Utilization and Outcomes of Robotic Acute Care Surgery (ACS): An EAST Prospective, Observational Propensity Matched Multicenter Trial

Summary and Impact

Robotic surgery adoption and utilization is progressing rapidly in all areas of surgery, including in Acute Care Surgery (ACS), however there is little research on this topic. Therefore , a retrospective and subsequent prospective observational cohort study with propensity score matching will be performed between robotic and laparoscopic ACS procedures. This study on technology and practice innovation will be at the forefront of research on robotics in ACS and has potential to be paradigm and practice changing. Additionally, further data collection will be continued to create an EAST Robotic ACS registry that can be utilized for future analyses.

Phase One: Retrospective Cohort Study

Primary Objective: The primary aim of the study is to evaluate the recent and current national utilization trends of robotic-assisted surgery in terms of case volumes per year, acuity of operations, and types of procedures performed by ACS.

> **Hypothesis**: During the most recent five-year period, we hypothesize that yearly volumes of robotic-assisted procedures will increase, that more types of robotic surgery will be performed, and for higher acuity cases.

Secondary Aim 1: The secondary aim of the study is to compare hospital length of stay (LOS) for robotic-assisted vs laparoscopic surgery in ACS patients by using a multi-center, retrospective cohort study. A propensity score matched analysis will be performed to compare LOS and secondary outcomes.

> **Hypothesis:** Patients undergoing robotic-assisted surgery will have a shorter LOS compared with patients undergoing laparoscopic surgery.

Secondary Aim 2: The next aim is to compare differences in secondary outcomes (operative complications, conversion rates, and inpatient mortality) for patients undergoing robotic-assisted vs laparoscopic surgery for ACS conditions.

> **Hypothesis:** Patients undergoing robotic-assisted surgery will have a decreased conversion rates and complications compared with patients undergoing laparoscopic surgery.

Phase Two: Prospective, Observational Propensity Matched Study

Primary Objective: The primary aim of the study is to compare hospital LOS for robotic-assisted vs laparoscopic surgery by using a prospective propensity score matched analysis of patients undergoing ACS in a national multi-center cohort.

> **Hypothesis:** We hypothesize that patients undergoing robotic-assisted surgery for ACS conditions will have a shorter LOS compared with patients undergoing laparoscopic surgery.

Secondary Objective: The secondary aim of this study is to conduct a prospective, propensity score matched analysis to compare outcomes for operative complications, conversion rates, and inpatient mortality for patients undergoing robotic-assisted vs laparoscopic surgery for ACS conditions.

> **Hypothesis:** We hypothesize that patients undergoing robotic-assisted versus laparoscopic surgery for ACS conditions will have decreased complications and conversion rates.

Significance

Background

The use of robotic-assisted surgery has rapidly increased for all types of elective surgery over the last decade[1] and by up to 24% in certain elective cases.[2] At the same time multiple studies have shown that robotic surgery is safe with comparable outcomes to laparoscopic surgery but with decreased rates of conversion to open and decreased risk of complications compared to open surgery by 20-50%.[3,4] Compared with laparoscopy, robotic-assisted surgery offers several advantages such as wristed instrumentation, 3D visualization, and improved ergonomics.[1,3,5] It also offers utilization of energy, stapling, and vessel sealing technologies as well as ICG fluorescent-angiography. In the current training paradigm, the majority of graduating surgery residents are now robotically trained, with 70% of general surgery programs having a formal robotic curriculum and 72% operating on the console by their PGY3 years. Similar to laparoscopy and endoscopy, there has been a recent focus to have robotic standardized training and testing with the implementation of the Fundamentals of Robotic Surgery curriculum, which has been shown to significantly improve robotic skills training.[6]

For patients undergoing surgery for ACS conditions, however, robotic-assisted surgery is not widely adopted, and robotic ACS training and outcomes have received limited attention. Because of this there is a dearth of research on robotic utilization and outcomes in urgent and emergent surgeries, especially by Acute Care Surgeons. Many thought leaders in ACS have recognized the opportunity and advantages of robotics and have begun using robotics for ACS operations, but currently lack data to drive their practice. Only one very recent study by Torres et al. still in press have described implementation of a training pathway and operative logistics for ACS surgeons but no patient outcome data was included.[7] Although adoption is limited in ACS, other specialties adoption of robotic training and implementation has led many training programs to perceive that robotics education should be a requirement for general surgery graduation[8] and has even prompted calls for robotics to be required for AAST ACS fellowship curriculum.[9]

