Evidence Synthesis Program

Robot-assisted Procedures in General Surgery: Cholecystectomy, Inguinal and Ventral Hernia Repairs

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of 4 ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

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This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **West Los Angeles VA Medical Center, Los Angeles, CA**, funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

ACKNOWLEDGMENTS

This topic was developed in response to a nomination by Dr. Mark Wilson, National Director of Surgery, and Dr. William Gunnar, Executive Director, National Center for Patient Safety and former National Director of Surgery. The scope was further developed with input from the topic nominators (*ie*, Operational Partners), the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

In designing the study questions and methodology at the outset of this report, the ESP consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

The authors gratefully acknowledge Roberta Shanman, Jon Bergman, and the following individuals for their contributions to this project:

Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

Mark Wilson, MD, PhD
National Director of Surgery
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William Gunnar, MD
Executive Director, National Center for Patient Safety
Former National Director of Surgery
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Technical Expert Panel (TEP)

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

Bryanna Emr, MD
General Surgeon, Clinical Assistant Professor, University of Pittsburgh and VA Pittsburgh Healthcare System

Timothy Frankel, MD
Assistant Professor, General Surgery and Surgical Oncology, University of Michigan Hospitals-Michigan Medicine and Veterans *Affairs Ann Arbor Healthcare System*

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Frederick Luchette, MD
Chief of Surgical Service Line, Edward Hines Jr., VA Hospital; Professor of Surgery, Department of Surgery Stritch School of Medicine, Loyola University of Chicago

Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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ABBREVIATIONS TABLE

ASA	American Society of Anesthesiologists
BMI	Body mass index
CCI	Charlson comorbidity index
Chole	Cholecystectomy
COI	Conflict of interest
Comp	Complications
dVSSC	Da Vinci single-site cholecystectomy
EBDIT	Earnings before depreciation, interest and tax
EBL	Estimated blood loss
ED	Emergency Department
Elective	Elective surgery
FDA	Food and Drug Administration
F/U	Follow-up
GRADE	Grading of recommendations assessment, development and evaluation
IOC	Intraoperative cholangiogram
Lap	Laparoscopic approach
LC	Laparoscopic cholecystectomy
LOS	Length of stay
Mesh	Repair with mesh
Narc	Narcotic use
NIS	National Inpatient Sample
OR	Operating room or operating room time (where indicated)
Preop	Preoperative
Primary	Primary hernia repair
QOL	Quality of life
RAC	Robot-assisted cholecystectomy
RAS	Robot-assisted surgery
RC	Robotic cholecystectomy
RCT	Randomized controlled trial
Recur	Recurrence
Reop	Reoperation
SILC	Single incision laparoscopic cholecystectomy
ROBINS-I	Risk of bias in non-randomized studies- of interventions
Skin-to-skin	Operating time from skin incision to skin closure
SSI	Surgical site infection
SSO	Surgical site occurrence
TAPP	Transabdominal preperitoneal inguinal *hernia repair*
TEP	Totally extra-peritoneal inguinal hernia repair
Txf	Transfusion
TR	Total recurrences
USD	United States dollar

EVIDENCE REPORT

INTRODUCTION

Across the world, the adoption of robot-assisted surgery continues to increase, particularly for commonly performed general surgery procedures. In the US, the robot-assisted surgical platform was introduced in 1999 and by the end of 2017, over 3,000 robotic platforms were being used.[2] While this new technology is becoming widespread, several questions about the utility of robot-assisted surgery as compared to laparoscopic and open surgery persist. In particular, does the use of the robot translate to better or similar clinical outcomes for patients? Are operating room times and length of stay comparable or improved with use of robot as compared to laparoscopic or open techniques? These questions are critical to answer, both for patient safety and satisfaction, particularly in our current health care climate where hospitals and physicians must provide efficient care while maintaining the highest quality, all the while working to curtail costs.

Cholecystectomy and hernia repair are commonly performed general surgery procedures. Over 1 million cholecystectomies and 800,000 ventral and inguinal hernia repairs are completed annually in the US.[3,4] Robot-assisted approaches to these procedures are becoming more common and accepted.[5] Specifically, inguinal and ventral hernia repairs are the most rapidly growing procedures for the robot-assisted platform in general surgery. For example, a cohort study from the Michigan Surgical Quality Collaborative Database shows an increase in robot-assisted surgery general surgery procedures from 1.8% to 15.1% between 2012-2018.[6] In addition to multi-port laparoscopic and robot-assisted techniques, there has been a shift to single-port robot-assisted and laparoscopic approaches as well, which reduces the number of incisions for the patient.[7,8]

Further fueling this debate is the economics of the robotic platform. The robotic platform requires a significant upfront investment, an annual maintenance contract, and ongoing instrument purchases, not to mention staff and training costs, advertising, and infrastructure upgrade expenses. Weighing these costs relative to the potential benefits of the robot-assisted approach, such as reduced length of stay, complications, readmissions, or improved patient centered outcomes, is critical in our climate of needing to curtail rising health care costs.

In light of recent evidence in other surgical disciplines questioning the utility of the robotic platform, there is considerable need to understand the evidence surrounding the use of the robotic platform in general surgery. Few comprehensive systematic reviews addressing each of these procedures exist – specifically where the critical patient factors and technique differences are assessed.

In summary, common general surgery procedures make up a large volume of the annual operations performed in the US, and we are experiencing dramatic recent growth in the number of robot-assisted surgery cases within this field. Yet there is no consensus or guidelines on when to use this surgical approach, and such decisions are left up to individual practitioners. To help clinicians, patients, and policymakers decide between robot-assisted and other surgical approaches for cholecystectomy, inguinal or ventral hernia repairs, we were asked to conduct a systematic review of the literature.

METHODS

TOPIC DEVELOPMENT

This topic was developed in response to a nomination by Dr. Mark Wilson, National Director of Surgery, and Dr. William Gunnar, former National Director of Surgery. Key questions were then developed with input from the topic nominator, the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

The Key Questions were:

KQ1A: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic surgery for cholecystectomy?

KQ2A: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic surgery for cholecystectomy?

KQ1B: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for inguinal hernia repair?

KQ2B: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for inguinal hernia repair?

KQ1C: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for ventral hernia repair?

KQ2C: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for ventral hernia repair?

Because the 3 surgical procedures were different, we constructed separate search strategies, inclusion and exclusion criteria for each procedure.

The review was registered in PROSPERO and is awaiting registration number.

SEARCH STRATEGY

We conducted separate searches for cholecystectomy, inguinal hernia, and ventral hernia. All searches included PubMed, Embase, and Cochrane (all databases) from 2010 to March 2020. For inguinal and ventral hernias, Medline was also searched from 2010 to 2020. The search used a broad set of common terms relating to "robotic surgical procedures" or “robotic-assisted” and “cost effectiveness”, and then the individual procedure-specific terms “inguinal hernia”, “ventral hernia” or “incisional hernia”, and “cholecystectomy”. Prior to 2010, robot-assisted procedures were not widely being performed and many surgeons were still in the so-called "learning curve". As such, our technical expert panel considered evidence from studies published prior to the year 2010 to be insufficiently relevant to modern practice. While we still anticipated finding studies assessing or including the robot-assisted surgery learning curve, this later search date will help lessen that occurrence. See Appendix A for complete search strategy.

STUDY SELECTION

Multiple team members working independently screened the titles of retrieved citations. For cholecystectomy, MMG and RS; for inguinal hernia repair, LY and MMG; for ventral hernia repair, LY, RS, MG, and MMG.

For titles deemed relevant by at least 1 person, abstracts were then screened independently in duplicate by multiple team members working in pairs. For cholecystectomy, RS and MMG; for inguinal hernia repair, LY, AT, and MMG; for ventral hernia repair, LY and MMG.

All disagreements were reconciled through group discussion. Full-text review was conducted in duplicate by 2 independent team members, with any disagreements resolved through discussion. For cholecystectomy, RS and MM; for inguinal hernia repair, LY and AT; for ventral hernia repair, LY and MMG.

Studies were included at either the abstract or the full-text level if they were randomized control trials or observational studies comparing robot-assisted surgery with either laparoscopic or open surgical approaches for any of the included surgical procedures. We also included publications of cost-effectiveness models that compared robot-assisted surgery with laparoscopic or open surgical approaches. We included all RCTs regardless of outcomes studied. We did not have sample size restrictions for cholecystectomy, but excluded studies with sample size <10 for inguinal and ventral hernia repairs. The cholecystectomy technique is very standard (with the exception of the number of ports). However, both hernia repair techniques are widely variable including factors such as mesh location, size of hernia, type of sutures, use of tacks, use of sutureless mesh, etcetera, and these continue to evolve. These factors were not consistently reported. As such, we made the decision that the small studies (<10 sample size) would have the potential for substantial unmeasured bias.

DATA ABSTRACTION

Data extraction was completed in duplicate. All discrepancies were resolved with full group discussion. We abstracted data on the following: study design, patient characteristics, sample size, intraoperative outcomes, postoperative outcomes, long-term functional outcomes and cancer outcomes, duration of follow-up, and data needed for the Cochrane Risk of Bias tool or Cochrane Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I).

QUALITY ASSESSMENT

Randomized controlled trials were assessed for quality (risk of bias) with the Cochrane Risk of Bias tool.[9] This tool requires an assessment of whether a study is at high or low (or unknown) risk of bias in 7 domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other (See Appendix C for tool; Appendix E for table). We used the Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) for observational studies.[10] This tool requires an assessment of whether a study is at critical, serious, moderate, or low risk of bias (or no information) in 7 domains: confounding, selection bias, bias in measurement classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result (see Appendix D for tool; Appendix F for table).

The review team operationalized the 7 domains in the following manner:

Confounding factors

- Low: if patients have similar baseline characteristics, *OR* if significantly different, are propensity matched
- Serious: if baseline data is not explicitly stated

Selection bias

- Low: if consecutive series, *OR* if *likely* consecutive from a database study

Bias in measurement classification of interventions & bias due to deviation from intended interventions

- Low: by nature of the included studies

Bias due to missing data

- Studies with outcomes of 30 days or less were assumed to be 100% follow-up
- Moderate if loss to follow-up is unclear; serious if follow-up is reported, but low
- If studies exclude missing data in their study design then serious selection bias, but low for bias due to missing data
- If studies report an n-value in postoperative/long-term outcome tables that is consistent with their original n-value then that implies 100% follow-up
- Low: if no/minimal loss to follow-up

Bias in measurement of outcomes

- Split up outcomes by risk if there are differences
- OR times: likely low risk due to retrospective nature of most of these studies
- Pain: moderate risk due to patient subjectivity, lack of concealment, possible physician counseling, etc.

Bias in selection of the reported result

- Low: if authors report all available data, especially data with no significant differences
- Depends on the purpose and intended outcomes of the study, and whether other similar studies report omitted outcomes

DATA SYNTHESIS

Because the RCTs were too heterogeneous, we did not conduct a meta-analysis of trials. The observational studies were too clinically heterogeneous to support meta-analysis; hence, our synthesis is narrative.

We assessed robot-assisted and laparoscopic approach for cholecystectomy, as open cholecystectomy is typically performed for only cancer pathology. Therefore, robot-assisted cholecystectomy to open cholecystectomy is not clinically relevant. We assessed robot-assisted, laparoscopic, and open approaches for inguinal and ventral hernia repairs. Of note, cholecystectomy (for benign disease) and most inguinal hernias are performed as outpatient surgery.

Further, since there were limited RCTs, specific considerations for each of the 3 operations types were warranted, in order to account for a number of potential differences between study arms. Specifically, we needed to assess for within-study variations in patient factors and varying surgical techniques, which could confound effect differences in clinical outcomes. For example, if a robot-assisted surgery study arm had a higher number of bilateral hernias than the laparoscopic group, this in and of itself could potentially be responsible for longer operative times or higher rate of complications. Studies that performed matching (propensity matching) in our review accounted for a number of important variables but typically did not control for all relevant patient or technique factors (*ie*, extent of fascial closure, hernia size, *etc*).

Specifically, our research team made the following judgments to allow for the most optimal comparisons of the studies identified (which were mainly observational).

- For cholecystectomy, we present the data by grouping studies based on the number of surgical access ports used:
  - *robot single-port compared to laparoscopic single port or robot multi-port compared to laparoscopic multi-port;*
  - *robot single-port compared to laparoscopic multi-port;*
  - *robot compared to laparoscopic for those with unknown number of ports* (in terms of outcomes).

  We did not identify any study reporting robot multi-port to laparoscopic single-port.

- For inguinal hernia repair, we present the data by grouping studies where hernia laterality (unilateral or bilateral) was:
  - *known and at least <25% between comparative arms, or outcomes reported by laterality*;
  - *laterality not known.*

- For ventral hernia repair, we present the data by grouping studies that:
  - *attempted matching on patient, hernia, or technique factors;*
  - *matching not performed.*

RATING THE BODY OF EVIDENCE

We used the criteria of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group.[11] GRADE assessing the certainty of the evidence based of the assessment of the following domains: risk of bias, imprecision, inconsistency, indirectness, and publication bias. This results in categories as follows:

High: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.

Very low/Insufficient: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

PEER REVIEW

A draft version of the report was reviewed by technical experts and clinical leadership. Reviewer comments and our response are documented in Appendix B.

RESULTS

For cholecystectomy, we identified 887 potentially relevant citations, of which 169 were included at the abstract screening. From these, a total of 90 abstracts were excluded. Excluded abstracts were categorized as wrong comparison (n=54), systematic review (n=14), review/editorial (n=14), no outcome of interest (n=1), and other (n=7). This left 79 publications for full-text review, of which 32 were excluded for the following reasons: wrong comparison (n=4), no clinical data (n=3), no outcome of interest (n=4), review/editorial (n=8), other (n=2), and duplicate (n=11). A full list of excluded studies from the full-text review is included in Appendix H. A total of 47 publications were identified at full-text review as meeting initial inclusion criteria: RCT with cost and clinical data (n=1), RCTs with clinical data only (n=3), observational studies with cost data only (n=3), observational studies with clinical outcomes only (n=25), and observational studies with both clinical and cost data (n=15). Descriptions of included publications are available in the Evidence Table (Appendix G).

For inguinal hernia repair, we identified 3,319 potentially relevant citations and 9 publications recommended by experts. From these, 185 were included for abstract screening. A total of 143 abstracts were excluded, categorized as wrong comparison (n=129), no outcome of interest (n=1), other (n=6), systematic review (n=3), review (n=1), and duplicate (n=3). This left 42 publications for full-text review, of which 19 were excluded for the following reasons: wrong comparison (n=2), no outcome of interest (n=6), no clinical data (n=3), procedure (n=1), systematic review (n=1), review/editorial (n=2), duplicate (n=3), and unavailable (n=1). A full list of excluded studies from the full-text review is included in Appendix H. A total of 23 publications were identified at full-text review as meeting initial inclusion criteria: RCT with clinical and cost data (n=1), observational studies with clinical outcomes only (n=18), and observational studies with both clinical and cost data (n=4). Eleven studies had known hernia laterality that were similar distribution between study arms (<25% difference in laterality). While 6 studies with known laterality had >25% difference between comparison groups, for the other 6 studies, laterality was unknown or not reported (between the comparative arms). Descriptions of included publications are available in the Evidence Table (Appendix G).

For ventral hernia repair, we identified 3,458 potentially relevant citations and 5 publications recommended by experts. From these, 369 were included for abstract screening. A total of 321 abstracts were excluded, categorized as wrong comparison (n=306), review/editorial (n=8), no outcome of interest (n=8), systematic review (n=1), and duplicate (n=3). This left 48 publications for full-text review, of which 26 were excluded for the following reasons: case series with sample less than 10 (n=2), comparison (n=6), no outcome of interest (n=7), sample size less than 10 in each arm (n=2), review/editorial (n=1), systematic review (n=1), duplicate (n=6), and unavailable (n=1). A full list of excluded studies from the full-text review is included in Appendix H. A total of 22 publications were identified at full-text review as meeting initial inclusion criteria: RCT with clinical data only (n=1), observational study with cost data only (n=1), observational studies with clinical data only (n=15), and observational studies with both clinical and cost data (n=5). 7 of the observational studies reported matched data and 14 had unmatched data. Descriptions of included publications are available in the Evidence Table (Appendix G).

THE RISK OF BIAS OF STUDIES

For cholecystectomy, there were 4 RCTs and 40 observational studies. The RCTs in general were assessed to have an overall low risk of bias. Overall, the majority of the observational studies had high to moderate risk of bias, except for those with propensity matching (n=4).

For inguinal hernia repair, 1 RCT and 22 observational studies met inclusion criteria, including 6 abstracts. The RCT was assessed to have an overall moderate risk of bias due to the single-blinded design, unclear allocation concealment and blinding of outcome assessment, and potential for author bias due to the significant funding to multiple authors by the robot manufacturer. Overall, the majority of the observational studies had a high risk of confounding bias, as only 5 studies were propensity matched. Large differences (>25%) in or lack of reporting of the proportion of unilateral to bilateral inguinal hernia repairs also introduced confounding bias in 10 observational studies. Selection bias for the majority of studies was low; however, 8 studies were judged to have greater risk of bias due to study-specific patient exclusion criteria. Several papers also had author disclosures due to involvement with Intuitive Surgical Inc. Finally, we identified 1 study that conducted a random sample from a web-based research panel and was subject to numerous methodological limitations due to low response rate and high recall bias.[12]

For ventral hernia repair, 1 RCT and 20 observational studies met inclusion criteria. The RCT was a conference abstract of a small sample of patients and was judged to have an overall high risk of bias due to lack of allocation concealment, blinding of patients and personnel, blinding of outcome assessment, selective reporting, and use of self-reported outcomes, such as quality of life. The majority of the observational studies had a high risk of confounding bias, as only 8 studies were propensity matched, and of the matched studies, there was variation on which variables were being matched (*eg,* patient characteristics vs hernia size). Selection bias was overall low.

For all procedures, bias in the measurement classification of interventions, bias due to deviation from intended interventions, and bias in selection of the reported result were generally low. Bias due to missing data was overall low, as most studies only reported short-term (≤ 30 day) outcomes, which were presumed to have minimal loss to follow-up. Studies with long-term outcomes had a higher risk of bias due to missing data if follow-up rates were low or not reported. For bias in measurement of outcomes, self-reported outcomes relating to pain and quality of life had a moderate risk of bias due to the subjectivity of these measurements, while objective assessments of pain, such as narcotic use, had a low risk of bias. Other outcomes, such as length of stay, complications, and OR time, had a low risk of bias.

