Registry-Based, Prospective, Single-Blind, Randomized Controlled Trial:

Robotic vs. Laparoscopic Ventral Hernia Repair with Intraperitoneal Onlay Mesh (IPOM)

PI: Ajita Prabhu, MD FACS

INTRODUCTION

Despite the adoption of the robotic platform for ventral hernia repair, there is still a paucity of literature to speak to the benefits of this approach. Potential benefits are currently being investigated. A report prepared for the Centers for Medicare and Medicaid Services (CMS) recently defined benefit to be defined in terms of improved service quality and increased financial performance (1). Service quality, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, encompasses pain (2). Decreased pain control has been associated with lower HCAHPS scores. The discussion concerning robotic ventral hernia repair must include a detailed analysis of surgical outcomes and cost.

In our recently-published propensity score analysis comparing laparoscopic and robotic ventral hernia repairs with intraperitoneal onlay mesh (IPOM) (3), we showed a 1-day decrease in hospital length of stay (LOS) with the robotic versus laparoscopic platform for laparoscopic ventral hernia repair with IPOM. The reasons for this decrease in stay remain unknown.

While multiple papers have described postoperative pain following laparoscopic ventral hernia repair (4-10), scant data exists evaluating postoperative pain following robotic ventral hernia repair (11). The few published papers currently available suggest that patients experience decreased pain following robotic repair. Tayar et al. assessed 11 patients and found that their average pain rating on postoperative day 1 following robotic ventral hernia repair was 3 (on a scale of 0 to 10) (11). In contrast, previous publications have suggested that patients have a score of 5-6 following laparoscopic ventral hernia repair (4, 5, 6, 7, 8, 9, 10). Waite et al. have also compared robotic and laparoscopic inguinal transabdominal preperitoneal (TAPP) repair and

detected postoperative day 1 pain scores of 2.5 versus 3.8 (12). These findings in sum, albeit from heterogeneous studies, suggest that patients experience decreased pain levels following robotic, versus laparoscopic, hernia repair.

Literature on cost analysis of robotic ventral hernia repair also remains sparse (13). Previous authors have posited that the robot is more expensive for other high-volume minimally invasive procedures, including TAPP inguinal hernia repair (12, 14). Mehaffey et al. performed a financial analysis showing higher median hospital costs of $1124 per case for robotic ventral hernia repair and higher associated fixed costs versus that of laparoscopic cases (15). These figures largely resulted from increased operative time for robotic procedures. Their analysis did not include a consideration of other variable costs of the surgery. In addition, no high-quality literature exists concerning long-term recurrence rates following robotic ventral hernia repair (3).

Our hypotheses are multiple: 1) Patients with ventral hernias undergoing robotic IPOM will experience a 30% decrease in pain scores by postoperative day 1 compared to patients undergoing laparoscopic IPOM; 2) Robotic IPOM will be associated with higher median direct costs per case versus laparoscopic IPOM, and 3) Robotic IPOM will be associated with equivalent 1-year hernia recurrence rates versus laparoscopic IPOM.

To help determine if the robotic platform has an impact on postoperative pain, cost and hernia recurrence, we propose a registry-based, randomized clinical trial (RCT) through the Americas Hernia Society Quality Collaborative (AHSQC). The AHSQC is a multicenter, nationwide quality improvement effort with a mission to improve value in hernia care. Data are collected prospectively in the routine care of hernia patients 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.

STUDY DESIGN

This will be a prospective, registry-based, single-blind, randomized controlled trial with a 1:1 allocation ratio. No important changes to the methods are anticipated. This will be a single-institutional study performed at the Cleveland Clinic Foundation in Cleveland, Ohio from 2017 to 2019, and the AHSQC will serve as our platform. All enrollments and surgeries in this study will take place at the Cleveland Clinic Comprehensive Hernia Center. Specific inclusion criteria are all patients of at least 18 years of age, primary ventral or incisional hernia defects, with an expected hernia width equal or less than 7 centimeters, presenting for an elective ventral hernia repair and who are considered eligible to undergo the operation through a minimally invasive approach (either laparoscopic or robotic). Patients should be able to give consent form and tolerate general anesthesia to take part in this study. Exclusion criteria will be defects greater than 7 centimeters, hernia defects requiring an open approach, and patients who are not able to understand and sign a written consent form.

The study will consist of 2 interventions: laparoscopic IPOM or robotic IPOM. The surgical technique is further described in the following section entitled “Surgical Technique”.