Given the lack of research in this area, The World Society of Emergency Surgery created a 2021 position paper on robotics use in ACS and provided a systematic review.[10] In this paper, there were no ACS specific robotic studies and of all emergency/urgent robotic general surgery research, there were only ten retrospective studies. Those studies were based on case reports or cohort series from non-ACS surgeons experience with a subset of pathology (hernia repair, cholecystectomy, etc.). Only three studies included in this systemic review compared patients undergoing laparoscopic vs open procedures. A subsequent systematic review in 2022 on urgent robotic procedures reported only four retrospective studies and no prospective studies.[11] Of these, only two were controlled. To our knowledge, there are no published large retrospective or prospective studies on robotic-assisted operations for Acute Care Surgery.

Research Gap Impact and Practice Change

Given the lack of knowledge on this topic, the first aim of this study is to evaluate the current utilization and case type of robotic ACS and will be the first such study in the medical literature. It will therefore give rise to many further studies and will help start a whole line of innovative research in the ACS community. The primary outcome of LOS was chosen given prior results of lower LOS in the elective population[12] and personal experience with its benefits. Additionally, given its continuous nature and present in all operative types, a statistically significant change should be detected if present. If we confirm that robotic surgery has a shorter LOS, then demonstratable benefit of robotic surgery to ACS patients will be evidenced for the first time. Equally importantly, this will drive adoption and provide evidence of potential financial advantage to hospitals and healthcare systems to support robotic programs. Given these patients will be physiologically stable enough to undergo minimally invasive surgery, complication, conversion, and mortality rates will be relatively low compared to the ACS population as a whole, and therefore less likely to detect a significant difference between groups in a smaller sample size. Therefore, these values were chosen as secondary outcomes. However, if shown to be an improvement over laparoscopic surgery, these results would directly imply a quality and outcomes benefits to robotic ACS implementation both for patients, healthcare systems, and surgeons.

Innovation

Robotic-assisted surgery is coming out of its infancy, and with improved haptics, visualization, and adjuncts (like stapling, ICG angiography, and energy devices), robotics is continuing to define innovation in surgery writ large. With each generation of robotics, adoption has increased, and more complex and technically difficult procedures are able to be performed. 20 years ago, performing a robotic Whipple would have been laughable but now is common practice and increasing exponentially. Now those with robotics skillsets are sought after by patients and referring physicians and create value for their marketability and patient outcomes. Similarly, Acute Care Surgery must adapt to the changing landscape of surgery and surgical technology, otherwise ACS risks an erosion of operative adaptability, patient volume, and operative indications. Just as the ACS model itself was born from the erosion of operative volume related to non-operative trauma, propagation of fellowships, and lack of advanced laparoscopic skillset; ACS needs to, not just embrace, but pioneer the use and evolution of robotic surgery in the urgent and emergent setting.

This technology is novel to many ACS faculty who were not trained in robotic surgery in their residency or fellowship. However, most centers have one or multiple robotics rooms and increasingly are encouraging their use by ACS to fund their capital investment costs. At the same time the robotic instrumentation is decreasing in cost, while their capability is increasing. Importantly, ACS services will increasingly have intra-operative consultation by non-ACS surgeons for intraoperative complications. Training and experience in robotics in these scenarios can result in robotic surgical rescue for things such as bowel injury repair, hernia repair, and lysis of adhesions.

However, the greatest area of potential benefit and paradigm change is in the hemodynamically stable EGS and Trauma patient with complex injury or pathology that is difficult to repair, resect, or evaluate with standard laparoscopy. Difficult cholecystectomies can be aided by ICG cholangiography, hard to reach diaphragm and pelvic injuries can be repaired with wristed instrumentation, and laparoscopic sewing is made both easier and quicker by an order of magnitude. To analyze and disseminate these advantages and compare patient outcomes, robust research is first required, and this proposed multicenter trial on ACS robotics will be the first and foremost evaluation of current practice, the technique moving forward, and act as a repository for studying future questions by EAST investigators. Therefore, the proposed study directly meets the purpose, mission, and vision of EAST to "advance the acute surgical management of the ill and injured patient."