Figure 1A. Literature Flow Chart

CHOLESCYSTECTOMY

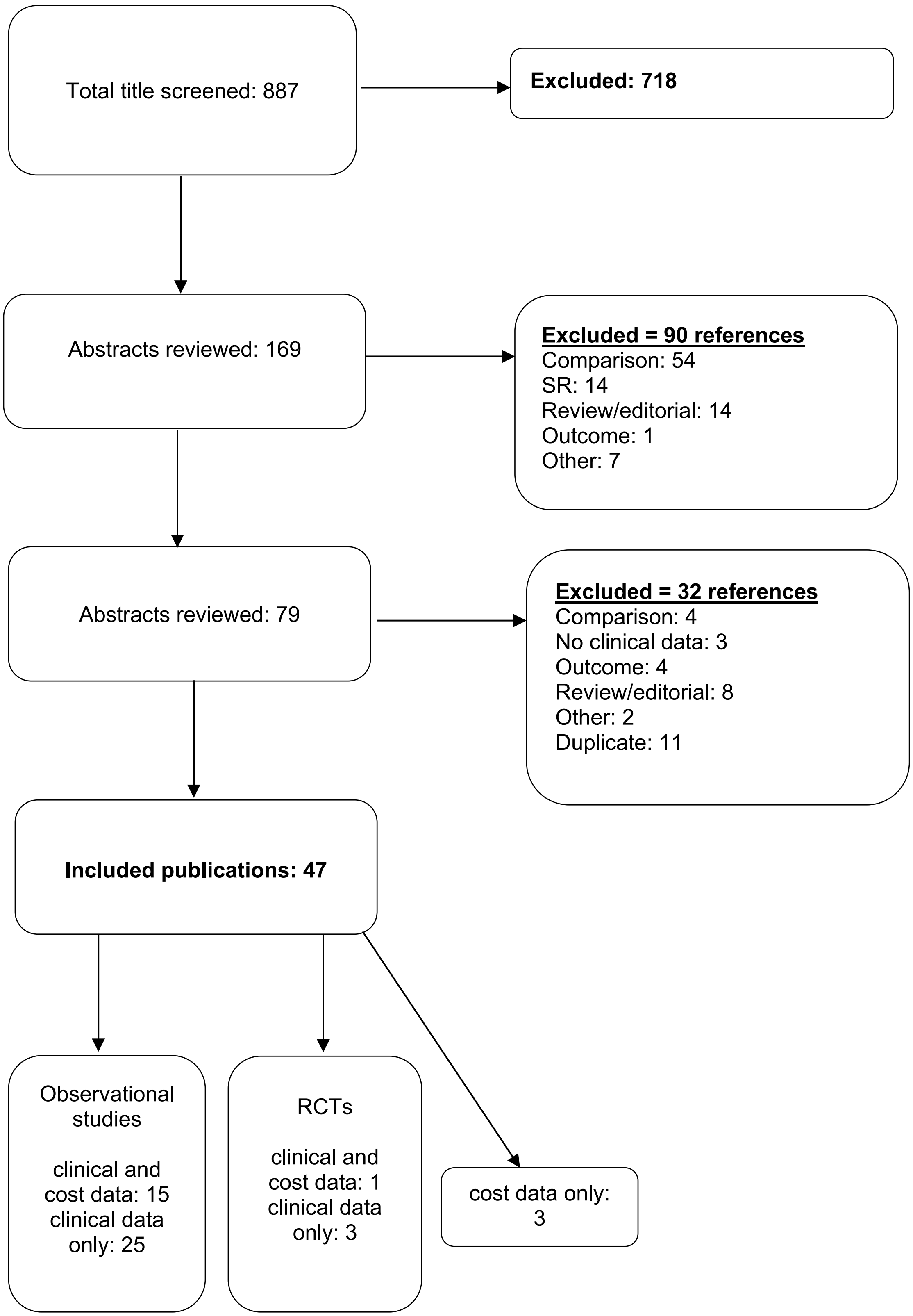


Figure 1B. Literature Flow Chart

INGUINAL HERNIA REPAIR

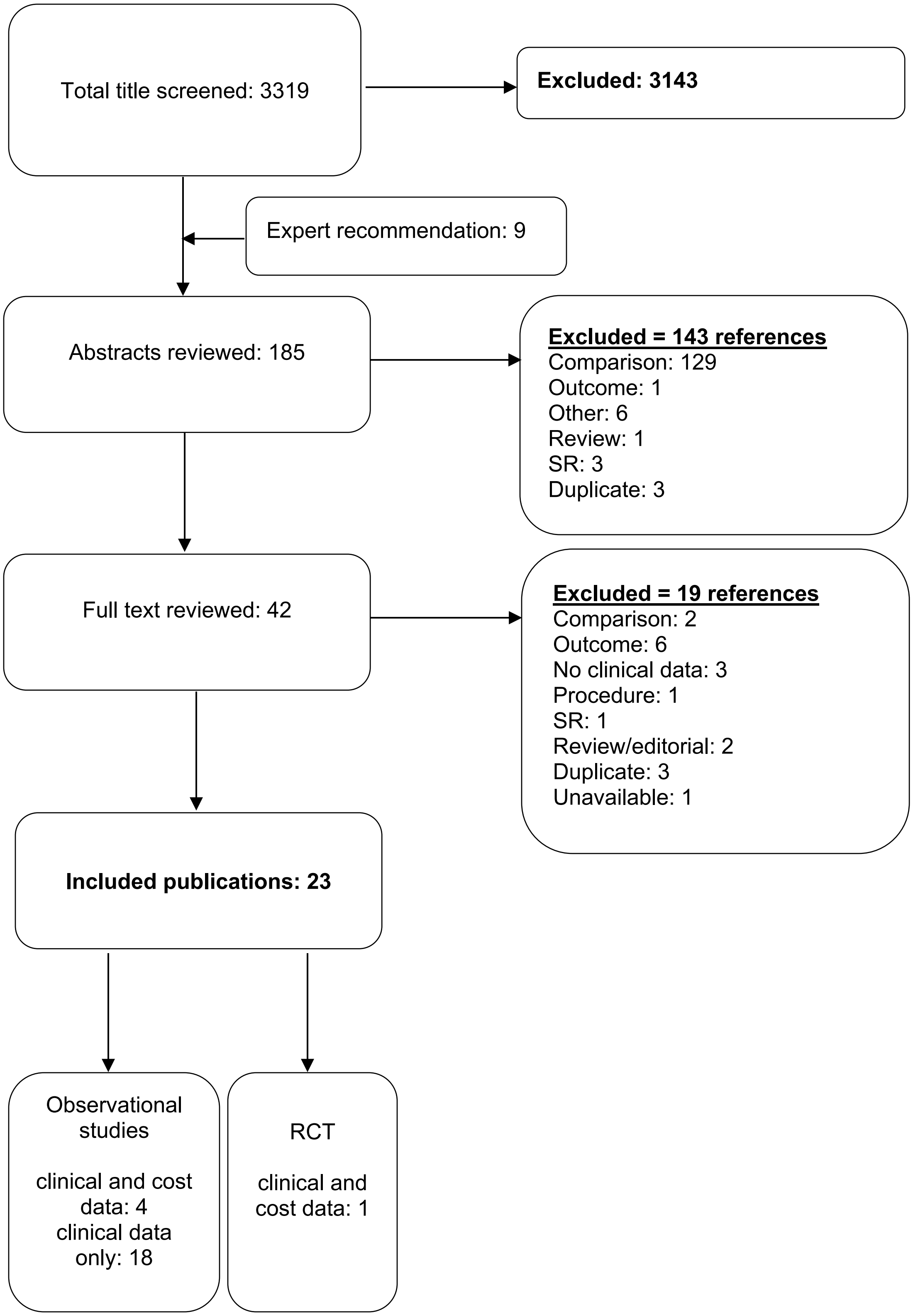
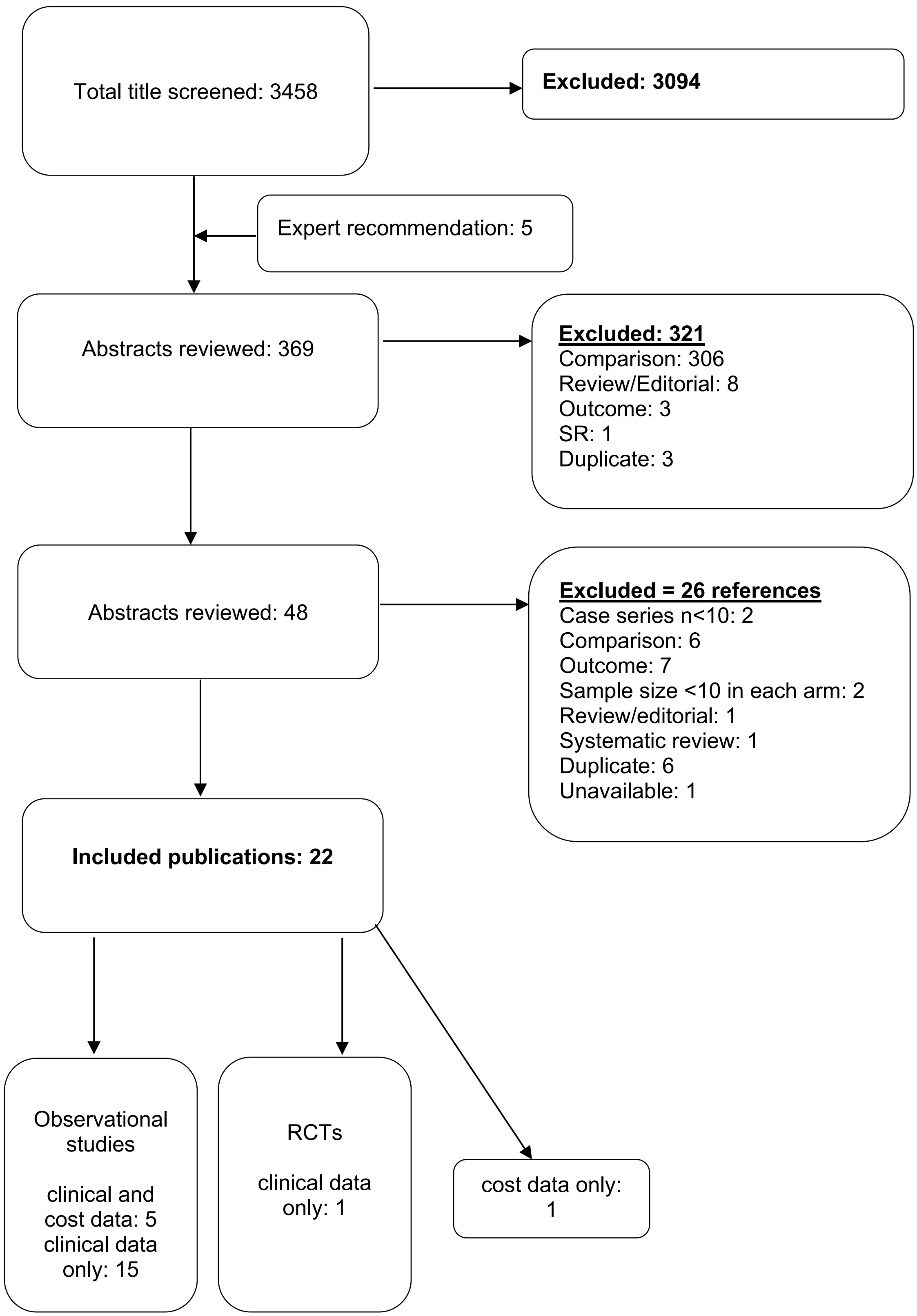


Figure 1C. Literature Flow Chart

VENTRAL HERNIA REPAIR

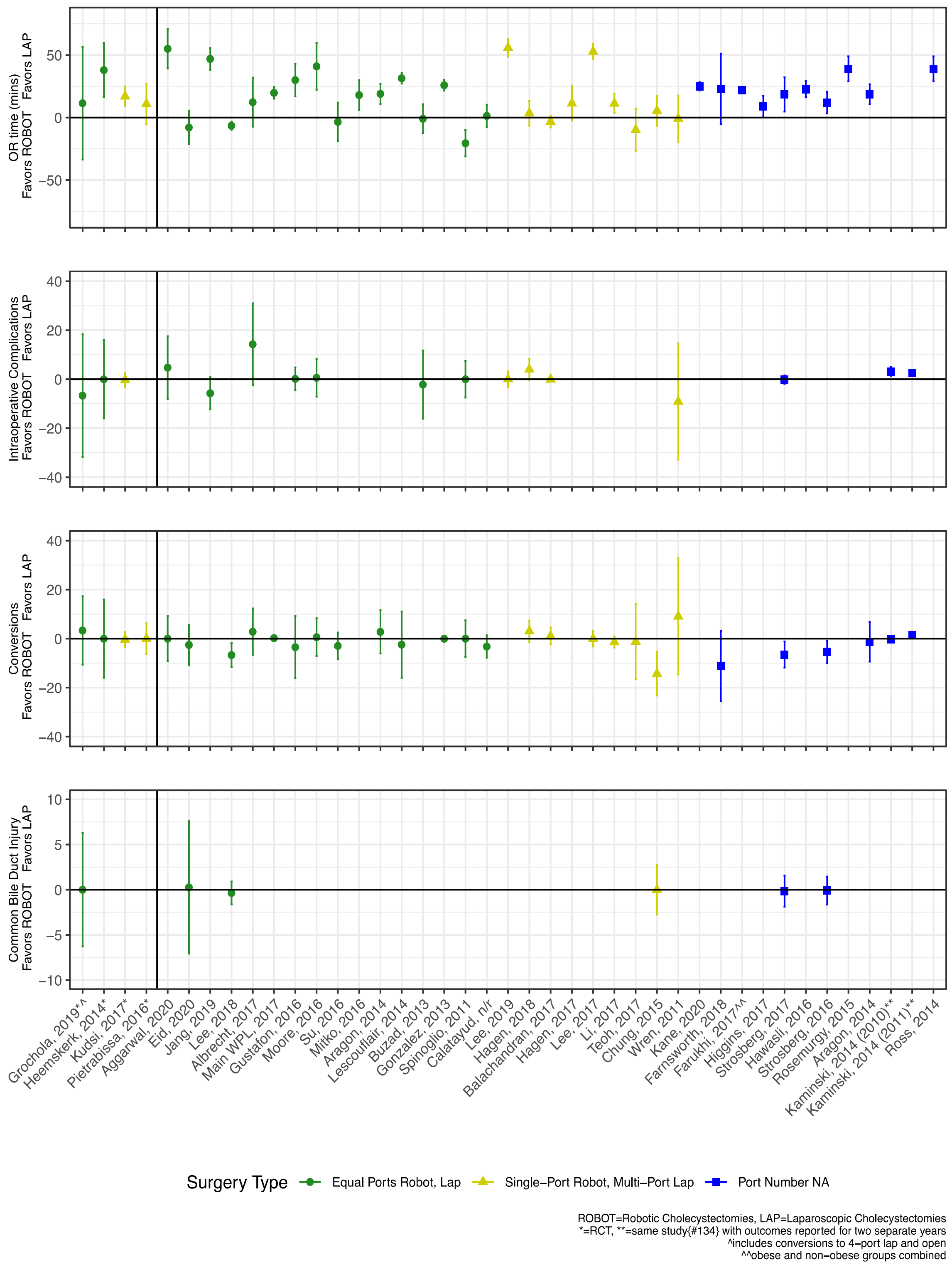


KEY QUESTION 1A – CHOLECYSTECTOMY: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic surgery for cholecystectomy?

We identified 44 publications that met the inclusion criteria; 4 studies were randomized trials,[13-16] and the remaining studies were observational. 7 studies compared multi-port robot-assisted cholecystectomy with multi-port laparoscopic cholecystectomy,[14,17-22] including 1 RCT[14]; 12 compared single-port robot-assisted cholecystectomy with multi-port laparoscopic cholecystectomy,[15,16,23-32] including 2 RCTs[15,16]; and 11 compared single-port robot-assisted cholecystectomy with single-port laparoscopic cholecystectomy,[33-43] including 1 RCT.[13] 1 study compared 3 arms: single-port robot-assisted cholecystectomy, multi-port robot-assisted cholecystectomy, and single-port laparoscopic cholecystectomy.[44] Thirteen studies either grouped all (single and multi-port) robot-assisted and laparoscopic cholecystectomies in separate groups or did not specify if the robot and laparoscopic arms were single-port, multi-port, or both.[45-57] The studies varied in size from 20 to 735,537 patients.

Figure 2 presents graphically the results for 4 intraoperative outcomes: operating room (OR) time, complications, conversion to open cholecystectomy (or conversion from robot-assisted to laparoscopic cholecystectomy), and common bile duct injury. In the 4 RCTs, OR time was consistently longer for robot-assisted cholecystectomy procedures, although these differences were only statistically significant in 2 studies (one compared single-port robot-assisted cholecystectomy to single-port laparoscopic cholecystectomy[15] and the other multi-port robot-assisted cholecystectomy to multi-port laparoscopic cholecystectomy).[14] From the observational studies, robot-assisted cholecystectomy took longer to perform in the great majority of studies with most of these differences being statistically significant. Of the studies that demonstrated a shorter OR time in the robot cohort, only 2 were statistically significant, and they compared single-port robot-assisted cholecystectomy and single-port laparoscopic cholecystectomy.[37,41] For the outcomes of intraoperative complications, bile duct injury as its own outcome, or conversion rates, differences between robot-assisted cholecystectomy and comparison procedures were minimal to none, both in the RCTs and in the observational studies.