A computer-generated randomization scheme will be built by a CCF statistician (who is listed in this protocol). Randomization will take place on the Research Electronic Data Capture (REDCap®) database program. Patients will be randomized to laparoscopic IPOM or robotic IPOM at the moment of enrollment, during preoperative evaluation.

Primary outcome measure is early postoperative pain. Secondary outcome measures are cost and hernia recurrence. We will also collect outcomes pertaining to abdominal wall-specific quality of life, and 30-day wound events. No changes to trial outcomes are anticipated, and no

interim analyses will be performed. No stopping guidelines are needed, as both the laparoscopic and robotic platforms represent current standards of care for ventral hernia repair, and both approaches are currently offered at Cleveland Clinic Comprehensive Hernia Center.

Subjects will be blinded to the intervention. An equal number of identical bandages will be applied to the abdomen in similar locations following each intervention. We are unable to blind the operating surgeon to the intervention arm. We are unable to blind the data collector, the research fellow, to the patients within each intervention arm. However, by utilizing data largely determined from the patients themselves, who will not be informed of the operation that they have received until after study completion, we believe that we are presenting an accurate data with limited bias. No subgroup analyses will be performed. Patients will be excluded from analysis if they are lost to follow-up.

OUTCOMES TO BE INVESTIGATED

Outcomes to be investigated are based on the aforementioned study hypotheses and are listed below:

Specific Aim #1: To determine if patients with ventral hernias undergoing robotic IPOM experience a 30% decrease in pain scores by postoperative day 1 compared to patients undergoing laparoscopic IPOM.

The primary outcome is early postoperative pain. Pain will be assessed by Patient-Reported Outcome Measurement Information System (PROMIS) Pain Intensity 3a survey and the Numeric Pain Rating Scale (NRS-11). The PROMIS pain intensity 3a survey is a National Institutes of Health developed a validated tool that focuses on patient-reported outcomes of pain characteristics (17). The NRS-11 is a frequently utilized pain assessment that consists of an

easily administered 0 to 10 Likert scale, in which higher scores reflect greater pain intensity(16). PROMIS Pain Intensity 3a survey pain scores will be assessed at baseline (at the time of enrollment), at 30 (± 15) and 365 (± 90) days. NRS-11 scores, often used to measure acute pain, will be obtained in the post-anesthesia care unit, and on postoperative days 1 (± 1 days), 7 (± 3 days) and 30(±15 days). The NRS-11 scores will be obtained either in person while the patients are hospitalized, or by telephone interviews following their hospital discharge. Postoperative narcotic requirements, converted into morphine equivalents, will also be obtained for the first 24 hours postoperatively through review of the patient medical records.

Specific Aim #2: To determine if robotic IPOM is associated with higher direct costs versus laparoscopic IPOM.

A secondary outcome is direct cost at the index admission surgery and at 30 days and 365 days after surgery. Cost data will be obtained from the Cleveland Clinic financial department and will include direct costs. Direct costs for the index operation will include operating room supply and time, intensive care unit, anesthesia, floor care, laboratory tests, radiology and endoscopy, pharmacy, and in-hospital rehabilitation therapies. The operating room supply direct costs for index surgeries will be further categorized into the following groups: mesh and general supply costs. Indirect costs and total charges will be excluded. This analysis is in keeping with that previously performed by one of our principal investigators (18). Capital costs, including the robotic system, laparoscopic towers, and non-disposable equipment, will not be included.

Specific Aim #3: To determine if robotic IPOM is associated with equivalent one-year recurrence rates versus laparoscopic IPOM.

Hernia recurrence will be assessed with the Ventral Hernia Recurrence Inventory survey (VHRI) at 365 (± 90) days. The VHRI, which uses patient-reported outcomes to detect hernia recurrence, is a validated tool that has been shown to detect ventral hernia recurrence with a sensitivity of 85% and a specificity of 81%.(19)

Additional outcomes include abdominal wall-specific quality of life and 30-day wound events. Abdominal wall-specific quality of life will be determined by the HerQLes questionnaire. HerQLes is a 12-question hernia-specific survey that has been previously validated in patients undergoing ventral hernia repair (20). This will be assessed at baseline, at 30 days (± 15 days) and at 365 days (± 90 days). Wound events are defined as surgical site infection (SSI), surgical site occurrence (SSO) and surgical site occurrences requiring procedural intervention (SSOPI), as defined by the Ventral Hernia Working Group (21,22). Wound events will be assessed by a physical exam at 30(± 15) days and 365 (± 90) days. This information is already routinely collected for all patients included in the AHSQC.

