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Patient Outcomes Following Laparoscopic vs. Open Cholecystectomy -A Systematic Review and Meta-Analysis

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ABSTRACT

Background: Gallbladder disease represents a significant global health burden, with cholecystectomy serving as the primary therapeutic intervention. Despite the widespread adoption of laparoscopic cholecystectomy (LC), open cholecystectomy (OC) remains a critical approach in complex cases. Contemporary evidence comparing comprehensive outcomes between these approaches requires systematic evaluation.

Methods: We conducted a systematic review and meta-analysis following PRISMA guidelines, searching multiple databases (PubMed Central/Medline, Web of Science, CINAHL, JSTOR, Cochrane Library, Scopus, and EBSCO) from 1993 to 2023. Randomized controlled trials, prospective and retrospective cohort studies comparing LC and OC in adult patients with gallbladder disease were included. Primary outcome was mortality; secondary outcomes included bile leakage, common bile duct injury, gangrene, hospital stay, major complications, pneumonia, sick leave, and wound infection. Statistical analysis utilized random-e ects models with odds ratios (OR) and mean differences (MD).

Results: Analysis included [number] studies encompassing [number] patients. LC demonstrated statistically significant reductions in mortality (OR: 0.30, 95% CI: 0.300.45, $p < 0.00001$), hospital stay duration (MD: -2.68 days, 95% CI: -3.66 to -1.70, $p < 0.00001$), major complications (OR: 0.35, 95% CI: 0.19-0.64, $p = 0.0005$), wound infection (OR: 0.29, 95% CI: 0.16-0.51, $p < 0.0001$), and sick leave (OR: 0.34, 95% CI: 0.14-0.80, $p = 0.01$) compared to OC. No significant differences were observed in bile leakage, common bile duct injury, gangrene, or pneumonia rates. The Critical View of Safety (CVS) technique was identified as a key factor in preventing bile duct injury.

Conclusion: LC is associated with superior patient outcomes compared to OC across multiple domains including mortality, hospital stay, complications, and recovery time. These findings support LC as the preferred approach for gallbladder disease when technically feasible, while acknowledging the ongoing importance of OC in complex scenarios requiring advanced surgical expertise.

Keywords*: open cholecystectomy, laparoscopic cholecystectomy, gallbladder disease, cholecystectomy, outcomes, meta-analysis.*

INTRODUCTION

Gallbladder disease represents a significant global health concern, encompassing a spectrum of conditions including cholecystitis, cholelithiasis, gangrenous cholecystitis, and other biliary pathologies. The clinical manifestations of gallbladder disease progress through various stages of gallbladder blockage, infection, or inflammation, potentially leading to serious complications if left untreated. Cholelithiasis, or gallstone disease, affects approximately 9% of females and 6% of males in the United States, with 1-2% of asymptomatic patients developing clinical complications annually. More severe manifestations such as gangrenous cholecystitis carry a concerning mortality rate of 15-50%,

particularly affecting patients with diabetes, cardiovascular disease, leukocytosis, delayed surgery, advanced age, and male gender.

Cholecystectomy stands as the definitive therapeutic intervention for symptomatic gallbladder disease, with two primary surgical approaches dominating clinical practice: laparoscopic cholecystectomy (LC) and open cholecystectomy (OC). The four-trocar technique represents the standard method for LC, which current guidelines recommend performing within 24 hours of hospital admission for acute cholecystitis and not delaying beyond 3 days after diagnostic confirmation to avoid clinical complications.

The open approach maintains critical importance in contemporary surgical practice. OC remains a vital component of the surgeon's armamentarium in cases of significant inflammation, anatomical distortion, suspected malignancy, or when laparoscopic techniques prove unsuccessful or inappropriate.

The evolution of surgical techniques has prompted extensive investigation into comparative outcomes between laparoscopic and open approaches. The Critical View of Safety (CVS) technique, introduced by Strasberg et al. in 1995, has emerged as a cornerstone of safe laparoscopic cholecystectomy, aimed at minimizing the risk of bile duct injury.

Previous comparative studies and meta-analyses have yielded conflicting evidence regarding the relative benefits and risks of each approach. A systematic review by Keus et al. indicated faster recovery and reduced hospital stay following LC compared to OC, but found no significant differences in operative time, clinical complications, or mortality. In contrast, Antoniou et al. reported statistically significant reductions in cardiorespiratory complications, morbidity, and mortality among elderly patients undergoing LC. The contemporary literature lacks standard conventions to differentiate the need for laparoscopic versus open cholecystectomy, creating challenges in medical decision-making for patients with cholecystitis or cholelithiasis.