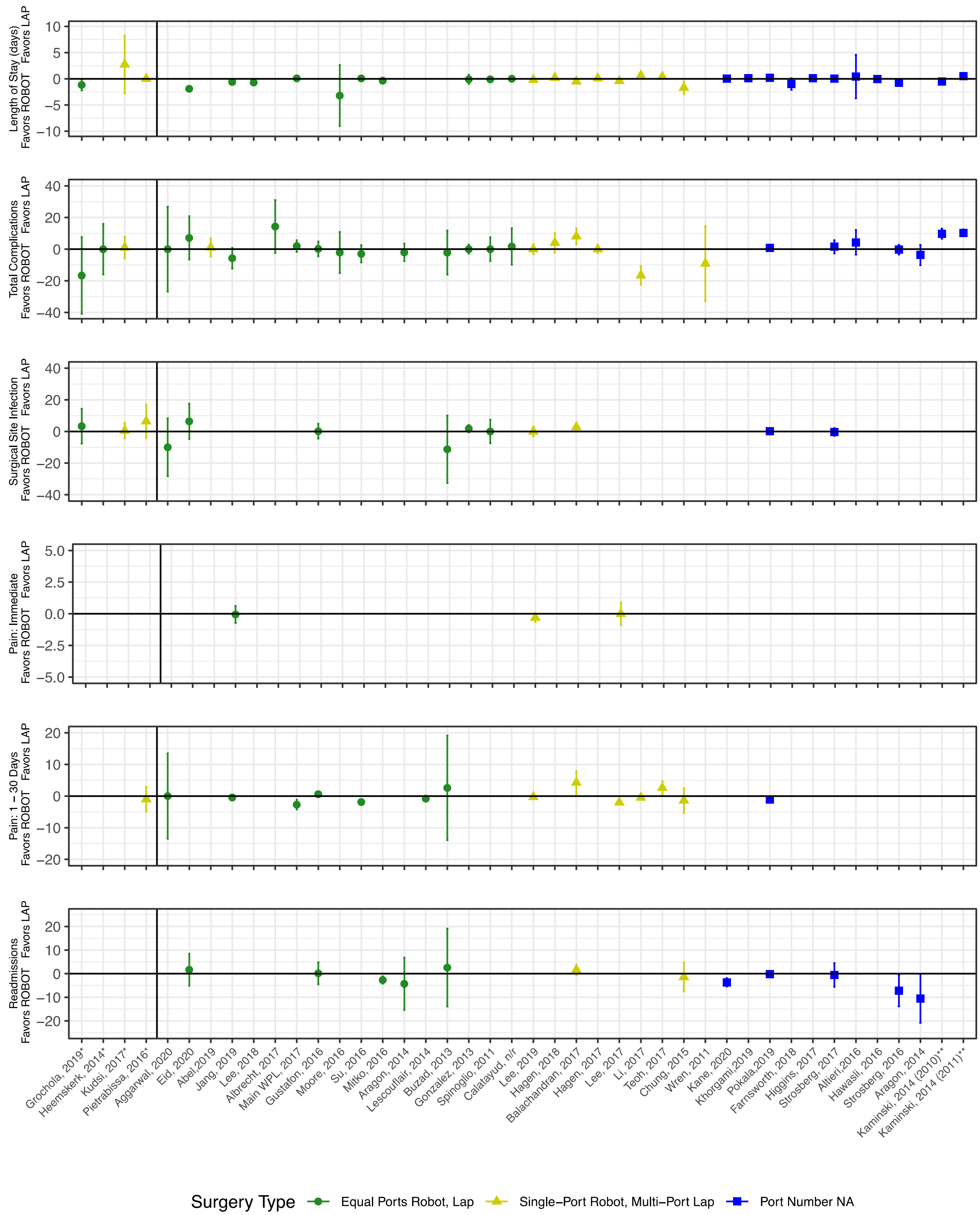
Figure 2. Cholecystectomy Intraoperative Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted cholecystectomy and laparoscopic approach. RCTs are listed in the left-hand side, while observational studies are listed on the right-hand side.

Figure 3 presents graphically the results of 6 short-term outcomes: LOS, all postoperative complications, surgical site infections, pain immediately following surgery, pain 1-30 days, and readmission rate. 3 out of 4 RCTs[13,15,16] reported on LOS, and this was significantly shorter in 1 study comparing the single-port robot-assisted cholecystectomy patients with single-port laparoscopic cholecystectomy patients.[13] In the other 2 RCTs, both of which compared single-port robot-assisted surgery to multi-port laparoscopic surgery, there was no significant difference in LOS.[15,16] In general, patients across all the RCTs and observational studies were discharged within 1 to 2 days without a suggestive pattern favoring any particular procedure. There were no significant differences in total complications or surgical site infections between procedures, and most point estimates were on or extremely close to the null value of no difference. There was somewhat more variation in point estimates of differences in the 2 pain outcomes, but no clear pattern favoring 1 procedure over another. Twelve observational studies reported readmissions, and 4 of these studies demonstrated a significantly higher readmission rate in the laparoscopic surgery patients.[20,44,54,57] Of those 4 studies, 1 had compared single-port robot-assisted cholecystectomy, multi-port robot-assisted cholecystectomy, and single-port laparoscopic cholecystectomy.[44]

Figure 3. Cholecystectomy Short-term Outcomes

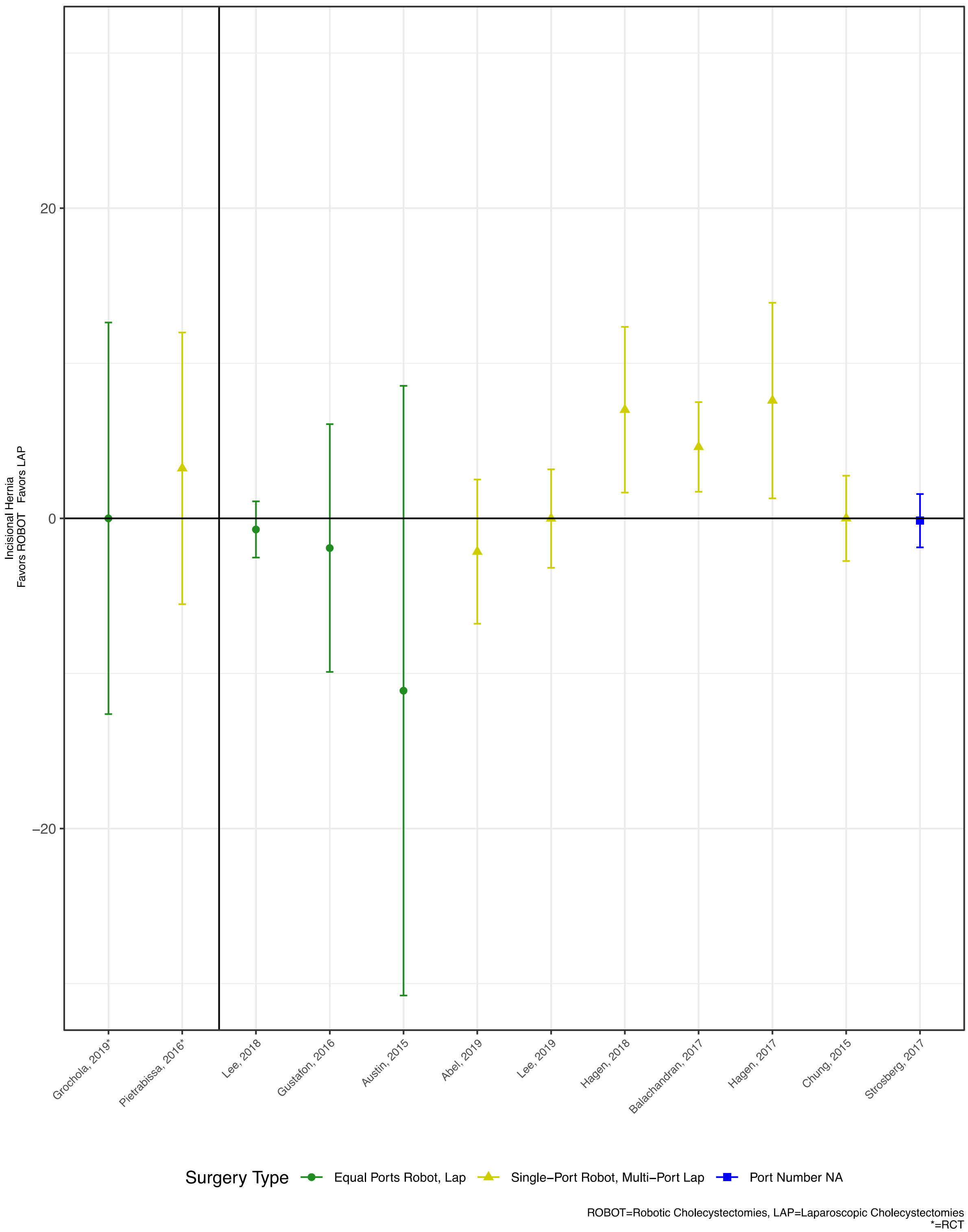


ROBOT=Robotic Cholecystectomies, LAP=Laparoscopic Cholecystectomies
*=RCT, **=same study{#134} with outcomes reported for two separate years

Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted cholecystectomy and laparoscopic approach. RCTs are listed in the left-hand side, while observational studies are listed on the right-hand side.

Figure 4 presents graphically the results of the only long-term outcome, incisional hernia rates. This outcome is less frequently reported than the short-term outcomes and is included in only 2 RCTs[13,16] and 10 observational studies.[23-25,27,30,32,36,39,41,51] The 2 RCTs[13,16] reported no statistically significant differences, but the 95% confidence intervals are very wide, and clinically important differences cannot be excluded. 3 observational studies[23,25,30] found higher incisional hernia rates in the single-port robot-assisted cholecystectomy patients compared to the multi-port laparoscopic cholecystectomy patients. The point estimate of effect for these 3 observational studies is within the 95% confidence interval of the 1 RCT of this comparison,[16] and in fact quite close to the RCT point estimate of effect. We interpret these findings as a possible signal that this long-term outcome may be worse in single-port robot-assisted cholecystectomy than multi-port laparoscopic cholecystectomy. In the remainder of the studies that reported on incisional hernia formation, there was no significant difference between robot-assisted cholecystectomy and laparoscopic cholecystectomy cohorts; 4 out of 6 of those studies compared single-port robot-assisted cholecystectomy to single-port laparoscopic cholecystectomy.

Figure 4. Cholecystectomy Long-term Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted cholecystectomy and laparoscopic approach. RCTs are listed in the left-hand side, while observational studies are listed on the right-hand side.

Summary of Findings

In general, OR time was longer in patients treated with robot-assisted cholecystectomy compared to laparoscopic cholecystectomy. While not always statistically significant, data are consistent across RCTs and observational studies, and also consistent with differences in OR time seen between other robot-assisted procedures and their laparoscopic or open counterparts. There was no evidence of differences in total intraoperative complications in total intra-operative complications or conversions, and most studies had point estimates close to the null value. Only 5 studies reported common bile duct injuries, and there was no evidence of differences between robot-assisted cholecystectomy and laparoscopic cholecystectomy. There was no evidence across most studies of differences in LOS, post-operative complications, or SSI. Pain was reportedly inconsistently among the studies and there was no evidence favoring robot-assisted or laparoscopic surgery. The lack of difference in outcomes between techniques could in part be related to patient selection and the type of gallbladder pathology for which each technique was used. Additionally, studies capturing surgeons' learning curve of the robot-assisted platform could factor in as well. The rate of incisional hernia may be higher in single-port robot-assisted cholecystectomy as compared to multi-port laparoscopic, a

All studies that demonstrated a statistically significant difference in incisional hernia rate compared single-port robot-assisted cholecystectomy to multi-port laparoscopic cholecystectomy. There was also no evidence of differences in the rate of incisional hernia rates for single-port robot-assisted and single-port laparoscopic cholecystectomy. This may be because the single-port approach with robot-assisted cholecystectomy or laparoscopic cholecystectomy involves a larger incision and confers a higher risk for developing an incisional hernia.

Certainty of Evidence for Key Question 1A

We judged the certainty of evidence for most outcomes as being moderate, with evidence from RCTs and from observational studies mainly in agreement on the direction of effect. We judged the evidence for most outcomes as imprecise, leading to a reduction in the certainty of evidence (from high to moderate). OR time outcomes for robot-assisted compared to laparoscopic cholecystectomy was deemed moderate because of imprecision. We judged the results for intraoperative complications as moderate due to some imprecision, and common bile duct injury was considered low because of imprecision and sparsity of data. We judged the certainty of evidence for conversion rate between robot-assisted cholecystectomy and laparoscopic cholecystectomy as high, based on the RCT data. We judged LOS as imprecise but moderate, since 3RCTs reported this result. All postoperative complications and surgical site infection as moderate certainty of evidence due to imprecision. We judged the certainty of evidence for readmission outcome between robot-assisted cholecystectomy and laparoscopic cholecystectomy as low. We judged the certainty of evidence for pain as low due to inconsistent and imprecise results. Certainty of evidence for postoperative incisional hernia formation between robot-assisted cholecystectomy and laparoscopic cholecystectomy was deemed low due to inconsistency among the comparison groups and imprecision.

Table 1. Certainty of Evidence for Cholecystectomy Studies

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Intra-operative					
OR Time Robot > Laparoscopic	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Complications Robot = Laparoscopic	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Common Bile Duct Injury Robot = Laparoscopic	RCT: Low Observational studies: Low	Consistent	Direct	Imprecise	Moderate
Conversions Robot = Laparoscopic	RCT: Low Observational studies: High	Consistent	Direct	Precise	High
Short-term Outcomes					
Length of Stay Robot = Laparoscopic	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Complications (total) Robot = Laparoscopic	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Surgical Site Infection Robot = Laparoscopic	RCT: Low Observational studies: High	Consistent	Direct	Imprecise	Moderate
Pain Robot = Laparoscopic	RCT: Low Observational studies: High	Inconsistent	Direct	Imprecise	Low
Readmissions Robot <Laparoscopic	Observational studies: High	Consistent	Direct	Imprecise	Low
Long-term Outcomes					
Incisional hernia Single port robot > multiport laparoscopic	RCTs: Low Observational studies: High	Inconsistent	Direct	Imprecise	Low

KEY QUESTION 2A – CHOLECYSTECTOMY: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic surgery for cholecystectomy?

Eighteen studies looked at robot-assisted cholecystectomy versus laparoscopic and included some measure of cost. There was 1 RCT.[13] Of the remaining 17, the majority were retrospective, single institution, or single health system studies. There were 3 studies that used a national database[49,56,58] and 1 study performed a budget impact analysis using existing published data.[59] Studies were mixed with respect to procedures performed. Studies included a combination of traditional laparoscopic multi-port surgery, laparoscopic single-port surgery, robot-assisted multi-port surgery, and robot-assisted single-port surgery. Because most studies came from single institutions, sample sizes were generally small, with the majority of studies including fewer than 100 patients in the robot-assisted arm.

Overall, 16 of 18 studies reported at least 1 measure of cost higher for the robot-assisted surgery compared to the laparoscopic approach. The 1 RCT was a single institution study in Switzerland that evaluated 30 patients receiving single site robot-assisted surgery and compared them to 30 patients receiving single site laparoscopic surgery for elective cholecystectomy.[13] They found nearly a 50% higher cost for the robot driven by higher consumable costs, amortization, and overhead costs ("the cost of OR time").

Table 2. Evidence Table for Cholecystectomy Cost Studies

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
Bedeir 2016[60]	Retrospective, single institution	Robot-assisted single site vs traditional laparoscopic for elective outpatient cholecystectomy	1 (robot) 5 (lap)	46 robot 195 lap	"Cost data were obtained from financial department. Hospital cost in US dollars, not billed or hospital revenue. Cost divided into fixed and variable costs. **Only variable costs are included**. Fixed costs include salaries and hospital infrastructure. Fixed costs don't differ between. procedures."	Total median variable cost: 1319 (robot) vs 1737 (lap), p<0.001	Provide OR time for robot but not for lap One author had financial COI with Intuitive
Buzad 2013[33]	Retrospective, single institution	Robot-assisted single incision vs historical control of laparoscopic single incision cholecystectomies	1	20 robot 10 lap	"Cost based on instrument cost from preference cards; did not include purchase price or maintenance of robot. Sensitivity analysis performed for instrument costs: SILC estimates were average cost, based on number of cases, and a theoretical range for single port. Theoretical savings of no cholangiogram for robot was calculated."	Preference card cost for instruments = $1268 (robot) vs $1281 (lap); no p-value as these are just single values for the preference card **Excluded cost of using 5 "reusable" robotic instruments**	Operative times 84 vs 85 min, p=NS One author had financial COI with Intuitive
Farnsworth 2018[46]	Retrospective, single institution Abstract only	Robot-assisted vs laparoscopic acute care surgery cholecystectomy	2	14 robot 37 lap	"day of surgery until discharge"	Unadjusted OR costs: $3490 (robot) vs $2190 (lap), p<0.001 Adjusted analysis found robot was $980 more than lap BUT included OR time in analysis model	OR time 158 (robot) vs 132 (lap); P=NS Financial COI not discussed

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
Grochola 2019[13]	RCT, single institution	Robot-assisted vs laparoscopic single site elective cholecystectomy	3	30 robot 30 lap	"Costs generated in the operating theatre include consumables needed for dVSSC and SILS (each patient), non-procedure-specific surgical and anaesthesiologic consumables (costs per min), amortization of equipment and staff salaries (costs per minute). Ward costs divided into medical and non-medical expenses as overhead per min.	Total cost (in Swiss Francs): 9743 (robot) vs 6900 (lap), p=0.001 Driven by: Higher consumables (2921 vs 882, p<0.001), amortization (932 vs 493, p=0.02), overhead costs in OR (1933 vs 1555, p=.017)	Total operative duration: 85.5 (robot) vs 74 (lap), p=NS Authors declared no conflicts
Gustafson, 2016[36]	Retrospective, single institution	Robot-assisted single-incision laparoscopic cholecystectomy (RSILC) vs traditional single incision laparoscopic cholecystectomy (TSILC)	1	38 robot 44 lap	"Operative costs were obtained from the hospital database"	Variable direct supply cost ($1,967 robot vs $1,969 lap, p=0.99) Variable direct labor cost ($1,234 robot vs $1,122 lap, p=0.34). Fixed direct cost:$8,961 robot vs $5,379 lap, p<0.0001 Mean service item charges (not defined):$14,594 robot vs $9,347 lap, p<0.0001). Total cost: $8,961.00 robot vs $5,379.00 lap	OR time 98 robot vs 68 lap, p<0.0001 Authors declared no conflicts