SURGICAL PROCEDURE

In both groups, patients will be positioned in supine position, with both arms tucked. All operations will be performed under general anesthesia. Antibiotic prophylaxis, prophylaxis of venous thromboembolic events, skin preparation and hair removal, will be performed per Surgical Care Improvement Project protocol.

Our surgical approach to laparoscopic IPOM is as follows: Initial access is performed in the left upper quadrant, at Palmer's point. Optical access into the peritoneal cavity is achieved

using a 5mm optical trocar. Insufflation of CO_2 is performed with a pressure of 15mmHg, under direct laparoscopic visualization. Two additional trocars are placed on the left side, along the anterior axillary line (usually one 12mm trocar and another 5mm trocar). If deemed necessary by the attending surgeon, an auxiliary 5mm port is placed on the right side. When present, hernia contents are reduced using gentle traction with atraumatic graspers. Adhesions between intra-abdominal contents and the anterior abdominal wall are lysed using cold, sharp dissection. The hernia defect is identified and measured internally with a sterile plastic ruler with the abdomen insufflated. Defect closure is performed with transfascial sutures of number 1, monofilament, nonabsorbable suture. This is accomplished with the aid of a Carter-Thomason suture passer. Mesh repair is performed using a standard piece of polypropylene mesh with an absorbable hydrogel barrier. A number 0 absorbable suture will be placed in the center of the mesh. The size of the mesh will be defined by the attending surgeon to achieve a minimum 3 to 5-centimeter overlap from the edges of the closed defect. Mesh is rolled and introduced into the cavity through a 12mm port. Inside the abdomen, the mesh is unrolled and adequate positioning is confirmed. Using the Carter-Thomason suture passer, the previously placed absorbable sutures in the mesh are pulled outside the cavity and tied, positioning mesh against the anterior abdominal wall. Using the double crown technique, mesh edges are fixed circumferentially to the anterior abdominal wall with permanent tacks. Four additional monofilament, nonabsorbable sutures are placed in the cardinal points of the mesh using the Carter-Thomason suture passer. The entire cavity is assessed, and adequate hemostasis is confirmed. Ports will be removed under direct visualization, and the abdomen will be desufflated. The anterior fascia of the 12mm port is closed with absorbable sutures. Skin and subcutaneous tissue are closed with absorbable sutures. Surgical skin glue will be applied.

Our surgical approach to robotic-assisted IPOM is as follows: The da Vinci® Surgical System robotic platform (Intuitive Surgical, Inc.) will be used. Initial access is performed in the left upper quadrant, at Palmer's point. Optical access into the peritoneal cavity is achieved using a 5mm optical trocar. Insufflation of CO_2 is performed with a pressure of 15mmHg, under direct laparoscope visualization. A 12mm and an 8mm robotic port are placed on the left side along the anterior axillary line. A 12 mm assistant port is placed on the right side of the abdomen under direct laparoscopic visualization. The left upper quadrant access port is upsized to a 8 mm robotic port. The robot is docked. When present, hernia contents are reduced using gentle traction with atraumatic graspers. Adhesions between intra-abdominal contents and the anterior abdominal wall are lysed using cold, sharp dissection. The hernia defect is identified and measured internally with a sterile plastic ruler with the abdomen insufflated. Defect closure is performed intracorporeally with 3-0 absorbable barbed suture. Mesh repair is performed using a standard piece of polypropylene mesh with an absorbable hydrogel barrier. A number 0 absorbable suture will be placed in the center of the mesh. The size of the mesh will be defined by the attending surgeon to achieve a minimum 3-5-centimeter overlap. Mesh is rolled and introduced into the cavity through a 12mm port. Inside the abdomen, the mesh is unrolled and adequate positioning is confirmed. Using the Carter-Thomason suture passer, the previously-placed absorbable sutures in the mesh are pulled outside the cavity and tied, positioning the mesh against the anterior abdominal wall. Mesh edges are fixed circumferentially using running, 3-0 absorbable barbed suture. The entire cavity is reviewed, and adequate hemostasis is confirmed. Ports will be removed under direct visualization, and the abdomen desufflated. Anterior fascia of the 12mm and 8mm ports are closed with absorbable sutures. Skin and subcutaneous tissue are closed with absorbable sutures. Surgical skin glue is applied.