Approach

Study Type

Phase One will be a retrospective cohort study of robotic versus laparoscopic ACS operations, with analysis performed with propensity score matching on key variables established *a prior*. Phase two will be an observational prospective cohort study with similar propensity score matching. Prospective data collection will continue past Phase Two data analysis in order to create a data repository for robotic-assisted ACS procedures for future subset analyses based on disease pathology, operative type, patient factors, or other investigator selected variables.

Study Population

The Phase One study population will include patient admitted to an Acute Care Surgery service (Trauma and EGS) or those receiving a consultation by the ACS service who undergo a minimally invasive procedure from January 1, 2018, through December 22, 2022. Additionally, elective surgical patients referred from emergency/urgent sources (Department of Emergency Medicine) or as sequela from emergency admission (e.g., colostomy, reversal, etc.) will be eligible if performed by ACS. Patients will be categorized by their admission type (e.g., emergency, urgent, elective). Phase Two will continuously enroll patients starting after IRB and data use agreement at the individual site, until projected required sample size is enrolled.

Facilities and Equipment

See separate document on required facilities and equipment. Of note, any hospital type and category are free to submit patient data as long as they meet inclusion criteria and have a dedicated Acute Care Surgery service (EGS and/or Trauma). These can include academic, community, teaching, non-teaching, trauma, and non-trauma centers. One day surgery and outpatient surgery cases are eligible. Services can be staffed by any modality trained surgeon (general, ACS, MIS) as long as dedicated to that ACS service while procedure performed.

Primary outcome measure
The primary outcome of interest is hospital LOS.

Secondary outcomes measures
Secondary outcomes include operative complications, conversion to open rates, and inpatient mortality. Complications evaluated will include surgical site infection (all levels), reoperation, readmission, VTE, cardiac events, CVA, sepsis, organ failure, and surgery specific complications such as hernia recurrence, anastomotic leak, and biliary leak or injury. Complication definitions will adhere to NSQIP/TQIP criteria.

Inclusion Criteria
Inclusion criteria consists of adults $\geq$ 18 years who undergo a robotic-assisted or laparoscopic procedure by an ACS surgeon for an EGS or Trauma pathology (blunt or penetrating). Elective, urgent, and emergent cases are eligible for inclusion if referred from an emergent source (Emergency department referral for hernia, cholelithiasis etc.) or sequela of EGS or trauma case (ostomy takedown, ventral hernia, etc.)

Exclusion Criteria
Exclusion criteria includes patients who are pregnant, minors, or prisoners. Patients will be excluded if they are hemodynamically unstable, have a hemorrhagic or septic shock (therefore excluding the use of MIS), traumatic brain injury, or multi-system polytrauma.

Availability of Patients
Given the volume of laparoscopic procedures nationally, the number of patients in the robotic-assisted arm will be the rate limiting step; however, the considerable number of laparoscopic procedures will provide an excellent pool for propensity matching. Therefore, non-robotic ACS programs are encouraged to submit laparoscopic cases.

Intervention
This will be an observational trial. Robotic-assisted surgery will be categorized by the surgeons at each site, but any robotic-assisted platform currently available or developed in the future will be included. The most popular platform for robotic-assisted surgery, Intuitive Surgical's da Vinci® system, provides automated data on surgical times, instrument utilization, and conservation of motion and this data will be requested when feasible.

Data Collection
Variables for entry into the dataset will include age, demographics, comorbidities, Charleson Comorbidity Scale, ACS type (trauma or EGS), diagnosis, acuity (emergent, urgent, elective), operation, operative type (laparoscopic, robotic, conversion), operative time, AAST severity grade when available, shock index, initial laboratory values, trauma specific variables (ISS, ED GCS, etc.), surgery specific variables (such as mesh use, IOC, anastomosis type, etc.), hospital and ICU LOS, ventilator days, complications (VTE, CVA, SSI etc.), surgery specific complications (hernia recurrence, anastomotic leak, and biliary leak or injury , etc.) unplanned reoperation, readmission, operative and disposable charges/costs when available, and inpatient mortality. Data will be collated and submitted through the AAST Online Data Portal or REDCap.