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
Hagen 2018[25]	Retrospective, single institution	Robot-assisted single site vs lap multi-port	Did not specify	99 robot 99 lap (matched analysis)	"Cost of the primary procedure was calculated including the capital investment and maintenance of robot with a flat fee per case as per hospital, instruments, and accessories per standardized OR procedure set, cost per OR-time of 17.3 USD per min in OR, and cost of hospitalization USD 627 for outpatients, and USD 1425 per day for inpatients as either previously established or per guidance of medical controlling department."	Total cost of index procedure $6158 (robot) vs $4288 (lap), p<0.0001 In addition: cost of follow-up surgery was $695 (robot) vs $0 (lap), p=0.02	Operative time: 97 min (robot) vs 94 min (lap), P=NS Incisional hernia requiring surgery rate: 7% (robot) vs 0% (lap), p=0.014 Author financial COI with Intuitive
Hawasli, 2016[55]	Retrospective, single institution	Robot-assisted cholecystectomy (14/26 with single incision RC, all included in 1 analysis) vs laparoscopic cholecystectomy (26/220 with single incision LC, all included in 1 analysis)	14	26 robot 220 lap	No discussion of cost methods	Mean direct cost: ($2,704.08 RC vs $1,712.50 LC, p<0.0001) Gross median margin w/ no difference ($1,726 LC vs $1,593 RC)	Mean case time RC: 121min vs LC: 98.4min, p<0.001 Mean OR time: RC: 86.6min vs LC: 63.9 min Financial COI not discussed
Higgins 2016[61]	Retrospective, single "health system"	Elective robot-assisted vs laparoscopic cholecystectomy	Did not specify	39 robot 343 lap	**See Footnote 1**	Total supply cost: $1699 (robot) vs $631 (lap), p<0.01	Case duration: 84 min (robotic) vs 76 min (lap), p=NS Authors had no financial ties to Intuitive

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
Kaminski 2014[58]	Retrospective, National Inpatient Sample (2010-2011)	Robot-assisted vs laparoscopic cholecystectomy for gallstone disease	Did not specify	524 + 1084 (robot, 2010/2011) 362,971 + 370,958 (lap, 2010/2011)	"NIS data include total charges for individual hospitalizations. HCUP provides cost-to-charge ratios, to convert charges to estimated hospital costs. Costs calculated as product of total charges and cost-to-charge ratio. Hospital costs reflect money expended for patient care (not physician expenses). Indirect (non-medical) costs were not available. NIS data don't allow calculating attributable costs."	Total costs: $21346 (robot) vs $13829 (lap) in 2010, p<0.05 $18224 (robot) vs $14181 (lap) in 2011, p<0.05	Authors declared no conflicts
Kane 2020[57]	Retrospective, Single Institution	Robot-assisted vs laparoscopic cholecystectomy	2	106 robot, 1060 lap	"Financial data were obtained from the Institutional Clinical Data Repository; Inflation estimates of the Center for Medicare and Medicaid Services Inpatient Prospective Payment System were used to adjust cost to 2017 US dollars to account for medical-specific inflation."	Hospital cost: $6611 (robot) vs $4930 (lap), p<0. 0001	Total OR time 185 min (robot) vs 160 min (lap), p<0.001 Authors declared no conflicts
Khorgami 2019[49]	Retrospective, National Inpatient Sample (2012-2014)	Robot-assisted vs laparoscopic cholecystectomy	Did not specify	1271 robot 69,402 lap	"Hospital total charges were converted to cost estimates using hospital specific cost-to-charge ratios provided by HCUP. Average total cost of hospitalization was compared for the LS and RAS cohorts. Difference between average costs of laparoscopic vs robotic were calculated for each surgical subgroup."	$10,944 (robot) vs $9618 (lap), "statistically significant", no p-value provided	Authors declared no conflicts

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
Lescouflair 2014[42]	Retrospective, single institution Abstract only	Robot-assisted single incision laparoscopic cholecystectomy (RSILC) vs single incision laparoscopic cholecystectomy (SILC)	1	41 RSILC 41 SILC	"Outcomes and cost were compared between the 2 groups." "Secondary outcomes include duration of narcotic use, time to independent performance of daily activities and cost."	Cost: $3,673 SILC vs $7,518 RSILC, p=0.056	OR time (min): RSILC 96.7 vs SILC 65.2 min, p<.00001 Conflicts not reported
Li, 2017[28]	Retrospective, single institution	Single-site RC vs conventional LC (Number of ports not specified)	2	78 robot 367 lap	"Assessed data of total operation time, length of hospital stay, hospital charge, outpatient department (OPD) visits after discharge, and OPD service charges."	Results in New Taiwan Dollars: Average hospital charge: RC: 204,125 vs LC: 49,218, p=0.001 Average OPD charge: RC: 836.6 vs 509.6, p=0.001	OR time higher for RC (RC: 75.7min vs 64.37min,p=0.035) Authors declared no conflicts
Morris 2014[59]	Budget impact model for the UK NHS Abstract only	Robot-assisted vs laparoscopic cholecystectomy	NA	NA	"A model-based economic evaluation investigating cost of procedure accounting for operating staff, assistant time, theatre time, laparoscopic and robotic systems, instruments and LOS. Data from published sources."	Lap 2703 pounds vs robot 2877-15,253 pounds depending on service life and number of procedures per year	Conflicts not reported

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
Newman 2016[62]	Retrospective, single institution	Traditional lap vs single site lap vs single site robot-assisted	Did not specify	39 robot 11 single lap 50 traditional lap	**See Footnote 2**	"Direct variable surgeon cost": traditional lap $929 Single incision lap $1407 Robotic $2608 (all comparisons p<0.05)	Exact values not provided for OR time, ~ 65-75 for traditional, ~ 75-110 for single incision lap, ~ 90-105 for robot Authors declared no conflicts
Pokala 2019[56]	Retrospective, Vizient national database	Lap vs robot-assisted cholecystectomy for minor or moderate severity of illness	Did not specify	1,314 robot 53,028 lap	"Ratio of cost-to-charge (RCC) methodology is applied to estimate the cost of patient care along service lines"	Total cost: $8620 (robot) vs $6503 (lap), p<0.001	LOS: 3.27 (robot) vs 3.1 (lap), p<0.001 One author had financial COI with a robotic surgical company
Rosemurgy, 2014[50]	Retrospective, single institution	Laparoscopic vs Robot-assisted Cholecystectomy (did not specify how many incisions)	Did not specify	31 robot 201 lap	"Through the Decision Support Team, … Hospital Charges, Hospital Cost, Net Revenue, earnings before depreciation, interest, and taxes (EBDIT), and Net Income. Hospital Charges were the value requested for reimbursement. Hospital Cost was the value of money used to produce care described. Net Revenue defined as money received, regardless of cost of operation. EBDIT defined as Net Income before depreciation, interest, and income taxes. Net Income is value after Hospital Cost has been applied to Net	Charges RC $33,238.42 vs LC $25,055.85, p<0.01 Net revenue: RC $9,121.49 vs LC $6,512.61, p = 0.29 EBDIT: RC $6,196.07 vs LC $3,507.86, p=0.26 Net income: RC $5,848.59 vs LC $3,058.83, p=0.25	Operative duration: RC 140 vs Lap 93, p<0.01) No authors had financial ties to Intuitive

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
					Revenue. Hospital Cost data were subdivided into variable costs, fixed costs, supply costs, drug costs, equipment costs, and facility costs. Fixed costs were defined as expenses that were not dependent on the level of care provided by the hospital. Facility Costs included basic Hospital Costs which cannot be traced to individual patient care and are, rather, allocated to all patients adjusted for severity of intervention and illness.	Variable costs : RC $1,714.30 vs LC $1,449.54, p=0.022 Fixed costs: RC $1,826.90 vs $1,915.93, p=0.1665 Supply costs: RC $594.74 vs LC $636.65, p=0.4191 Drug costs: RC $92.91 vs LC $76.93, p=0.5575 Equipment costs RC $336.96 vs LC $345.14, p=0.5076 Facility costs: RC $22.60 vs LC $22.71, p=0.3099 Total costs: RC $4,723.26 vs $4,578.88, p=0.7265	
Strosberg, 2017[51]	Retrospective, single institution	Robot-assisted vs laparoscopic cholecystectomy (did not specify how many incisions)	1	97 lap (total) 140 robot (total) 35 lap (cost analysis)	"Cost data was obtained for each patient in the study group by our institution's financial division. Variables including total charges, total payments, total direct cost, total indirect cost, and total overall cost were collected. Direct cost defined as the sum of	Total charges: RC $33,120 vs $21,024, p<0.01 Total payments: RC $7,478 vs $5,887, p=0.34	Length of surgery longer for RC (74.5min vs 56min, p<0.01)

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. (Additional cost-pertinent outcomes and financial COI)
				68 robot (cost analysis) *Patients that had IOC, conversion to open or did not have a payment were excluded from cost analysis	operative and hospital cost. Revenue was calculated as total payments minus total overall cost. Exclusion for cost analysis included cases with uncaptured operative and in-hospital payments, inpatient procedures, and cases with intraoperative cholangiogram or conversion to open.”	Total direct cost: RC $4,692 vs $2,983, p<0.01 Total indirect cost: RC ($4,243 vs $2,801, p<0.01 Total cost: RC $8,870 vs $5,771, p<0.01 Median revenue: RC -848 vs 186, p<0.01	

Footnote 1: "All data were obtained from the Surgical Profitability Compass Procedure Cost Manager System. Outcomes measured: LOS, case duration, and total supply cost. Total supply cost accounted for the cost of mesh. For robotic cases, total number and cost of robotic instruments were determined. Cost accounting for robotic instruments is determined by the purchase price of a particular instrument distributed equally among all the patients in whom the instrument was used."

Footnote 2: "We developed mechanics that could identify the portion of procedure cost under control of the surgeon. This was defined as direct variable surgeon cost (DVSC): surgical supply cost (drapes, gloves, etc); physician preference items; technology cost (per-use laparoscope cost, service contract amortized); and procedure time cost was variable cost of operating room use: 2.5 full-time equivalents per case minute. Proprietary robotic instruments are disposable after a pre-programmed number of uses, 5 or 10. Total cost of instrument divided by intended number of uses as each case cost: not corrected for actual number of uses.”

Many of the studies had significant limitations, primarily related to the measurement of costs. Studies varied in terms of the detail provided as it relates to cost, with some providing no information at all. Others provided more specifics but only looked at 1 component of cost, such as disposable supply costs. Given the upfront cost of the robot, including the purchase price and ongoing maintenance costs, these cost assessments are incomplete. Studies also varied in their use of charges, payments, and costs, each of which will be more relevant to different parties. Charges, for example, are rarely paid by insurers and do not necessarily reflect the resources expended to care for the patient. Using cost-to-charge ratios to convert charges to costs is a blunt measure that is likely inaccurate, especially in surgery.[11] Even among studies that focused on hospital costs, whether they included staff costs or indirect costs varied from 1 study to the next and these details were often not explicitly mentioned. As a result, cost estimates varied markedly across studies from as low as $1400 to as high as $33K. No study commented on updating costs based on inflation nor did they reference any type of recognized methodology when reporting cost information (*eg*, Second Panel on Cost Effectiveness, CHEERS).

Summary of Findings

While there are a number of studies comparing robot-assisted versus laparoscopic surgery for cholecystectomy, all had significant limitations, primarily surrounding the cost methodology used (or lack of methodology). Nevertheless, there was an almost unanimous finding, including in randomized data, that the robot-assisted approach is more expensive than laparoscopic.

Certainty of Evidence for Key Question 2A

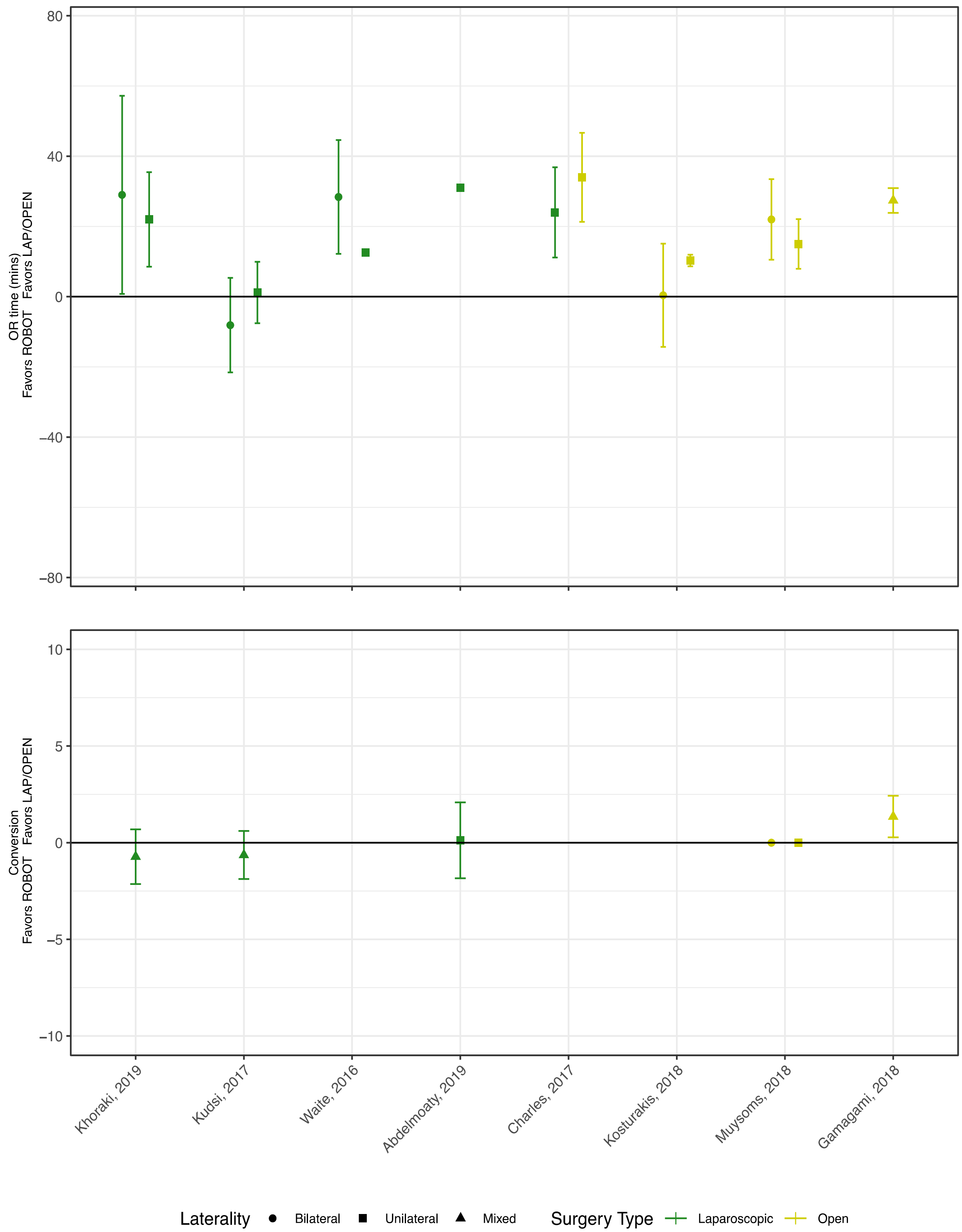
Despite wide heterogeneous methodologic approaches to assessing cost in these studies and differing definitions of cost, nearly all found that robot-assisted approach for cholecystectomy was more expensive than laparoscopic. This directness and consistency support that that we have moderate certainty that robot-assisted is more expensive than laparoscopic cholecystectomy. How much more expensive is not known with precision.

KEY QUESTION 1B – INGUINAL HERNIA SURGERY: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for inguinal hernia repair?

We identified 23 publications that met inclusion criteria. There was 1 RCT, which was a US multi-institutional study of 102 patients assessing short-term outcomes between robot-assisted and laparoscopic unilateral inguinal hernia repair.[63] The remaining 22 studies were observational. Of these, 16 specified laterality in the patient demographics.[64-79] 4 studies reported on unilateral inguinal hernia only, [64,68,71,75] while 12 reported on both unilateral and bilateral.[65-67,69,70,72-74,76-79] The robot-assisted approach was compared to the laparoscopic approach in 18 studies.[12,64,65,68,70-83] Similarly, the open approach was compared to robot-assisted in 14 studies.[12,66-72,77,79,80,82-84] 8 studies included primary and recurrent hernias.[67,69,70,73-76,78] Of the remaining 14 studies, 5 reported only on primary hernias[68,71,79,80,84] and the other 9 did not specify.[12,64-66,72,77,81-83] Two studies were performed outside of the US.[72,73] Also, 3 studies reported outcomes from patients who were served at the Veterans Affairs hospital system.[67,68,70] 8 studies utilized prospectively maintained datasets.[64,68,,71,73,77,80,82,84] The studies varied in size from 55 to 75,981 patients. Propensity matching was performed in 5 studies.[12,66,69,77,83] Of note, 2 studies published by the same group utilized overlapping patient samples,[66,69] of which 1 study only examines the outcomes for the subgroup of patients who are obese.[66] Thus, only the study assessing the broader subset of patients is plotted in the subsequent figures.[69]

Intraoperative outcomes included OR time and rate of conversion from robot-assisted or laparoscopic surgery to open (Figure 5). Of the 8 studies included in this analysis, 5 compared robot versus laparoscopic approach, and 4 compared robot to open approach.[65,67-69,73-75,78] With 2 exceptions, all studies found that OR time was longer for the robot-assisted approach compared to either the laparoscopic approach or the open approach. One study reported similar increased OR time with unilateral laparoscopic robot-assisted inguinal hernia repair compared to robot-assisted laparoscopic surgery.[67] However, there was no evidence of differences between the 2 approaches for bilateral inguinal hernia repair. Another study assessed the learning curve of an experienced surgeon and found length of OR time decreased with experience and was not different at the end of the study.[74] There was no evidence of differences in conversions between robot-assisted and laparoscopic approaches.

Figure 5. Inguinal Hernia Intraoperative Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted inguinal hernia repair and either laparoscopic (green) or open (gold) approaches.

Four postoperative short-term (≤30 days) outcomes were assessed for inguinal hernia repair: LOS, surgical site infections (SSI), readmissions, and total complications (Figure 6). Of the 5 studies assessing outcomes for LOS,[65,69,75,77,78] 2 studies demonstrated significantly decreased inpatient LOS for robot-assisted inguinal hernia repair compared to open approach,[69,77] and 1 of these studies[77] demonstrated significantly decreased inpatient LOS for robot-assisted repair compared to laparoscopy as well. We elected to only graph the outpatient LOS in the corresponding figure, for which there was no difference among the 3 approaches, as this represents the more common disposition for this surgery. Two studies that looked at unilateral repairs did not show a difference between robot-assisted and laparoscopic approaches.[75,78] The final study reported outcomes for both unilateral and bilateral repairs, and they also found no difference in LOS for robot-assisted versus laparoscopic approach.[65]

Of the 7 studies assessing outcomes for SSI,[63,64,67-69,74,78] the RCT reported a trend to lower SSI rate when comparing robot-assisted to laparoscopic surgery,[63] and 2 studies reported a trend to lower SSI rate in robot-assisted surgery compared to open,[67,69] but none of these studies met statistical significance (Figure 6). In contrast, 2 studies reported a non-significant trend to higher SSI rate in robot-assisted surgery compared to laparoscopic and open surgery.[68,78] The 2 remaining studies did not report a significant difference in SSI rates between robot-assisted versus laparoscopic approaches.