ANTICIPATED TIME FRAME

Estimated patient accrual time is two years 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, patients may experience pain, bleeding, and discomfort. Possible morbidities following hernia repair by either the laparoscopic or robotic platform include seroma, hematoma, inflammation, wound dehiscence, and infection. As both platforms represent current standards of care, patients in neither intervention are expected to incur unusual risk of harm.

PATIENT BENEFITS

There are no direct benefits to subjects for participation in this study. Subject participation will, however, help physicians and hospital administrators better understand the pain outcomes and costs associated with the robotic versus laparoscopic platforms for ventral hernia repair.

COSTS TO THE SUBJECTS

There are no extra costs to the subjects associated with this research endeavor other than the minimal amount of time (less than 1 minute) required to answer the NRS-11 surveys at 1 and 7 days postoperative. The remaining surveys and physical exams will be performed at routine postoperative visits. If the patient is contacted by phone for routine follow up and the questionnaires are answered, data including physical exam and CT results from any subsequent office visits in the defined study window, will be collected for analysis.

Procedures related to preoperative evaluation, hernia repair, and postoperative monitoring are considered standard of care and will be billed to the subject or the subject's insurance company.

ALTERNATIVES TO PARTICIPATION

Patients are under no obligation to participate in this study. The principal investigator will discuss all available surgical options with patients. It will be emphasized that refusal 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 SUBJECTS

There will be no direct payments or financial benefit to the subjects. Participation will be voluntary.

PLAN FOR OBTAINING INFORMED CONSENT

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

Following identification of a potential study participant, the investigator or co-investigator 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 to ask questions. The informed consent document will be reviewed with the subject in depth by the participating investigator or by a designated member of the research team to ensure that the potential participant has a thorough understanding of the study protocol and understands 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 and ask additional questions before signing 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 his/her records.

PROVISIONS FOR SUBJECTS FROM VULNERABLE POPULATIONS

The population to be studied includes adults of at least 18 years of age. Children, cognitively-impaired persons, pregnant women, students and house staff under the direct supervision of the investigator are considered vulnerable populations and will, therefore, be excluded from participation. If a Cleveland Clinic Foundation staff member or employee is a potential candidate for the study, the subject will be informed during the consent process that

his/her participation or refusal to participate will not influence grades, employment, or subsequent recommendations.

If 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 be present during this encounter.

SUBJECT PRIVACY AND DATA CONFIDENTIALITY

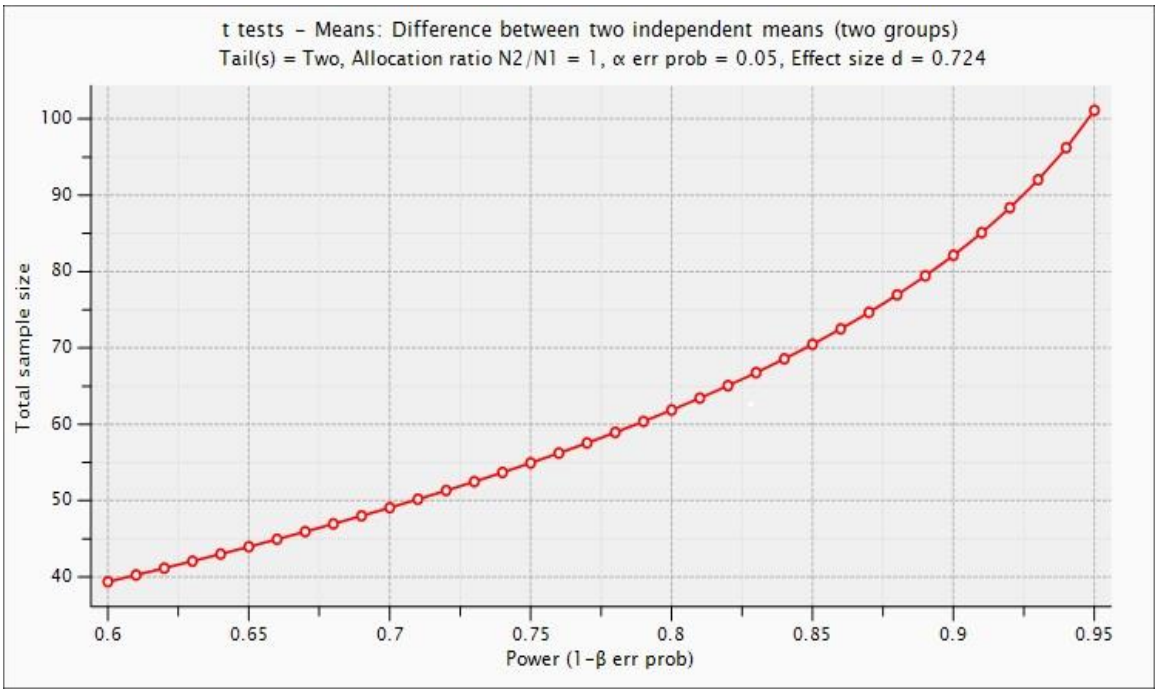
Subject anonymity and data confidentiality will be maintained throughout this study. Every effort will be made to maintain the confidentiality of documents that identify the subject by name (e.g., signed informed consent documents, clinic charts), except to the extent necessary to allow monitoring by the Office of Research Compliance at the Cleveland Clinic or by other regulatory authorities.