Statistical Analysis Plan
For the retrospective and prospective analyses, standard descriptive, unadjusted univariate, and multivariate logistic regression analysis are planned to compare robotic-assisted with laparoscopic surgery. A propensity score matched analysis will be performed based on surgery type (EGS vs trauma), patient demographics, acuity, operative type, and AAST severity grade (if feasible) to compare like patients and operations between the two cohorts. Descriptive statistics including means, standard deviation, counts, percentages, median and interquartile range, and five-point summary statistics will be used to describe the study population on all variables. A two tailed

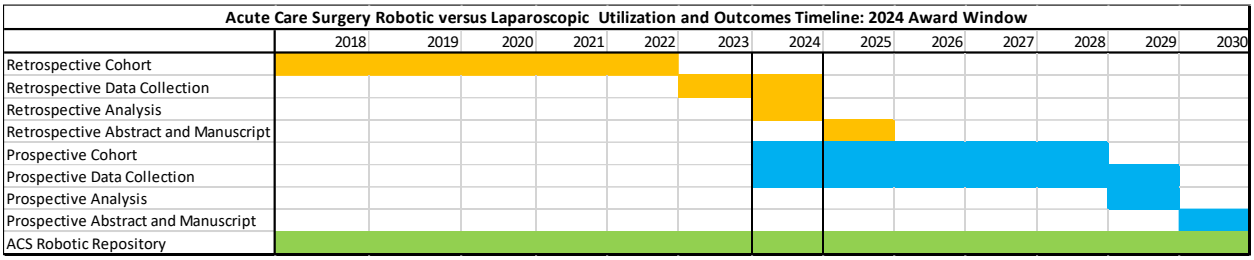
P value of < .05 will be used for all statistical significance determinations. All data will be analyzed using Statistical Analysis Software, version 9.3 (SAS Institute, Inc., Cary, NC).

Sample Size and Power Estimates

Although no current comparison data exists to inform the sample size calculation needed for a prospective trial, a best estimate is provided below. Using an alpha of .05, power of .80 and estimate hospital LOS of 4 ±3 days as an average LOS in laparoscopic EGS,[13] it would take 141 patients in each arm to predict a decrease in one hospital day. For an estimated all-type complication rate of 15%[14] to decrease by half to 7.5%, would take 277 patients per arm. Given the prevalence of laparoscopic surgery, the number of patients in the robotic-assisted arm will be the rate limiting step; however, the substantial number of laparoscopic cases will provide an excellent pool for propensity matching. Our center has more than 200 current robotic-assisted cases within the 2018 through 2023 cohort to contribute to the study. We expect to enroll at least 400+ robotic-assisted and cases within the 2018 through 2023 period from the multiple sites. More than 4 sites are already currently interested in joining the trial and expect to enroll 10 or more sites. Therefore, feasibility of completing required enrollment is exceedingly high.

Study Duration

Data of patients presenting between January 1, 2018, through December 31, 2022, will be evaluated for the retrospective study. The study data collection will proceed during the first 9 months of the study period (2024) and data organization, analysis, and writing of the abstract and manuscript will be performed in remaining time.



Study Limitations

Potential Limitation 1: Identification of retrospective robotic-assisted and laparoscopic procedures may be difficult for facilities without current EGS registries. However, robotic-assisted procedures may be identified from ACS surgeon queries within the Intuitive system to identify past and present cases. Data abstraction can be user dependent and biased, leading to incorrect categorization or complication identification. The use of AAST standardized severity scaling will help to compare similar procedure types and complexity, and TQIP/NSQIP complication definitions will standardize outcome measurement.

Potential Limitation 2: Given the already documented benefits of laparoscopic surgery, the sample size needed to find a small statistical change in categorical outcomes may be exceedingly high. Therefore, continuous variables (LOS, charges) will be evaluated as well.

Communication Limitation: Problems with data sharing and IRB transfer are common in MCT and our team has worked on several in the past to trouble shoot those issues and produce a streamlined process for both. Data safety monitoring and analysis will be provided by the lead site and PI and not required at each site.