Five studies assessed outcomes for readmission following inguinal hernia repair.[64,68,69,74,78] One study that compared all 3 approaches for unilateral hernias found that readmission rates were lower for robot-assisted as compared to either laparoscopic or open approaches.[68] The remaining 4 studies did not find a significant difference in readmission rates: 3 assessed robot versus laparoscopic repair (unilateral and a mix of laterality),[64,74,78] and 1 assessed robot versus open (for mix of laterality).[69]

Nine studies assessed outcomes for total complications.[63,64,67-69,71,73,74,78] Only 1 observational study found lower complication rates for the robot-assisted approach, which was seen in both the laparoscopic and open comparative arms.[71] Of note, this study looked at only unilateral hernia repair. The remaining 10 studies, including the RCT, did not demonstrate significant differences in complications by approach: 6 studies assessed robot-assisted compared to laparoscopic approach (4 of which were on unilateral and 2 were mixed laterality)[63,64,68,74,75,78] and 4 assessed robot-assisted to open repair (2 on unilateral hernias, 1 on bilateral hernias, and 3 on a mix of laterality[67-69,73]).

Figure 6. Inguinal Hernia Postoperative Short-term Outcomes

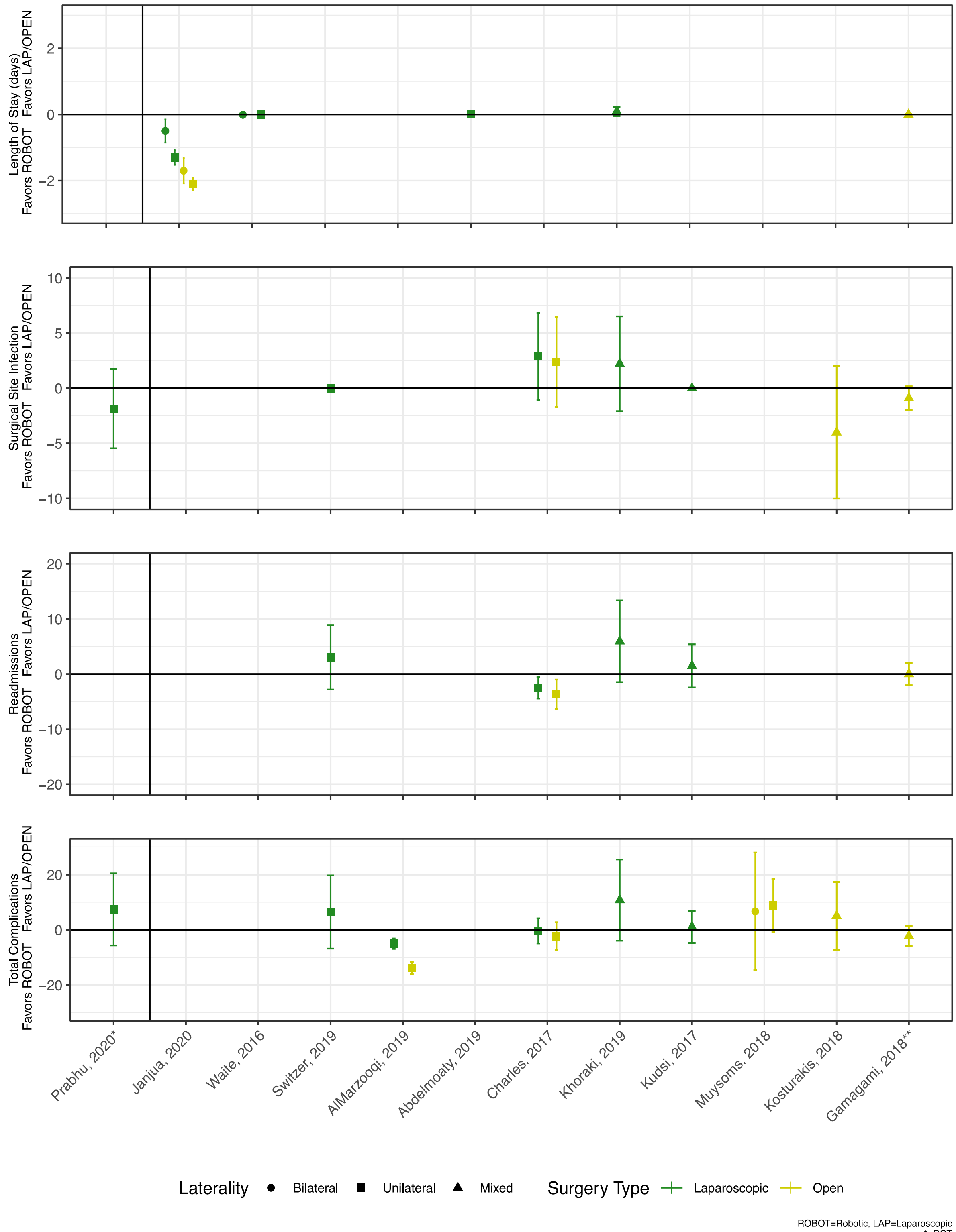
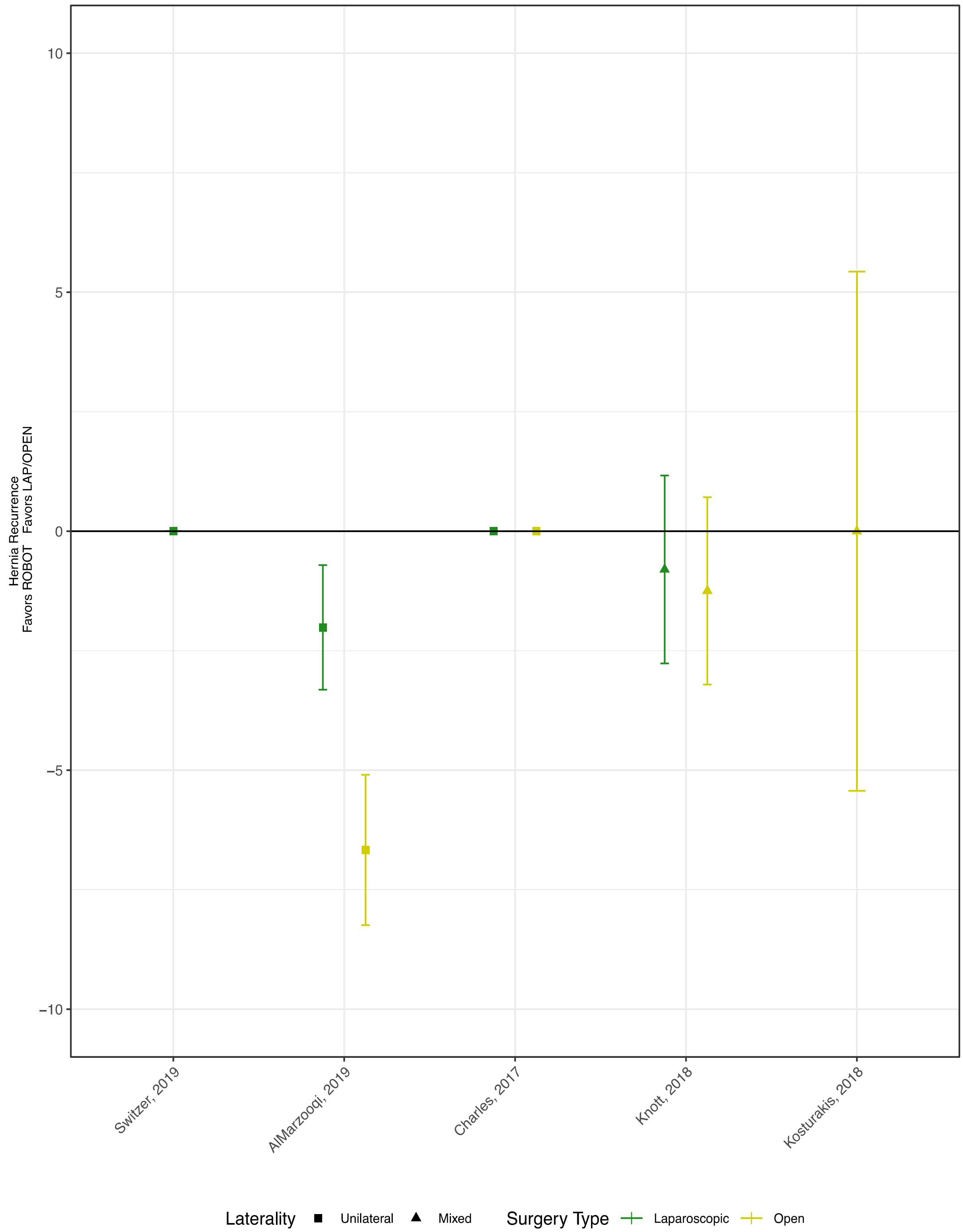


Figure 6 footnote: Only outpatient LOS was plotted for the LOS outcome.
Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted inguinal hernia repair and either laparoscopic (green) or open (gold) approaches.

For long-term outcomes, 5 studies assessed inguinal hernia recurrence (Figure 7).[64,67,68,71,80] One study demonstrated lower recurrence rate for the robot-assisted approach as compared to both laparoscopic and open repair (for unilateral hernia repair).[71] Two did not demonstrate a statistically significant difference that assessed both robot-assisted to laparoscopic and open comparative arms.[68,80] Two additional studies also didn't show differences in recurrence rates: 1 assessed robot-assisted to laparoscopic comparing unilateral hernia repairs,[64] and another study comparing a mix of hernia laterality for robot to open repair.[67]

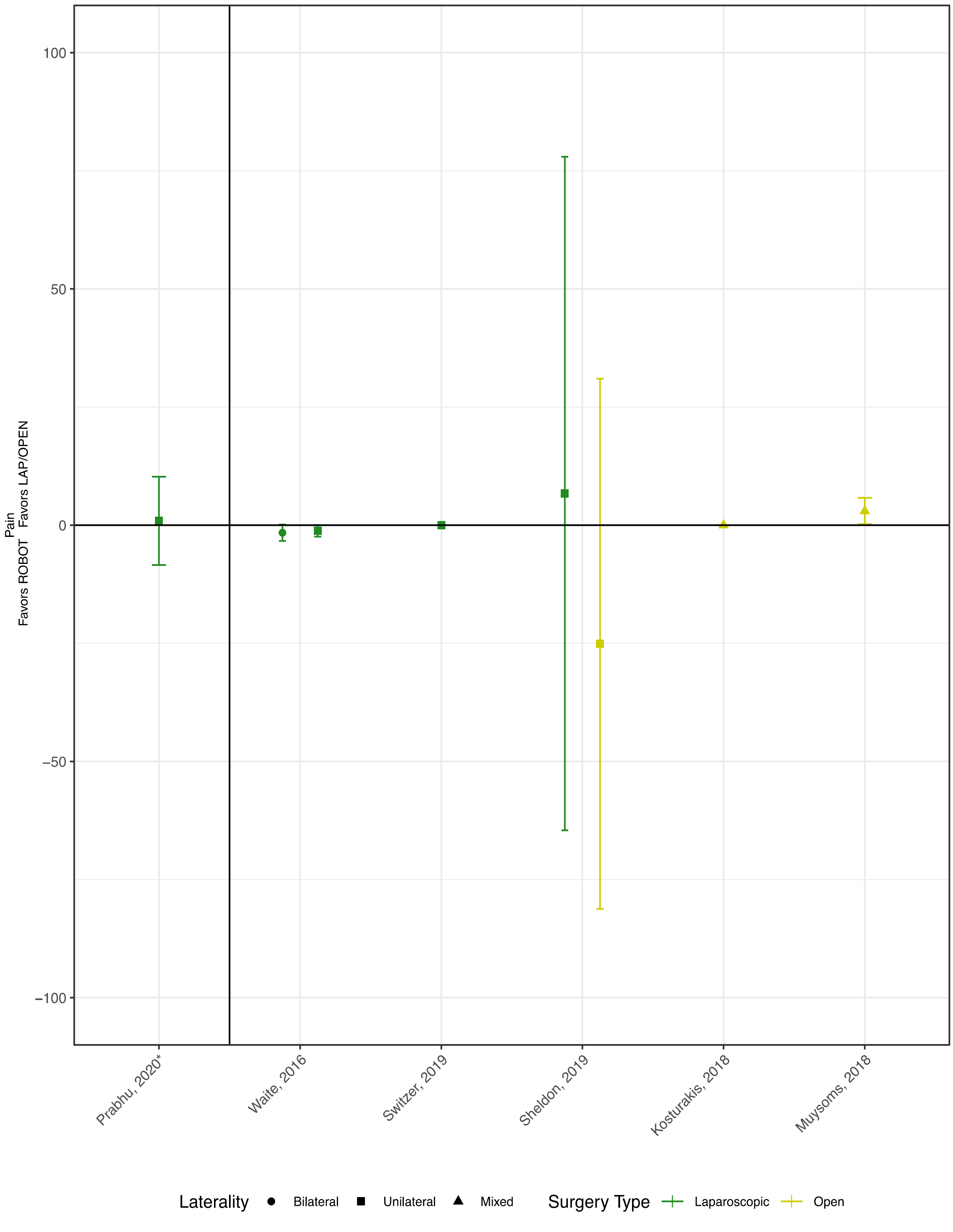
Figure 7. Inguinal Hernia Postoperative Long-term Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted inguinal hernia repair and either laparoscopic (green) or open (gold) approaches.

Six studies assessed postoperative pain following inguinal hernia repair (Figure 8).[63-65,67,73,79] The RCT did not show a significant difference in pain outcomes for robot-assisted compared to laparoscopic inguinal hernia repair.[63] One observational study reported worse pain for the robot-assisted approach as compared to open repair for a mix of hernia laterality.[73] The remaining observational studies did not demonstrate a significant difference in pain among robot-assisted, laparoscopic, and open inguinal hernia repair for unilateral, bilateral, and mixed laterality repairs.

Figure 8. Inguinal Hernia Postoperative Pain Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted inguinal hernia repair and either laparoscopic (green) or open (gold) approaches.

Summary of Findings

Operative room time was longer in patients treated with robot-assisted inguinal hernia repair compared to laparoscopic or open repair, particularly for unilateral hernia. There were no differences in conversions between robot-assisted and laparoscopic approaches. In terms of LOS, there may be a signal of a small benefit favoring the robot-assisted approach compared to open surgery for inpatient stays, but no difference for outpatient surgeries, which is the more common practice. There does not appear to be a signal of benefit with regard to SSI for the robot-assisted approach compared to laparoscopic or open surgery. There may be a small signal of benefit for lower readmissions with the robot-assisted approach for unilateral hernias. Regarding total short-term postoperative complications and hernia recurrences, there is minimal to no benefit of the robot-assisted approach for inguinal hernia repair compared to the laparoscopic or open approaches. Most studies demonstrated no difference among approaches when assessing postoperative pain.

Certainty of Evidence for Key Question 1B

Only 1 RCT was included in our analysis, for which there was greater certainty of evidence; however, it was judged as having moderate study limitation due to its single-blinded design with unclear allocation concealment and blinding of outcome assessment and potential for author bias. Due the observational nature of all remaining eligible studies, the study limitations were high and certainty of evidence was subsequently lower. We judged the certainty of evidence for the outcomes of longer OR time for robot-assisted inguinal hernia repair compared to laparoscopic and open inguinal hernia repair as low, primarily because data was imprecise. We judged the certainty of evidence that LOS for inpatient stays following robot-assisted surgery is shorter compared to open repair and no difference in outpatient LOS as moderate. Evidence that LOS for robot-assisted was not different compared to laparoscopic repair was determined to be moderate. We judged the certainty of evidence that SSI rates following robot-assisted surgery were not different as compared to laparoscopic and open repair as low due to inconsistency and imprecision of the data. We deemed certainty of evidence that readmissions following robot-assisted surgery were similar to the other 2 approaches as low based on inconsistency in the data. The evidence of no difference in major complications and recurrences among the surgical techniques was assessed as very low due to inconsistency and imprecision of the data. The certainty of evidence that there is no difference in postoperative pain among the 3 approaches was judged as low due to inconsistency and imprecision.

Table 3. Certainty of Evidence for Inguinal Hernia Repair Studies

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Intraoperative					
Operating Room Time Robot > Open/Laparoscopic	Observational studies: High	Consistent	Direct	Imprecise	Moderate
Postoperative Short-Term Outcomes					
Length of Stay Robot < Open (inpatient)	Observational studies: High	Consistent	Direct	Precise	Moderate
		Consistent	Direct	Precise	Moderate

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Robot = Open (outpatient) Robot = Laparoscopic		Consistent	Direct	Precise	Moderate
Surgical Site Infection Robot = Open/ Laparoscopic	RCT: Moderate Observational studies: High	Inconsistent	Direct	Imprecise	Low
Readmissions Robot = Open/ Laparoscopic	Observational studies: High	Consistent	Direct	Imprecise	Low
Total complications Robot = Open/ Laparoscopic	RCT: Moderate Observational studies: High	Inconsistent	Direct	Imprecise	Low
Postoperative Long-Term Outcomes					
Hernia Recurrence Robot = Open/ Laparoscopic	Observational studies: High	Consistent	Direct	Imprecise	Very Low
Pain Robot = Open/ Laparoscopic	RCT: Moderate Observational studies: High	Inconsistent	Direct	Imprecise	Low

KEY QUESTION 2B – INGUINAL HERNIA SURGERY: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for inguinal hernia repair?

There were 5 studies that reported cost information for inguinal hernia repairs. There was 1 RCT.[63] Of the remaining 4 studies, 3 were single-institution retrospective reviews[65,68,78] and the last was a retrospective review of a national database.[77] The 1 randomized trial compared robot-assisted and laparoscopic transabdominal hernia repairs at 6 institutions in the United States. They limited inclusion to only surgeons who had performed at least 25 prior robot-assisted and laparoscopic procedures. With respect to cost, they found the robot-assisted approach had over twice the hospital cost of the laparoscopic approach ($3,258 vs $1,421). They did not include capital equipment costs in their analysis.