All of the information collected, such as name or medical record number, will be stored in the Americas Hernia Society Quality Collaborative (AHSQC) and on REDCap®. The AHSQC is a secure database that is used nationally to track clinical outcomes in patients who undergo hernia repair. Randomization will occur with the use of a customized REDCap® database program, a secure network/firewall-protected electronic database for which only the investigator and the designated members of the study team will have access using an individually-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 data quality assessment and data analysis. 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.

SAMPLE SIZE / POWER CALCULATION

Power calculation was performed with G*Power 3 software for Windows (Faul, Erdfelder, Lang, & Buchner, 2007). The sample size was determined by the primary outcome of interest, the change in NRS-11 pain score at postoperative day 1. We hypothesize that the robotic approach will be associated with a 30% decrease in NRS-11 pain score at postoperative day 1. The 30% reduction used for power calculations was determined from clinical judgment, as little literature exists evaluating the minimal clinically important difference of the NRS-11 scale for ventral hernia repair. Mean NRS-11 pain score (4.76) and standard deviation (1.975) with the laparoscopic approach (control group) was determined from previously published manuscripts [7]. Assuming an alpha of 0.05, a beta of 0.20, we will need a total sample size of 62 patients (31 per arm). Considering and a 20% drop-out rate to occur in each arm, we will need approximately 74 patients (37 patients per arm). This sample size and power calculation were reviewed by the DDSI statistician listed in this protocol.



STATISTICAL ANALYSIS

Descriptive statistics, including means, standard deviations, and/or percentages, will be calculated for demographic and baseline variables. Categorical variables will be reported using proportions. Continuous variables will be reported using either means and standard deviations for normally distributed data or median and interquartile range for non-parametric data.

Specific Aim #1: Pain scores will be compared between intervention arms at each time point using either a Student's *t*-test (normal distribution) or a Kruskal-Wallis test (nonparametric distribution). Differences in PROMIS scores between baseline, 30 and 365 days, respectively, will be assessed via Wilcoxon signed-rank test.

Specific Aim #2: A univariate analysis of cost will be conducted in which costs will be logarithmically transformed to offset the effects of outliers and then analyzed with a Student's *t*-test.

Specific Aim #3: Recurrence rates will be compared between intervention arms via Pearson's chi-square.

Additional outcomes: Abdominal wall-specific quality of life scores will be compared between intervention arms via Kruskal-Wallis test. Wound events will be compared between intervention arms via Pearson's chi-square.

R software will be used for all analyses. A two-tailed p-value <0.05 will be considered statistically significant.

DATA SAFETY MONITORING BOARD

A data safety monitoring board comprised of surgeons and statisticians from the Cleveland Clinic Foundation will oversee the progress of this trial. This will be a group of 2 DDSI surgeons and 1 statistician. This group of individuals will meet at regular intervals to monitor the safety and progress of this trial.

CLINICAL SIGNIFICANCE/INNOVATION

Scant data exist evaluating pain following and cost associated with robotic ventral hernia, in addition to long-term (1 year) outcomes following robotic repair. Our study is among the first high-quality initiatives to investigate these aspects of a new surgical platform whose merits are constantly debated. Our findings will contribute to hospital administrators' decisions on whether to purchase expensive robotic equipment and subsequently, surgeons' initiative in further developing their operative skills on this platform.

