug, a single dose of 600mg of Clindamycin will be administered. Pharmacological prophylaxis of venous thromboembolic events is usually not necessary for usual laparoscopic inguinal hernia repair. Although, if deemed necessary, this will be performed per SCIP protocol and will not be considered a protocol deviation. Foley catheterization will be performed preoperatively in all patients in order to the bladder be decompressed during the operation. Skin preparation and hair removal will be performed per SCIP protocol. All necessary materials, including the SpaceMaker™ balloon, will be available in the operative room before the start of the procedure.

After induction of anesthesia, randomization will occur. Randomization will be performed according to a computer-generated block randomization scheme, which will take place in RedCAP. The operative room nurse will call a designated phone number where will be able to speak to the research coordinator who will perform the randomization in RedCAP and will inform in which group the patient has been assigned.

The procedure begins with a juxta-umbilical incision. Subcutaneous tissue is dissected to expose the rectus sheath. A small transverse incision in the fascia is made, where the rectus muscles fibers can be identified. Muscle fibers are retracted laterally exposing the posterior rectus sheath.

- **For the balloon dissector group**

A blunt tip 10mm disposable balloon trocar is placed in the preperitoneal space. The balloon dissector is inserted through this port, into the direction of the pubic bone. After the proper position is confirmed with direct visualization, the balloon is inflated under direct visualization. After dissection is completed, the balloon is deflated and removed from the preperitoneal space. Insufflation of CO<sub>2</sub> is performed with a 15mmHg pressure through the trocar.

- **For the telescopic dissection group**

After the rectus muscle fibers are retracted laterally, a gentle finger dissection is performed in the retrorectus/preperitoneal space in order to create space for insertion of a 10mm, blunt tip, balloon trocar. Insufflation of CO<sub>2</sub> is performed with a 15mmHg pressure through the trocar. A 30 degrees laparoscopic scope is inserted, and blunt dissection of the preperitoneal space is performed with the probe, under direct visualization, in the direction of the pubic bone, creating space on the midline.

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

After the initial workspace is created, two 5mm disposable trocars are placed in the midline. One 5mm trocar is placed 3 fingerbreadths above the pubic bone. The other is placed between the initial and the suprapubic trocar. Complete dissection of the preperitoneal space is performed. This includes medial dissection into the space of Retzius and lateral dissection into the lateral space of Bogros. Proper identification of the inferior epigastric vessels, cord structures, vas deferens, iliac vessels, pubic bone and Cooper's ligament, is mandatory. Anatomic landmarks known as the "Triangle of Doom" and "Triangle of Pain" have to be identified. Correct dissection and exposure of the entire myopectineal orifice are mandatory. For indirect inguinal hernias, the hernia sac is dissected free from the cord structures and reduced. Preperitoneal lipomas are reduced and resected. The "pseudosac" of direct defects is also dissected and reduced. In case a femoral or obturator defect is identified, the contents are dissected and reduced with gentle traction. When complete dissection is achieved, the mesh repair can be performed. Any tears in the peritoneum should be repaired. This can be accomplished by suture, stapling or through endoloops, according to surgeon's preference and expertise.

Mesh selection will be at the discretion of the co-investigator surgeon. A standard piece of polypropylene mesh will be utilized, and the size and type will be recorded. A minimum of 10x15 cm mesh will be used. Mesh is rolled and placed under direct visualization into the preperitoneal space through the 10mm trocar. Mesh is unrolled and placed in position, adequately covering the entire myopectineal orifice, with sufficient overlap. Mesh fixation is performed according to the surgeon's discretion and type and number of tack fixation devices will be recorded. Hemostasis is reviewed, and CO2 is desuflatted from the preperitoneal space under direct visualization, confirming proper mesh position. Ports are removed, and the anterior rectus sheath incision is

closed with absorbable sutures. Subcutaneous tissue and skin are closed according to surgeon's preference.