Three of the 4 remaining studies also found the cost of the robot-assisted approach to be higher than the cost of the laparoscopic approach. Details regarding what went into cost estimates were generally limited. One study did not mention any information aside from "financial data were obtained from the institutional Clinical Data Repository." The 1 study that did not find a cost difference excluded a large component of robot-assisted costs (purchase price of equipment and annual contract),[2] likely accounting for their null findings. None of the studies comment on how they accounted for staff/labor costs, which are the largest component of OR costs.[10] This point is important as all 4 that reported operative time found operative time to be longer in the robot-assisted arm compared to the comparison arms. None of the studies reference a recognized methodology when reporting cost information (*eg*, Second Panel on Cost Effectiveness, CHEERS).

Table 4. Evidence Table for Inguinal Hernia Cost Studies

Author, Year, Number	Study Design, Number of Institutions	Comparison(s)	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. outcomes
Charles, 2017[68]	Retrospective review, single institution	Robot-assisted vs lap vs open primary unilateral inguinal hernias	10	69 robot 241 lap 191 open	"Financial data were obtained from the institutional Clinical Data Repository."	Hospital cost: Robot $7162, lap $4527, open $4264 (p<0.001)	OR time longer for robotic surgery (105 min robot, 81 min lap, 71 min open; p<0.001) No difference discharge home same day
Janjua 2020[77]	Retrospective, HCUP-State Inpatient Databases & AHA data from 8 states (2009-2015)	Robot-assisted vs lap vs open inguinal hernia repairs for inpatients	Not stated	2960 (open), 2960 (lap), 1480 (robot); propensity matched	"HCUP-provided cost-to-charge ratios were used to calculate cost by multiplying total charges with cost-to-charge ratio. For dataset containing cost, years 2011 - 2014 for Iowa were dropped because no cost data was available."	$18,494 (robot) vs $14,738 (lap) vs $16,740 (open); p<0.0001 for robot vs open and lap comparisons	LOS: 5.0 (open), 3.6 (lap), 2.2 (robot); p<0.0001 for robot vs open and lap comparisons
Khoraki 2019[78]	Retrospective, single institution	Robot-assisted vs lap inguinal hernia repair	4	45 (robot) 138 (lap)	See footnote 1	Total hospital cost: $9994 (robot) vs $5995 (lap), p<0.01	Operative time: 116 min (robotic) vs 95 in (lap), p<0.01
Prabhu 2020[63]	Multi-institutional RCT	Robot-assisted vs lap TAPP	Not stated	54 lap 48 robot	Costs per case at each institution were reported as total cost, operating room cost (cost per min OR time per case), and disposable/ reusable cost, include disposable	Total cost $3258 (robot) vs $1421 (lap); p<0.001	Operative time (skin to skin) 75.5 min (robot) vs 40.5 min (lap), p<0.001

					materials and reusable materials - robotic instruments. Robotic and laparoscopic capital equipment cost were not amortized.		
Waite, 2015[65]	Retrospective, single institution	Robot-assisted vs laparoscopic TAPP repair	Not stated	24 lap 39 robotic	"institution financial department… included direct costs, facility net revenue, and contribution margin" Direct costs were variable costs of surgery (*ie*, mesh, disposable lap equipment, reposable robotic equipment). Capital costs (*ie*, robotic system, lap towers, and non-disposable equipment) **NOT** included.	Average direct cost per case was $3216 (lap) vs $3479 (robot), p=NS	Operative time was longer robotic (77.5 minutes vs 60.7 minutes, p=0.001)

Footnote 1: 3 separate cost analyses were performed: 1. Total hospital costs: estimated cost of anesthesia, operating room, and recovery in addition to the disposable supplies and medications used during surgery. A combination of case-level and time-based system (per 1/2 h increment) used to calculate cost of surgery. Case-level is determined by ASA, procedure complexity, and equipment and staff. 2. Total disposable supplies and categories costs: combined operating room usage with supply pricing. Each surgery had its disposable supplies usage queried. Amount and costs for trocars, fixation devices, meshes, medications, drapes, and all accessories and other disposable equipment were collected. Cost adjusted to 2017 dollars. 3. Capital and service cost of the Robotic da Vinci® Surgical Systems: actual cost of systems was obtained and its depreciation was calculated based on an estimated 6-year lifespan. Capital cost associated with utilizing the robot per case was calculated as total depreciation during the study period divided by number all robotic cases performed by all surgeons. Cost of maintenance services per case was added.

Summary of Findings

Five studies compared the costs of robot-assisted as compared to laparoscopic or open surgery for inguinal hernia repair. While there were significant limitations with the methodology, there is a consistent finding, including from randomized data, that the robot-assisted approach is more expensive than the laparoscopic and the open approach. How much more expensive is not known with precision. However, the lack of cost-effectiveness studies suggests that weighing the balance between the added cost against possible benefits and risks of the robot-assisted approach are not known.

Certainty of Evidence for Key Question 2B

Based on directness and consistency in the evidence, including from randomized data, we have moderate certainty that robot-assisted surgery is more expensive than laparoscopic or open surgery for inguinal hernia repair. As there were no formal cost-effectiveness analysis, no conclusion can be made in that regard.

KEY QUESTION 1C – VENTRAL HERNIA SURGERY: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for ventral hernia repair?

We identified 21 publications that met the inclusion criteria for assessing clinical outcomes. There was only 1 RCT, which was a conference abstract comparing robot-assisted to laparoscopic ventral hernia repair.[85] The remaining 20 studies were observational studies, of which 7 studies compared robot-assisted ventral hernia repair to open repair only,[86-92] 11 studies compared robot-assisted surgery to laparoscopic surgery only,[76,93-102] and 2 studies compared robot-assisted surgery to both laparoscopic and open approaches.[103,104] Six studies included analysis of patients who underwent transversus abdominis release as a component of the ventral hernia repair.[86-88,90,92,101] The only RCT was a single institutional study from Brazil and included 38 subjects.[85] All of the observational studies were done in the United States; of these, only 4 were specified to be multi-institutional,[87,90,96,97] while 9 were specified to be from a single institution.[76,86,88,92,93,95,100-102] Eleven of the observational studies utilized retrospective data from prospectively maintained databases.[89-92,94,96,98,99,101,103,104] The studies varied in size from 25 to 46,799 subjects. Of the observational studies, 7 studies utilized matching of various preoperative patient or hernia characteristics in their outcome analysis.[87,89,90,96,97,99,103]

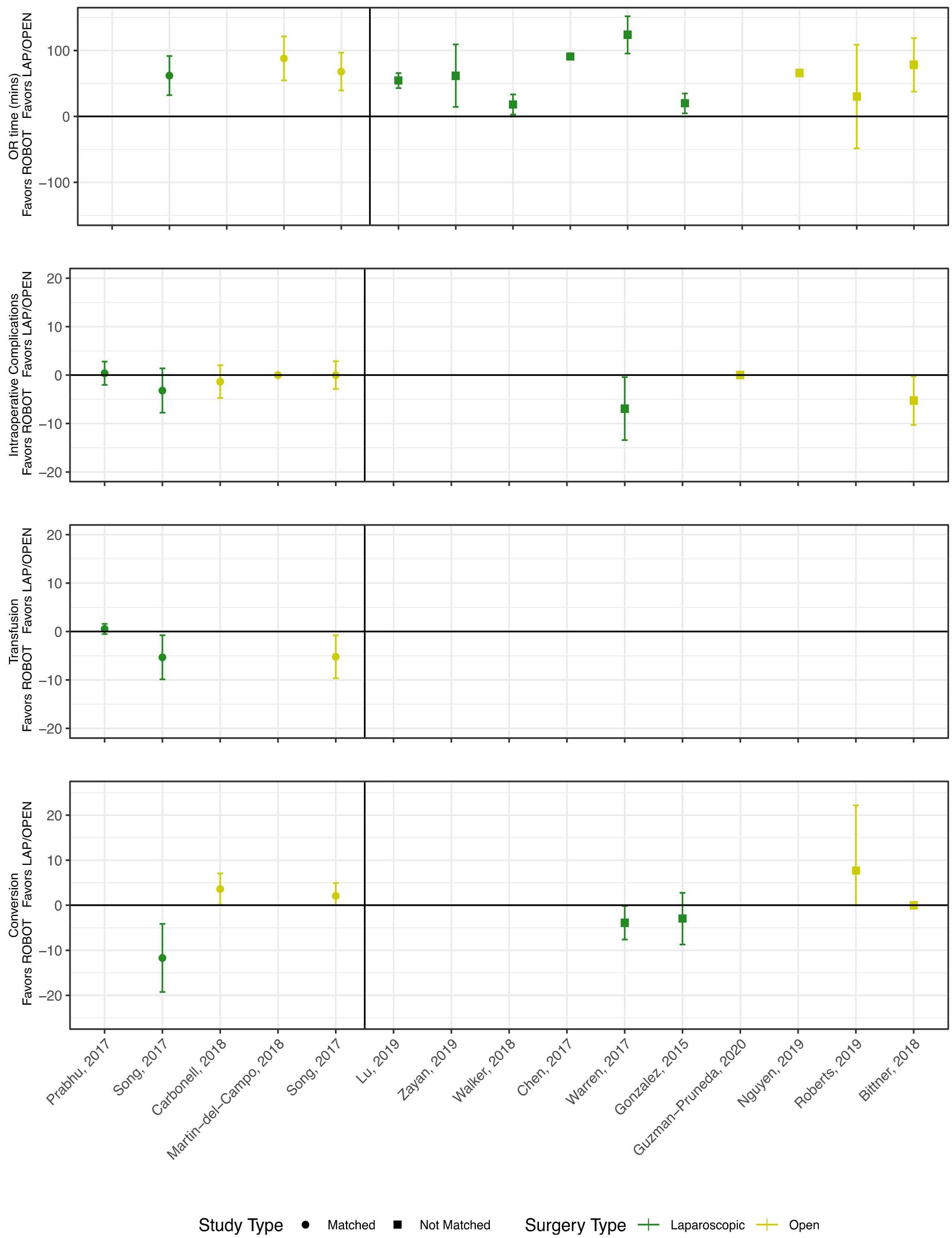
The RCT warrants specific mention.[85] It was very limited in terms of the data the authors presented and was only an abstract. The sample sizes were quite small, 19 in each arm. The study compared robot-assisted ventral hernia to laparoscopic, but other details of the operative techniques were not provided. They did not report on our intraoperative outcomes of interest (OR time, intraoperative complications, transfusions, or conversion to open surgery) or the majority of our postoperative short-term outcomes (LOS, complications, SSI, or readmissions). They did report (without actual supporting data) that "QOL before and after the procedures showed improvement in both groups and but in favor of the robot-assisted group as well as the gain in the abdominal wall function." They reported lower recurrence rate for robot group, 10.5% (2/19) as compared to 21.1% (4/19) at 1 year. One death was reported in the laparoscopic group. They did not comment on any deaths in the robot-assisted group. Therefore, this RCT was not abstracted along with the observational data analyzed below.

Figure 9 presents results for 4 intraoperative outcomes: OR time, intraoperative complications, transfusions, and conversion to open surgery. Fourteen observational studies were included in this subset of analysis.[76,86-88,90-93,95-97,100,101,103] One study compares robot-assisted surgery to both laparoscopic and open approaches,[103] while 7 studies only compare to laparoscopic,[76,93,95-97,100,101] and 6 studies only compare to open surgery.[86-88,90-92] Four studies[87,90,96,103] utilize preoperative patient characteristics for matching, while the remaining 8 do not utilize matching.

Of the 11 studies assessing OR time, all studies demonstrate a statistically significant increase with robot-assisted ventral hernia repair compared to open and laparoscopic approaches,[76,86-

[88,93,95,97,100,101,103] with the exception of 1 study that demonstrated no difference comparing robot to open repair.[92] Of the 7 studies assessing intraoperative complications,[86,87,90,91,96,101,103] 2 unmatched studies demonstrate a significantly decreased complication rate with robot-assisted ventral hernia repair compared to laparoscopic and open repairs,[86,101] and the remaining unmatched study demonstrated no difference in complication rate between robot-assisted and open repair.[91] The 4 matched studies do not demonstrate a significant difference in complication rate among the approaches.[87,90,96,103] Two matched studies were included in the analysis for transfusion,[96,103] of which 1 study demonstrated a significant decrease in transfusions in robot-assisted ventral hernia repair compared to both open and laparoscopic approaches,[103] while the other study did not demonstrate a difference between robot-assisted and laparoscopic surgeries.[96] Of the 6 studies included in the analysis for conversion,[86,90,92,95,101,103] 1 matched[103] and 1 unmatched[101] study each demonstrated a decreased conversion rate to open surgery with robot-assisted surgery compared to laparoscopy, while a third study[95] favored decreased conversion rates with robot-assisted surgery but was not significant. Of the 4 studies assessing robot-assisted conversion rates when compared to open ventral hernia repair, 1 matched study showed a significantly increased conversion rate of robot-assisted surgery,[90] while another matched study demonstrated a non-significant increase in conversion.[103] Of the remaining 2 unmatched studies, 1 showed a non-significant increase in conversion from robot-assisted surgery to open,[92] while there was no difference in the remaining study.[86]

Figure 9. Ventral Hernia Intraoperative Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted ventral hernia repair and either laparoscopic (green) or open (gold) approaches. Studies utilizing matching (circles) are listed in the left-hand side, while studies that did not utilize matching (squares) are listed on the right-hand side.

Figure 10 presents the results for 5 postoperative short-term outcomes: LOS, complications, surgical site infection (SSI), readmissions, and mortality. Nineteen observational studies were included in this subset of analysis.[76,86-88,90-104] Two studies compared robot-assisted surgery to both open and laparoscopic approaches,[103,104] 11 studies compared to only laparoscopy,[76,93-102] and 6 studies compared to only open surgery.[86-88,90-92] Five studies[87,90,96,99,103] utilized matching while the remaining 14 did not.

Of the 18 studies assessing outcomes for LOS,[76,86,87,90-104] 6 studies comparing the robot-assisted to laparoscopic approaches,[76,96,99,101,102,104] of which 2 were matched,[99,105] demonstrated a significantly lower LOS for the robot-assisted arm. All 7 studies comparing robot-assisted ventral hernia repair to the open approach,[86,87,90-92,103,104] of which 3 were matched,[87,90,103] also demonstrated a significantly lower LOS. Within the matched cohort, only the laparoscopic comparison arm of 1 study demonstrated no difference in LOS.[103] In contrast, 1 unmatched study demonstrated a small but statistically significant increase in LOS with robot-assisted surgery compared to laparoscopy.[97] However, the remaining 5 studies did not demonstrate a significant difference.[93-95,98,100]

Of the 13 studies assessing outcomes for complications,[87,90,92,93,95-101,103,104] 4 matched studies revealed a significantly lower rate of postoperative complications of robot-assisted ventral hernia repair compared to both laparoscopic and open approaches,[87,96,99,103] and 1 unmatched study demonstrated a lower robot-assisted complication rate compared to laparoscopy.[93] Only 1 matched study demonstrated a non-significant trend toward lower complication rates in the robot-assisted arm compared to open surgery.[90] In 1 unmatched study, robot-assisted ventral hernia repair demonstrated a slight but significant decrease in complication rate compared to the open approach, while within the same study, the robot-assisted surgery demonstrated a similarly slight but significant increase in complications when compared to laparoscopy.[104] The remaining 6 studies demonstrated no difference in complication rate in robot-assisted ventral hernia repair compared to laparoscopy or open surgery.[86,92,95,98,100,101]

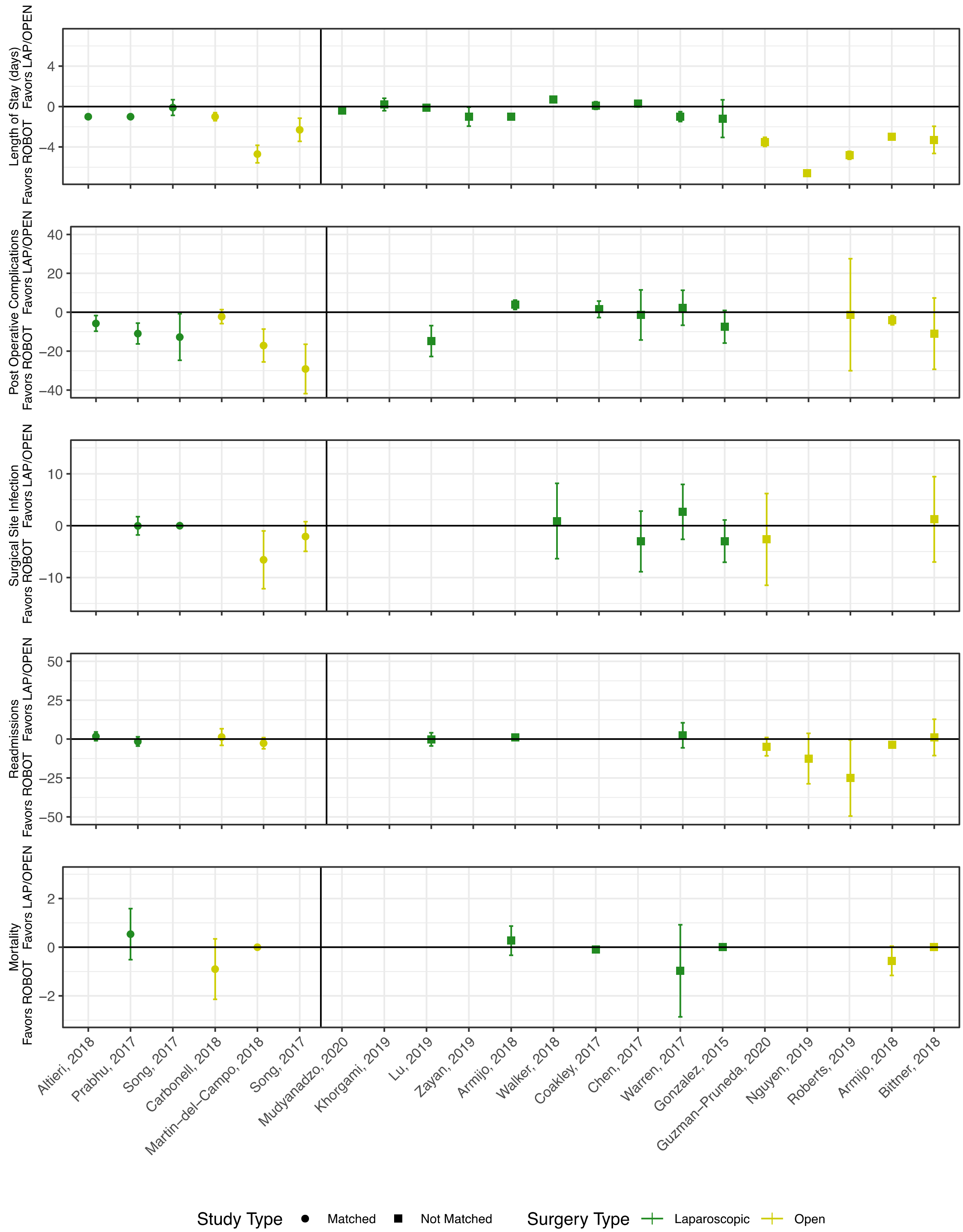
Of the 9 studies examining the outcome of SSI,[86,87,91,95-97,100,101,103] only 1 matched study[87] demonstrated a significantly lower SSI rate with robot-assisted surgery compared to open repair. In a matched study comparing robot-assisted ventral hernia repair to both open and laparoscopic approaches, there was a trend toward lower SSI with robot-assisted surgery when compared to open surgery, but there was no difference when compared to laparoscopic repair.[103] The remaining 7 studies did not demonstrate a significant difference among the approaches in SSI rates.[86,91,95-97,100,101]