REFERENCES

1) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/downloads/HCAHPSCostsBenefits200512.pdf
2) Thiels CA, Hanson KT, Yost KJ, et al. Achieving a 5-star rating: Analysis of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores among patients undergoing elective colorectal operations. Surgery 2016 Oct;160(4):902-14.
3) Prabhu AS, Dickens EO, Copper CM, et al. Laparoscopic vs robotic intraperitoneal mesh repair for incisional hernia: An Americas Hernia Society Quality Collaborative Analysis. J Am Coll Surg 2017 Apr 24.
4) Eker HH, Hansson BM, Buunen M, et al. Laparoscopic vs. open incisional hernia repair: A randomized clinical trial. JAMA Surg 2013 Mar;148(3):259-263.
5) Rosen MJ, Duperier T, Marks J, et al. Prospective randomized double-blind placebo-controlled trial of postoperative elastomeric pain pump devices used after laparoscopic ventral hernia repair. Surg Endosc 2009 Dec;23(12):2637-2645.
6) Rogmark P, Petersson U, Bringman S, et al. Short-term outcomes for open and laparoscopic midline incisional hernia repair: A randomized multicenter controlled trial: The ProLOVE (prospective randomized trial on open versus laparoscopic operation of ventral eventrations) trial. Ann Surg 2013 Jul;258(1):37-45.
7) Asencio F, Aguilo J, Peiro S, et al. Open randomized clinical trial of laparoscopic versus open incisional hernia repair. Surg Endosc 2009 Jul;23(7):1441-8.
8) Barbaros U, Asoglu O, Seven R, et al. The comparison of laparoscopic and open ventral hernia repairs: A prospective randomized study. Hernia 2007 Feb;11(1):51-6.

9) Misra MC, Bansal VK, Kulkarni MP, et al. Comparison of laparoscopic and open repair of incisional and primary ventral hernia: Results of a prospective randomized study. Surg Endosc 2006;20(12):1839-45.

10) Pring CM, Tran V O'Rourke N, et al. Laproscopic versus open ventral hernia repair: A randomized controlled trial. Australian N Z J Surg 2008;78(10):903-6.

11) Tayar C, Karoui M, Cherqui D, et al. Robot-assisted laparoscopic mesh repair of incisional hernias with exclusive intracorporeal suturing: A pilot study. Surg Endosc 2007 Oct;21(10):1786-9.

12) Waite KE, Herman MA, Doyle PJ, et al. Comparison of robotic versus laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair. J Robot Surg 2016 Sep;10(3):239-244.

13) Stoikes N, Webb D, Voeller G. Robotic hernia repair. Surg Technol Int 2016 Oct 26;XXIX:119-122.

14) Schwaitzerg SD. Financial modeling of current surgical robotic system in outpatient laparoscopic cholecystectomy: How should we think about the expense? Surg Endosc 2016 May;30(5):2082-2085.

15) Mehaffey JH, Michael AD, Mullen MG, et al. Adoption of robotics in a general surgery residency program: At what cost? J Surg Res 2017 Jun 1;213:269-273.

16) Beilin Y, Hossain S, Bodian CA. The numeric rating scale and labor epidural analgesia. Anesth Analg 2003 Jun;96(6):1794-8.

17) Broderick JE, Schneider S, Junghaenel DU, et al. Validity and reliability of patient-reported outcomes measurement information system instruments in osteoarthritis. Arthritis Care Res (Hoboken) 2013 Oct;65(10):1625-33.

18) Harth KC, Rose J, Delaney CP, et al. Open versus endoscopic component separation: A cost comparison. Surg Endosc 2011 Sep;25(9):2865-70.

19) Baucom RB, Ousley J, Feurer ID, et al. Patient reported outcomes after incisional hernia repair-Establishing the ventral hernia recurrence inventory. Am J Surg 2016 Jul;212(1):81-8.

20) Krpata DM, Schmotzer BJ, Flocke S, et al. Design and initial implementation of HerQLes: A hernia-related quality-of-life survey to assess abdominal wall function. J Am of Surg 2012 Nov;215(5):635-42.

21) Kanters AE, Krpata DM, Blatnik JA, et al. Modified hernia grading scale to stratify surgical site occurrence after open ventral hernia repairs. J Am Coll Surg 2012 Dec;215(6):787-93.

22) Ventral Hernia Working Group, Breunig K, Butler CE, Ferzoco S, Franz M, Hultman CS, Kilbridge JF, Rosen M, Silverman RP, Vargo D. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. Surgery 2010 Sep;148(3):544-58.