Experience of the PI and Team

Dr. Ross is the site-PI for several EAST and AAST multicenter trials. He is also the site-PI for several industry funded trials including the CSL Bering Trauma and PCC study. Atrium Health Carolinas Medical Center has a team of 6 research coordinators and separate research director to be able to organize and coordinate the MCT. Communication will be via email and IRB and DUA documentation will be shared with each site. The home IRB will

be Atrium Health Wake Forest School of Medicine. Dr. Ross has extensive statistical training and experience with a background in biostatistics and epidemiology during his MPH training. However, he will also have statistical support from The Carolina Centers for Surgical Outcomes Science, including Dr. Kyle Thompson, PhD and Dr. Hannah Wang, PhD who have extensive data management and statistical analysis experience, respectively.

Budget

The grant amount will use to fund the AAST portal and/or research coordinator time for the project.

Future Funding

Ultimately, we hope this study serves as catalyst for a ground swell of clinical and research interest in robotic-assisted ACS operations and the benefits it may provide surgeons and patients. This will serve to directly provide important data for further extramural funding such as the NIH and Department of Defense. The robotic technology was first funded by the DoD and demonstrating its utility and effectiveness in trauma patients will be especially beneficial to future funding awards.

Conflict of Interest

Dr. Ross has no conflicts of interest to disclose and has no *significant* financial disclosures for any companies. Importantly, Intuitive Surgical nor any other company had any role in this grant conception, writing, etc.

References

1. Sheetz KH, Claflin J, Dimick JB. Trends in the Adoption of Robotic Surgery for Common Surgical Procedures. *JAMA Netw Open.* 2020;3(1):e1918911.
2. Muaddi H, Stukel TA, de Mestral C, et al. The evolving use of robotic surgery: a population-based analysis. *Surgical endoscopy.* 2023;37(3):1870-1877.
3. Muaddi H, Hafid ME, Choi WJ, et al. Clinical Outcomes of Robotic Surgery Compared to Conventional Surgical Approaches (Laparoscopic or Open): A Systematic Overview of Reviews. *Annals of surgery.* 2021;273(3):467-473.
4. Muaddi H, Stukel TA, de Mestral C, et al. Adverse events following robotic surgery: population-based analysis. *The British journal of surgery.* 2022;109(8):763-771.
5. Marohn MR, Hanly EJ. Twenty-first century surgery using twenty-first century technology: surgical robotics. *Curr Surg.* 2004;61(5):466-473.
6. Satava RM, Stefanidis D, Levy JS, et al. Proving the Effectiveness of the Fundamentals of Robotic Surgery (FRS) Skills Curriculum: A Single-blinded, Multispecialty, Multi-institutional Randomized Control Trial. *Annals of surgery.* 2020;272(2):384-392.
7. Torres CM, Florecki K, Haghshenas J, et al. The Evolution and Development of a Robotic Acute Care Surgery Program. *J Trauma Acute Care Surg.* 2023.
8. Porras Rodriguez P, Kapadia S, Moazzez A, et al. Should Robotic Surgery Training Become a General Surgery Residency Requirement? A National Survey of Program Directors in Surgery. *J Surg Educ.* 2022;79(6):e242-e247.
9. Haghshenas J, Florecki K, Torres CM, et al. Incorporation of a robotic surgery training curriculum in acute care surgical fellowship. *J Trauma Acute Care Surg.* 2023;95(2):e11-e14.
10. de'Angelis N, Khan J, Marchegiani F, et al. Robotic surgery in emergency setting: 2021 WSES position paper. *World J Emerg Surg.* 2022;17(1):4.
11. Reinisch A, Liese J, Padberg W, Ulrich F. Robotic operations in urgent general surgery: a systematic review. *J Robot Surg.* 2023;17(2):275-290.
12. Liu L, Lewis N, Mhaskar R, Sujka J, DuCoin C. Robotic-assisted foregut surgery is associated with lower rates of complication and shorter post-operative length of stay. *Surgical endoscopy.* 2023;37(4):2800-2805.
13. Arnold M, Elhage S, Schiffern L, et al. Use of minimally invasive surgery in emergency general surgery procedures. *Surgical endoscopy.* 2019.
14. Ingraham AM, Cohen ME, Bilimoria KY, et al. Comparison of 30-day outcomes after emergency general surgery procedures: potential for targeted improvement. *Surgery.* 2010;148(2):217-238.