Of the 11 studies assessing outcomes for readmissions,[86-88,90-93,96,99,101,104] 1 unmatched study demonstrated significant decrease in readmission rate following robot-assisted ventral hernia repair compared to open.[92] Two other unmatched studies demonstrated non-significant decreases in readmission following robot-assisted surgery compared to open.[88,91] The remaining 4 studies comparing robot-assisted to open surgery[86,87,90,104] including 2 matched studies,[87,90] demonstrated no difference. There was no difference in readmission rate in the 5 studies comparing robot-assisted ventral hernia repair to laparoscopy,[93,96,99,101,104] of which 2 were matched.[96,99]

Of the 8 studies assessing mortality, the data was overall mixed with none of the studies demonstrating significantly different mortality rates among the approaches.[86,87,90,95,96,98,101,104]

While 1 matched[90] and 1 unmatched[104] study demonstrate non-significant trends toward decreased mortality rates with the robot-assisted approach when compared to open surgery, another pair of matched[87] and unmatched[86] studies showed no difference in mortality between these approaches. When comparing robot-assisted ventral hernia repair with the laparoscopic approach, 2 studies,[96,104] of which 1 was matched,[96] had a trend toward increased mortality with robot, while 1 unmatched study[101] trended toward decreased mortality with robot, and the remaining 2 unmatched studies demonstrated no difference between these approaches.[95,98]

Figure 10. Ventral Hernia Postoperative Short-term Outcomes

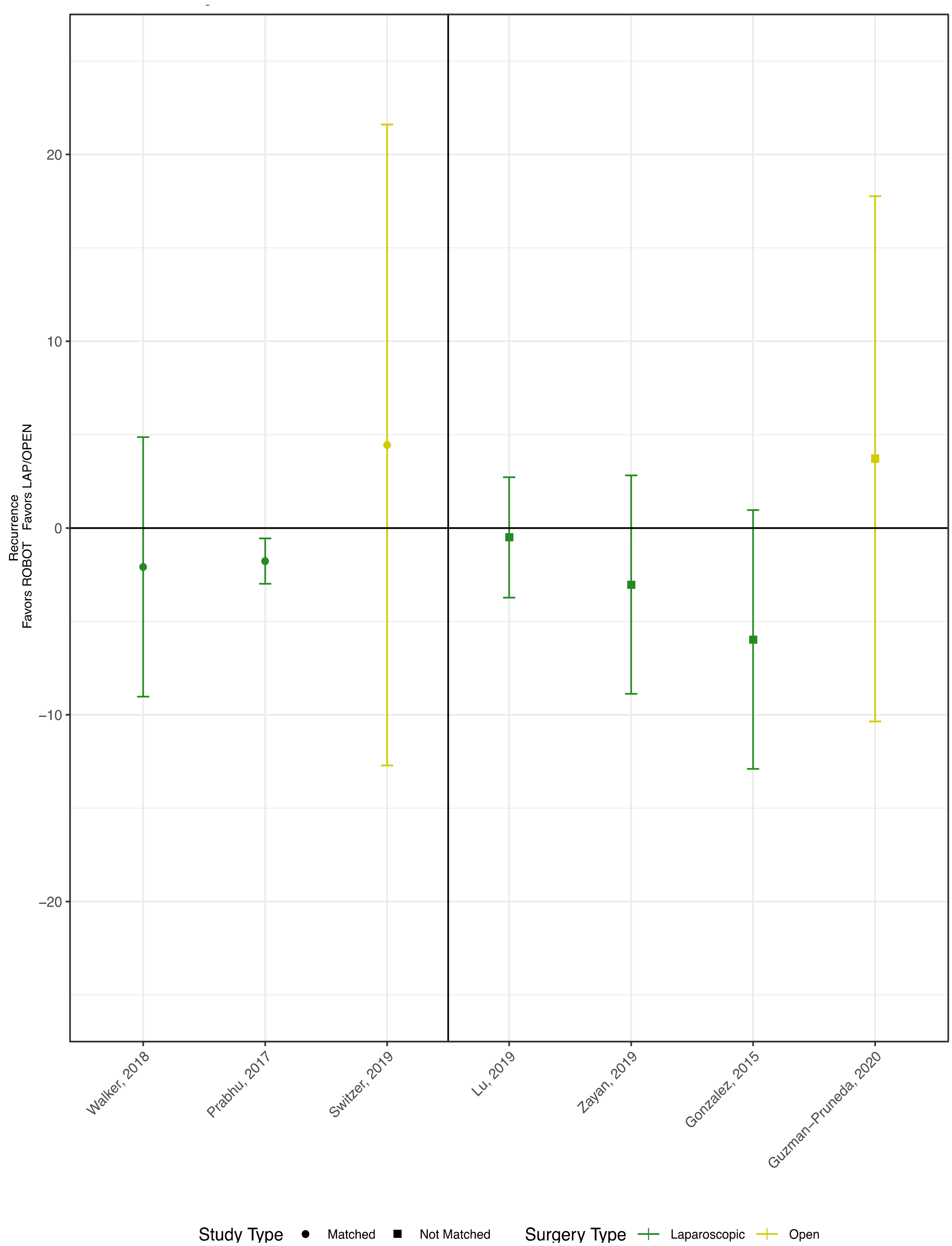


Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted ventral hernia repair and either laparoscopic (green) or open (gold) approaches. Studies utilizing propensity matching (circles) are listed in the left-hand side, while studies that did not utilize propensity matching (squares) are listed on the right-hand side.

Figure 11 presents the results for ventral hernia recurrence, the only postoperative long-term outcome for ventral hernia repair. Of the 7 studies included in this analysis,[89,91,93,95-97,106] 5 studies compared robot-assisted surgery to the laparoscopic approach,[76,93,95-97] while 2 studies[89,91] compared the robot-assisted approach to the open approach. Only 1 matched study demonstrated a slight but significantly decreased recurrence rate following robot-assisted ventral hernia repair compared to laparoscopic repair,[96] while the other matched study[97] and 3 unmatched studies[76,95,97] demonstrated a trend toward decreased hernia recurrence compared to laparoscopic repair without significance. The 2 studies comparing robot-assisted to open approaches revealed a non-significant trend toward increased recurrence rate.[89,91]

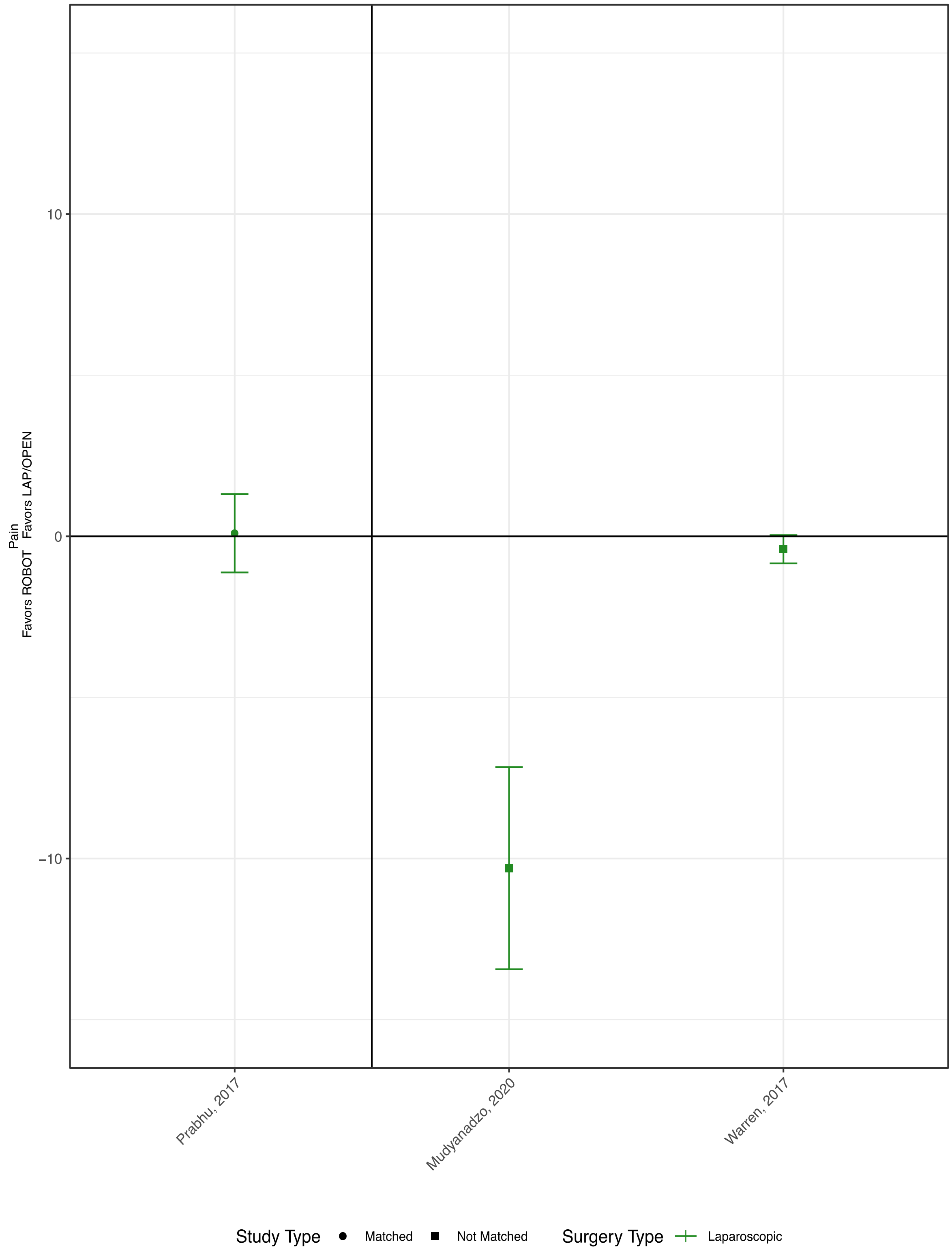
Figure 12 presents the results for postoperative pain following ventral hernia repair. Only 3 studies were included in this analysis,[96,101,102] which all compared robot-assisted surgery to laparoscopic repair. The matched study demonstrated no difference between the approaches,[96] while 1 unmatched study demonstrated a significant decrease in pain following robot-assisted ventral hernia repair,[102] and the remaining unmatched study favored the robot-assisted approach without significance.[101]

Figure 11. Ventral Hernia Postoperative Long-term Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted ventral hernia repair and either laparoscopic (green) or open (gold) approaches. Studies utilizing matching (circles) are listed in the left-hand side, while studies that did not utilize matching (squares) are listed on the right-hand side.

Figure 12. Ventral Hernia Postoperative Pain Outcomes



Graphed is the point estimate and 95% confidence intervals for the difference in the indicated outcome between robot-assisted ventral hernia repair and laparoscopic (green) approaches. Studies utilizing matching (circles) are listed in the left-hand side, while studies that did not utilize matching (squares) are listed on the right-hand side.

Summary of Findings

Operative room time was significantly longer in robot-assisted ventral hernia repair compared to both the laparoscopic and open approaches in all but 1 study included. There was no evidence of a difference in intraoperative complication rate among the 3 approaches. There is a possible trend toward decreased transfusion rate with robot-assisted surgery compared to laparoscopic and open repairs, with 1 matched study demonstrating a significant difference favoring robot-assisted surgery and another demonstrating no difference. With regard to conversion to open surgery, most studies demonstrate a decreased rate of conversion with robot-assisted surgery compared to the laparoscopic approach. Robot-assisted ventral hernia repair appears to have significantly decreased LOS compared to open repair; however, this decrease may be less significant when compared to laparoscopic repair. There is a likely decrease in postoperative complication rate following robot-assisted repair compared to both laparoscopic and open approaches based on the results of matched studies (unmatched studies do not support this trend). There may be a small signal favoring robot-assisted ventral hernia repair for reducing postoperative SSIs compared to open surgery; however, there does not appear to be evidence of a difference when compared to the laparoscopic approach. There is no evidence of a difference in readmission or mortality rates among the approaches. In terms of hernia recurrence, the 2 studies comparing robot-assisted ventral hernia repair to open surgery demonstrated no difference, while there may be a slight trend favoring robot-assisted ventral hernia repair compared to laparoscopic surgery based on results from 1 matched study. Finally, there may be a small signal of decreased postoperative pain favoring the robot-assisted approach when compared to the laparoscopic approach based on significant findings from 1 unmatched study. However, the matched study does not support this.

Certainty of Evidence for Key Question 1C

All studies included in this analysis were observational studies, which decreased the overall certainty of evidence. The 1 available RCT was too limited in detail to use in our analysis. We judged the certainty of evidence for the outcome of increased OR time for robot-assisted ventral hernia repair compared to open and laparoscopic repairs as high due to the consistency among nearly all studies included in this analysis, except for 1 unmatched study. We judged the certainty of evidence that there is no difference in intraoperative complications among the approaches as low due to inconsistency and imprecision. We judged the certainty of evidence that there is the same or slightly decreased rate of transfusion for robot-assisted surgery compared to open and laparoscopic hernia repairs as low because the few matched studies that assessed this particular outcome were inconsistent and imprecise. We judged the certainty of evidence that there is a decreased conversion rate to open surgery with robot-assisted surgery compared to laparoscopic surgery as low, as the data was consistent but imprecise. We judged the certainty of evidence that robot-assisted ventral hernia repair decreased LOS compared to open surgery and less significantly when compared to laparoscopic surgery as moderate, based on preciseness and consistency across matched and unmatched studies. Both outcomes of postoperative complications and SSI were deemed to have low certainty of evidence due to the inconsistency and imprecision of the data. Mortality and readmissions were judged to be equivalent across the 3 approaches with moderate certainty of evidence. There is low certainty that there may be a minimal difference in hernia recurrence favoring robot-assisted ventral hernia repair compared to laparoscopy and no difference compared to open surgery. Finally, there is a low certainty that there is no difference in postoperative pain following ventral hernia repair in the 3 approaches, based on only 2 studies.

Table 5. Certainty of Evidence for Ventral Hernia Repair Studies

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Intra-operative					
Operating Room Time Robot > Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Consistent	Direct	Precise	High
Intraoperative Complications Robot = Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Inconsistent	Direct	Imprecise	Low
Transfusion Robot < Open/ Laparoscopy	Matched observational studies: Moderate	Inconsistent	Direct	Imprecise	Low
Conversion to Open Surgery	Unmatched observational studies: High				
Robot < Laparoscopy	Matched observational	Consistent	Direct	Imprecise	Low
Robot > Open	studies: Moderate	Consistent	Direct	Imprecise	Low
Postoperative Short-term					
Length of Stay Robot < Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Consistent	Direct	Precise	Moderate
Postoperative Complications Robot < Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Inconsistent	Direct	Imprecise	Low
Surgical Site Infection	Unmatched observational studies: High				
Robot < Open	Matched observational	Inconsistent	Direct	Imprecise	Low
Robot = Laparoscopy	studies: Moderate	Inconsistent	Direct	Imprecise	Low
Readmissions Robot = Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Consistent	Direct	Imprecise	Moderate
Mortality Robot = Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Consistent	Direct	Imprecise	Moderate
Postoperative Long-term					
Hernia Recurrence Robot = Open/ Laparoscopy	Unmatched observational studies: High Matched observational studies: Moderate	Consistent	Direct	Imprecise	Low
Pain					
Pain Robot < Laparoscopy	Unmatched observational studies: High	Consistent	Direct	Imprecise	Low

Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
	Matched observational studies: Moderate				

KEY QUESTION 2C – VENTRAL HERNIA SURGERY: what is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for ventral hernia repair?

We identified 6 studies that compared robot-assisted ventral hernia to other approaches and provided some data on costs. Two were single institution studies,[103,107] 2 used the National Inpatient Sample,[94,98] 1 used the Vizient administrative database,[104] and 1 used a surgical registry.[101] One study reported only cost data and no clinical outcomes.[107] All compared robot-assisted to laparoscopic surgery, with 2 also including an open comparison. Three studies found the robot approach to be more expensive than laparoscopic surgery, 1 found the robot-assisted approach had a non-statistically significant higher cost than laparoscopy, and 2 found the robot-assisted surgery and laparoscopy were similar with respect to costs.

As with inguinal hernia, the methodology of the included studies was very limited, especially as it relates to details regarding how costs were derived. Evidence of the diversity of methods used is the fact that cost estimates ranged from as low as $4,000 to as high as $61,000 for the cost of the robot. This reflects the fact that when measuring costs, investigators must be very specific about the perspective (cost vs charge), time frame (just OR, OR and hospital stay, hospital stay + 30/90 days), and explicit details about what is and is not included in cost estimates (direct vs indirect, variable vs fixed, *etc*). None of the studies included all of these details. Most studies provided less than 1 sentence about how cost estimates were derived. Several studies relied on administrative databases and used cost-to-charge ratios to estimate hospital costs. Previous research has demonstrated that these measures are prone to bias, especially in surgery.[11,108] It is unlikely that these methods adequately capture the nuance of cost intrinsic to the robot, such as the amortization of the purchase price, the service contract, and the semi-variable cost of the surgical instruments. As with the inguinal hernia studies, none of these studies comment on staff costs nor did they follow reporting guidelines (*eg*, Second Panel on Cost Effectiveness, CHEERS). Two of the included studies did find the operative time was longer for the robot-assisted approach compared to the laparoscopic approach, with 1 study finding the operative times of robot-assisted cases were approximately double those of the laparoscopic cases (240 minutes versus 120 minutes). When dealing with large differences in time, consideration must be given to staffing costs and, perhaps more importantly, the opportunity cost of not performed cases.