#### ANTICIPATED TIME FRAME

Estimated patient accrual time is one year with data collection to occur over one year from the last enrolled patient. 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 risks will be discussed in a separate surgical consent form. The subjects may experience some pain, bleeding, and discomfort; however, this is with any surgical operation. Common occurrences 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 a laparoscopic transabdominal preperitoneal (TAPP) approach or 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 minimally invasive 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 ventral 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.

After a potential study patient is identified, the investigator or the study coordinator listed in this protocol as a person who will obtain consent 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 visit 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/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/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. 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.

Any information about the subject will be stored in the AHSQC, a secure database that is used at our institution to track clinical outcomes in patients who undergo hernia repair.

**POWER CALCULATION**

Sample size and power calculation were performed according to the primary outcome measure, which will be operative time. All TEP laparoscopic inguinal hernia repairs performed in the last year (from June 2016 through June 2017) by the participating surgeons were identified. Operative times from 22 randomly chosen laparoscopic TEP repairs for unilateral inguinal hernias using the balloon (control group), were abstracted. Mean operative time was 56.31 minutes with a standard deviation of 14.47 minutes.

Using a two-sample t-test allowing for an equal variance with equal sample sizes (1:1) group allocation of telescopic and balloon dissection, and assuming the hypothesis that the intervention group (telescopic dissection) will be associated with a 15-minute increase in total operative time when compared to the control group (balloon dissection), 15 patients per group will achieve a target power of 80% given an alpha of 0.05. Assuming a 30% loss to follow-up at 1 year, a total of 40 patients will be recruited for this study (20 patients in each group).

#### STATISTICAL ANALYSIS

Categorical variables will be examined using Pearson's Chi-Square and all continuous variables will be examined using the nonparametric Wilcoxon signed rank test. The categorical variables will be reported using proportions and continuous variables will be reported using the median and interquartile range.

*Specific Aim 1:* Total operative times between intervention arms will be compared using Kruskal-Wallis Test.

*Specific Aim 2:* Univariate cost analysis will be performed through a Student's t-test

of logarithmically transformed mean values of direct and total hospital costs. Net revenue earned will be determined by subtracting the cost of the balloon dissector (only in the balloon dissector arm) from the cost saved for less operative time.

*Specific Aim 3:* Pain scores can be compared at each time-point using Kruskal-Wallis Test. Differences in pain scores between intervention arms (baseline subtracted from pain at each time point) will also be compared using Wilcoxon rank-sum test.

*Specific Aim 4/5: 30-day wound events, intraoperative complications, and one-year hernia recurrence:* Outcomes will be compared using Pearson's chi-square.

A two-tailed test with p-value <0.05 will be considered statistically significant. All statistical calculations will be performed with SAS, version 9.1.

#### DATA SAFETY MONITORING BOARD

A data safety monitoring board will oversee the progress of this trial. This board will be comprised of surgeons and statisticians from the Cleveland Clinic Foundation. This group of individuals will meet at regular intervals to monitor the safety and progression of this trial.

#### CLINICAL SIGNIFICANCE/INNOVATION

Both the use of a balloon dissector and the telescopic dissection are well accepted and largely performed manners to create the extraperitoneal space for laparoscopic TEP repairs. The use of the balloon dissector depends on institutional availability, surgeon preference, and expertise. Both arms evaluated in this study represent a well-accepted technique for laparoscopic

TEP repair. Nevertheless, to date, a cost effectiveness, time savings, or pain reduction analysis using the balloon dissector in experienced surgeons hands has not been performed. Besides conferring shorter operative time and lower conversion rates for surgeons at an early point of the learning curve, the use of the balloon dissector might be deferred in experienced hands, decreasing direct costs without impairing quality, patient safety and value of hernia repair.

As previously mentioned, this trial will be another registry-based randomized prospective study performed in the hernia disease space by our institution. Registry-based clinical trials have recently been proposed as a way to achieve the scientific power of an RCT while minimizing the cumbersome nature often associated with running such a trial. 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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