Table 6. Evidence Table for Ventral Hernia Cost Studies

Author, Year, Number	Study Design, Number of Institutions	Comparison	Number of surgeons	Sample Size	Source of cost data	Cost data	Misc. outcomes
Armijo, 2018[104]	Retrospective review of Vizient database	Robot-assisted vs laparoscopic vs open ventral hernia repair	Not stated	39,505 open 6,829 lap 465 robotic	"Ratio of cost-to-charge method applied for estimating cost of patient care…"	Total direct cost: $9000 (open), $7000 (lap), $10,000 (robot)	Median LOS was 5 days (open), 3 days (lap), 2 days (robot)
Coakley, 2017[98]	Retrospective review of National Inpatient Sample (2008-2013)	Robot-assisted vs laparoscopic ventral hernia repair	Not stated	351 robotic 32,243 lap	"Total hospital charges…"	Adjusted model (controlling for CCI, geographic, public vs private etc) mean charges were $41,911 (lap) vs $61,205 (robot)	LOS no different lap vs robot (3.4 days lap, 3.5 days robot, p=NS)
Khorgami, 2019[94]	Retrospective review of National Inpatient Sample (2012-2014)	Robot-assisted vs laparoscopic ventral hernia repair	Not stated	3600 lap 99 robotic	"Hospital total charges were converted to cost estimates using hospital specific cost-to-charge ratios provided by HCUP. Admissions with total charges below 0.1 percentile or above 99.9 percentile were considered outliers and excluded from analysis."	$10,739 (lap) vs $13,441 (robotic); p-value not provided	LOS 2.7 days (lap) vs 2.9 days (robot); p-value not provided
Song, 2017[103]	Retrospective review, Premier Perspectives Database, Abstract only	Robot-assisted vs lap vs open elective ventral hernia repairs in patients with BMI > 30	Not stated	2 samples (depending on comparison)… 94/94 robot vs lap and 96/96 robot vs open	"total cost included direct cost and overhead cost and was adjusted for inflation to 2015 US dollars"	All were the same… approximately $10,500 (p=NS)	OR time was 231 min (robot), 169 min (lap), and 163 min (open)… robot and lap (<.0001) LOS was 3.1 days (robot), 3.2

							days (lap), 5.3 days (open); robot vs open (p=0.003)
Tan, 2017[107]	Retrospective review, single institution, Abstract only	Robot-assisted vs laparoscopic ventral hernia repairs	1	46 robotic 47 lap	Primary outcome: "disposable operating room costs" Secondary outcomes: "technical direct costs such as costs from the laboratory or pharmacy…"	Median total variable costs were $4,551 (lap) versus $4362 (robot), p=NS; OR median costs were $3,391 (lap) versus $3,095 (robot), p=NS	Results state no difference in OR time or LOS but no data
Warren, 2017[101]	Retrospective review, Americas Hernia Society Quality Collaborative (multi-institutional)	Robot-assisted vs laparoscopic ventral hernia repair	Not stated	103 lap 53 robotic	No details provided	Mean direct hospital cost $13,943 (lap) vs $19,532 (robotic), P=NS	Operative time 121 min (lap) vs 245 min (robotic), p<0.001

Summary of Findings

There are only a handful of cases comparing the costs of robot-assisted versus laparoscopic or open surgery for ventral hernia repair. All had significant limitations, primarily surrounding the cost methodology used. However, 4 of the 6 studies reported that the robot-assisted approach was more expensive than either the laparoscopic or open approach (with large effect size) and the other 2 studies reported no difference in cost as compared to laparoscopic repair.

Certainty of Evidence for Key Question 2C

We have low certainty that robot-assisted surgery is more expensive than laparoscopic ventral hernia repair or open ventral hernia repair based on inconsistency and imprecision (studies were all observational). We have insufficient data to render a statement regarding the cost of robot-assisted versus the other surgical approaches. Importantly, since there were no formal cost-effectiveness analyses, no conclusion can be made in this regard as well.

SUMMARY AND DISCUSSION

SUMMARY OF EVIDENCE BY KEY QUESTION

Key Question 1A: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for cholecystectomy?

In general, OR time was longer in patients treated with robot-assisted cholecystectomy compared to laparoscopic cholecystectomy. While not always statistically significant, data are consistent across RCTs and observational studies. There was no evidence of differences in total intra-operative complications or conversions, and most studies had point estimates close to the null value. Only 5 studies reported common bile duct injuries, and there was no evidence of a difference between robot-assisted cholecystectomy and laparoscopic cholecystectomy. Most studies did not demonstrate a significant difference in LOS, postoperative complications, or surgical site infections. Pain was variable among the studies and did not demonstrate a pattern. The rate of incisional hernia may be higher in the robot-assisted cholecystectomy cohort when performed using a single-port compared to a multi-port laparoscopic surgery. This finding is not unexpected and may not be an appropriate comparison, as the single-port robot-assisted cholecystectomy requires a larger incision than the smaller incisions needed for the multi-port laparoscopic cholecystectomy. Studies comparing single-port robot-assisted assisted cholecystectomy and single-port laparoscopic cholecystectomy were not different in hernia outcomes. This is an important consideration, since the single-port approach with robot-assisted cholecystectomy or laparoscopic cholecystectomy involves a larger incision and confers a higher risk for developing an incisional hernia. Thus, the interpretation of this finding may be related to single-port versus multi-port, not robot versus laparoscopic.

Key Question 2A: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for cholecystectomy?

While there are a number of studies comparing the cost-effectiveness of robot-assisted versus laparoscopic surgery for cholecystectomy, all had significant limitations, primarily surrounding the cost methodology. None were formal cost-effectiveness analysis studies. Nevertheless, there was an almost unanimous finding, including in the randomized data, that the robot-assisted approach is more expensive than the laparoscopic approach. We therefore have moderate certainty that robot-assisted surgery is more expensive than laparoscopic cholecystectomy.

Key Question 1B: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for inguinal hernia repair?

Operative room time was longer in patients treated with robot-assisted inguinal hernia repair compared to laparoscopic and open repair, particularly for unilateral repairs. In terms of LOS, there may be a signal of a small benefit favoring the robot-assisted approach compared to open surgery for inpatient stays. There does not appear to be a signal of benefit with regard to SSI for the robot-assisted approach compared to laparoscopic or open surgery. There may be a small signal of benefit for lower readmissions with the robot-assisted approach for unilateral hernias. Most studies demonstrated no difference among approaches when assessing complications and postoperative pain. There was no difference in hernia recurrence among all approaches.

Key Question 2B: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for inguinal hernia repair?

Only 5 studies compared costs of robot-assisted compared to laparoscopic or open surgery for inguinal hernia repair. All had significant limitations, primarily surrounding the cost methodology. Robot-assisted surgery was more expensive in these studies as compared to laparoscopic or open inguinal hernia repair. Based on somewhat limited directness and consistency in the evidence, we have low certainty that robot-assisted surgery is more expensive than laparoscopic or open surgery for inguinal hernia repair. Importantly, since there were no formal cost-effectiveness analyses, no conclusion can be made in this regard as well.

Key Question 1C: What is the clinical effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for ventral hernia repair?

Operating room time was longer in patients who underwent robot-assisted ventral hernia repair compared to both the open approach and laparoscopic approach. This was an almost universal finding among all the studies evaluating this outcome. Conversion to open surgery from a robot-assisted approach may be less than from a laparoscopic approach. This finding was demonstrated in 1 matched[103] and 1 unmatched study[101] with a third study[95] showing no difference. LOS also may be favored by performing a robot-assisted surgery for ventral hernia. This was a statistically significant difference between robot-assisted and open ventral hernia repair; however, this effect was not shown when compared to the laparoscopic approach. There was no evidence of differences in readmissions, SSI, postoperative complications, and mortality. The outcome of recurrence was evaluated in 1 matched study[96] and 5 unmatched studies[76,89,93,95,97] showing no significant difference except in the matched study. Only 2 studies evaluated postoperative pain, which showed no difference between the groups of patients.[96,101]

Key Question 2C: What is the cost-effectiveness of robot-assisted surgery compared to conventional laparoscopic or open surgery for ventral hernia repair?

There are a handful of cases comparing the costs of robot-assisted versus laparoscopic or open surgery for ventral hernia repair. All had significant limitations, primarily surrounding the cost methodology. However, 4 of the 6 studies reported that the robot-assisted approach was more expensive than either the laparoscopic or open approach (with large effect size) and the other 2 studies reported no difference in cost as compared to laparoscopic repair. As seen for cholecystectomy and inguinal hernia, no cost-effectiveness studies were identified.

LIMITATIONS

Publication Bias

We were not able to test for publication bias and can make no conclusions about its possible existence. However, we believe it is extremely unlikely that there exists a high-quality randomized trial of robot-assisted surgery versus other surgical approaches that we did not identify, and has similarly escaped detection by all other experts in this field. There are probably a plentitude of observational experiences about robotic therapies, from individual institutions, that have never been published, and the published literature likely represents only a small fraction of what could be known using observational studies.

Study Quality

The randomized trials for were judged to be at low risk of bias for short-term outcomes, like intraoperative and postoperative outcomes. They were judged to be at moderate risk of bias for longer-term outcomes. Likewise, the observational studies were judged to be at moderate risk of bias (due to their non-random assignment of treatments) for short-term outcomes and high risk of bias for longer-term outcomes.

Heterogeneity

As mentioned, the studies were very heterogeneous across patient and technique factors as well as how the outcomes were measured. Since we only found 4 RCTS for cholecystectomy, 1 for inguinal hernia repair, and 1 small RCT for ventral hernia repair, the vast majority of our data was observational. There are potential strong selection biases by the surgeons for when they would choose to perform a robot-assisted case over the standard approaches – which often leads to differences in the comparative groups, which we saw in the studies included in our review. The technique used for the robot-assisted approach is also different – how the mesh is secured, fascial closure, bilateral repair, or number of ports.

Some outcomes had heterogeneous measurements across studies. These included: OR time, LOS, and pain. OR time was most commonly reported as skin cut time to closure, but others reported the room time, console time, or didn't define their measurement. Length of stay was also challenging to compare across studies as these operations could be performed as outpatient or inpatient and there was often a mix of time scale between or within studies. Pain as an outcome was reported using a variety of measures: different scales, variable time intervals, receipt of pain medications, time needing pain medication, and occurrence of chronic nerve pain. This greatly limited the ability to compare results across studies.

Applicability of Findings to the VA Population

Only 2 studies were specific to VA populations – 1 for cholecystectomy[29] and 1 for inguinal hernia repair[67] – therefore strong conclusions from this data cannot be made. Unfortunately, we are not aware of any robotic cost data within the VA, but utilization data is available and this may serve as a first step towards future research in this area.

However, the applicability of these results to VA populations may depend on both the similarity of the patients studied to VA patients and the experience of the surgical teams using the robot to VA surgical team experience. Yet the benefits for robot-assisted approach may still be realized despite patient-level differences (VA patient population has greater burden of comorbidities than the general population), which will need to be confirmed in future studies. Urology as a surgical field has widely adopted robot-assisted surgery, so this experience will likely translate well into the expansion of robot-assisted approach to general surgery in the VA setting.

Research Gaps/Future Research

Numerous research gaps are apparent. There is a need for randomized data or propensity matching that addresses patient- and technique-related factors. The variability in the use of the robot-assisted approach based on these factors currently limits the ability to compare across study arms, as variations at baseline or differences in how the operation was performed are large and may likely be responsible for realized clinical differences or lack thereof. Importantly, there are advantages of the robot that are clear and notable – enhanced, three-dimensional visualization, augmented dexterity and range of motion, reduction of tremor, to name a few. The heterogeneous nature of the studies limited the ability to show how these features translate into better clinical outcomes. Studies that control for key patient factors, case complexity, technical aspects of procedures, and surgeon experience may provide insight into this overarching question. Additionally, adequate long-term follow-up for certain outcomes is greatly needed. Several areas warrant specific discussion.

Surgeon Learning Curve

The surgeon learning curve is a well-characterized surgical concept that has similarly been applied to robot-assisted surgery. As with any new platform the need for training, practice, and experience is needed. Even open surgical procedures, such as pancreatectomy, suffer from inexperienced surgeons that require tutelage before displaying mastery of the technique. The advent of laparoscopy more than 30 years ago brought this concept more into the forefront and showed the impact of surgeon learning curves on clinical patient outcomes. Likewise, surgeon learning curve for robot-assisted cases is a multifaceted issue. Previous reviews found that the surgeon experience (*ie*, ability as a function of cases completed) is fluid, as it has multiple phases and surgeons tend to add increasingly complex patient cases as they gain experience.[1] In our review, we found that 90% of the studies for robot-assisted cholecystectomy acknowledged the possibility of a learning curve; however, only 5/46 provided data/assessment (and findings on OR time and incisional hernia occurrence were mixed).[22,23,29,34,37] A learning curve impact may likely vary by procedure as well. Research assessing surgeon experience needs to include a variety of clinical outcomes, not just efficiency such as OR time. With emerging technologies, research should routinely comment on and address the potential impact the level of experience of the surgeon or surgeons played.

Resident Training

Robotics as an evolving technology is also changing how surgical residents are educated. Furthermore, faculty surgeons need to gain their own experience while balancing training residents. 1 recent survey of program directors by Tom et al found that a 92% of programs have residents participating in robot-assisted surgery, while 68% offer formal curriculum; 44% track residents' robot-assisted experience, and about half (55%) recognize curriculum training completion.[109] Another study also found wide variations "in requisite components, formal credentialing, and case tracking and role of simulation training".[110] There is also no standardized approach on how to incorporate this training based on level of trainee. Overall, there is a need to adopt a standardized training curriculum and document resident competency.[111]

Long-term Follow-up

Our work identified a lack of high-quality evidence with adequate long-term follow-up and sufficient statistical power to properly assess clinical outcomes between the operative approaches for inguinal hernia repair and ventral hernia repairs. For hernia repairs, outcomes of interest need to include recurrent hernias beyond 1 year, long-term pain, and functional status. Only 1 small RCT was found for ventral hernia repair, none for inguinal, and it only reported on 1 main outcome of interest. The data we found was too limited to provide conclusions in this regard.

Cholecystectomy Research Gaps

Our review focused on use of robot-assisted surgery for benign, elective gallbladder disease. However, there is a need for future studies on cholecystectomy for non-benign pathology and emergent cases. As the robot-assisted technique is becoming more common, certain institutions are beginning to use it for cancer cases and non-elective surgeries, which are notably more complex. Given the differences in patient populations that experience these indications and the higher rates of complications for non-elective surgeries, the results from our study may not be generalizable to these populations. In fact, the robot-assisted approach may prove to be particularly advantageous for these more complex cases. The study of differences in cancer outcomes, and morbidity, for robot-assisted versus laparoscopic and open surgery is essential. As such, future research may consider expanding this review to examine different indications for cholecystectomy.

Inguinal Hernia and Ventral Hernia Repair Research Gaps

Specific to hernia repairs, the robot-assisted approach may offer several technical advantages. For inguinal hernias, the potential for avoiding tacks or even the need for suturing mesh (sutureless mesh) may lead to less postoperative acute and chronic pain. For ventral hernia, the robot-assisted approach with improved suturing technique can also forego placement of tacks as well as possibly decrease recurrent hernia formation. Unfortunately, these technical details were not uniformly available across the studies in our review and outcomes were typically not reported by these factors. As such, it was not possible to determine their specific roles. Additionally, baseline pain was often not reported, perioperative quality of life and pain data were sparse, and long-term data on chronic pain and recurrence were rare. Standardized reporting in future work is needed in order to sufficiently assess pain outcomes. Guidance should be provided on reporting technical aspects of the repair and requirements for clinical outcome assessment – for instance, specific time intervals, tools for assessing pain, and amount of pain medications taken.

Ergonomics for the Surgeon

An important issue that deserves study is the impact of the robot-assisted approach on the physical stress on the surgeon performing the operation. There is a high rate of musculoskeletal disorders attributed to poor ergonomics of laparoscopic surgery as well as the open approach. There are those that claim robot-assisted surgery ergonomics are superior, leading to decreased physical stress and workload. However, there is also growing evidence that a prolonged time sitting at the robot-assisted console adds new physical challenges as well.[112] Two recent studies reported physical discomfort and symptoms[113] or poor posture[114] in over half of surgeons. Although data are sparse, it would be a valuable area for future research. While challenging to study, the outcomes would need to be comparative, long-term (5 year plus) and would require assessing detailed quality of life, assessment of chronic physical injuries, and longevity of operating over a career.

Future Innovation in Surgical Robotics

An overwhelming number of the studies in our review used the da Vinci system from Intuitive (only 1 study used the Senhance robot).[22] The robotic field is changing soon, as a number of new robotic platforms are becoming available; there are 8 with FDA approval, and more pending approval.[5] These will bring with them potentially new advantages (*eg*, improved computer optics, machine learning, and automation) and possibly new challenges (*eg*, different technology with new learning curves, unknown impact on patient outcomes). Future research will be critical to assess the differences between these technologies. With these new market forces, there is anticipation for reduced cost as well.

Conflict of Interest

It is notable that reporting bias in robot-assisted surgery research has been identified. A recent study found that author payments from Intuitive were not declared in more than half (52%) of robot-assisted surgery research,[115] and they reported more positive findings as compared to those that did declare their conflict of interest (COI) payments. There is a need to ensure full disclosure of COI with more accountability and journals may want to adopt standardized processes to achieve better transparency.

Costs

Lastly, the lack of well-designed comparative studies also limits evaluations of cost. There is a need for standardized approaches to assess cost, which would apply to all 3 of these robot-assisted operations (*ie*, analytics approach, consistent definitions of cost, how upfront capital was accounted for, how to adjust for training staff, *etc*). Along these lines, formal cost-effectiveness studies that weigh the benefits and risks along with cost are needed.

Conclusions

Across 3 common general surgery procedures there is evidence that OR time is longer for the robot-assisted approach, and some signals that select intraoperative and postoperative complications are more favorable with the robot-assisted approach based on the operation. Overall, the studies were heterogeneous in terms of patient characteristics and how the operations were performed and definitive conclusions cannot be made. Cost is probably higher across these procedures, but the balance between the added expense and potential gains in effectiveness are unknown, until we adopt better, standardized methods of assessment.

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