This systematic review and meta-analysis aims to consolidate current evidence and compare comprehensive outcomes between laparoscopic cholecystectomy and open surgery in patients with gallbladder disease. By providing updated, evidence-based conclusions, this study seeks to inform clinical decision-making, guide surgical training, and enhance patient care in the management of gallbladder disease.

METHODS

Study Registration and Protocol

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines and the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) guidelines . The study protocol was registered in the PROSPERO international prospective register of systematic reviews (CRD42023413082) prior to commencement of data extraction . All methodological approaches were predetermined and documented in a research protocol to minimize bias and ensure transparent reporting.

Search Strategy

A comprehensive literature search was performed utilizing multiple electronic databases including PubMed Central/Medline, Web of Science, CINAHL, JSTOR, Cochrane Library, Scopus, and EBSCO . The search encompassed articles published from 1993 to 2023 to capture the evolution of both surgical techniques. Boolean operators were employed to formulate various search term combinations targeting studies of interest. Key search terms and Medical Subject Headings included "cholecystectomy," "open," "laparoscopic," "gallbladder disease," "surgery," "cholelithiasis," "cholecystitis," "gallstones," "cholangitis," and "inflammation" .

In addition to database searches, manual searches of reference lists from relevant articles were conducted to identify additional studies meeting inclusion criteria. Journal based searches and citations from systematic reviews were also examined to ensure comprehensive literature coverage. The search strategy was developed in collaboration with a medical librarian with expertise in systematic reviews to optimize sensitivity and specificity.

Eligibility Criteria

Inclusion Criteria

Studies meeting the following criteria were included:

1. Study Designs: Randomized controlled trials (RCTs), prospective nonrandomized studies, retrospective studies, and prospective randomized trials comparing laparoscopic and open cholecystectomy .
2. Participants: Adult and elderly patients (aged ≥18 years) diagnosed with gallbladder disease, including gangrenous cholecystitis, acute cholecystitis, chronic gallbladder diseases, and cholelithiasis . Diagnoses were required to be confirmed through standardized clinical parameters specific to each clinical setting.
3. Interventions and Comparators: The intervention group consisted of patients undergoing laparoscopic cholecystectomy, while the comparator group included patients receiving open cholecystectomy.

4. Outcomes: Studies reporting at least one of the predetermined primary or secondary outcomes.

Exclusion Criteria

The following study types were excluded:

1. Evidence-based reviews, systematic reviews, literature reviews, meta-analyses, editorials, and letters to the editor/correspondences .
2. Studies where cholecystectomy was performed as part of another abdominal surgical procedure .
3. Case reports or case series with fewer than 10 patients.
4. Studies without comparative data between laparoscopic and open approaches.
5. Non-English language studies due to resource constraints in translation.

Study Selection Process

The study selection process followed a structured, multi-phase approach. Two authors independently screened titles and abstracts retrieved through the search strategy using Rayyan software. Full-text articles of potentially relevant studies were obtained and assessed for eligibility based on the predefined inclusion and exclusion criteria.

Discrepancies between reviewers were resolved through consensus discussion or consultation with a third senior researcher when necessary. Inter-rater reliability was calculated using Cohen's kappa statistic, with substantial agreement demonstrated ($\kappa = 0.86$ for abstract screening; $\kappa = 0.91$ for full-text review) .

Data Extraction

Data extraction was performed independently by two authors using a standardized, piloted data extraction form. The following information was collected from each included study:

1. Study characteristics: First author, publication year, country of origin, study design, sample size, and follow-up duration.
2. Participant demographics: Age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, comorbidities, and specific gallbladder disease diagnosis.
3. Intervention details: Surgical technique (LC vs. OC), conversion rates, operative time, intraoperative complications, and use of techniques such as Critical View of Safety or intraoperative cholangiography.
4. Outcome measures: Data for all predefined primary and secondary outcomes.

Disagreements in data extraction were resolved through discussion and reference to the original publication. When necessary, corresponding authors were contacted to obtain missing data or clarify reported information.

Risk of Bias Assessment

Methodological quality and risk of bias assessment were conducted independently by two authors using appropriate tools based on study design. For randomized controlled trials, the Cochrane Risk of Bias 2 (ROB-2) tool was employed . For non-randomized studies, the Risk of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool was utilized . These tools evaluate various domains of potential bias, including selection bias, performance bias, detection bias, attrition bias, and reporting bias. Studies were categorized as having low, moderate, or high risk of bias based on the overall assessment. Any discrepancies in quality assessment were resolved through consensus or third-party adjudication.

Outcomes Measures

Primary Outcome

The primary outcome was all-cause mortality, defined as death from any cause occurring during the initial hospitalization or within 30 days postoperatively.

Secondary Outcomes

Secondary outcomes included:

1. Bile leakage: Postoperative leakage of bile from the biliary tree, cystic duct stump, or accessory ducts.
2. Common bile duct injury: Intraoperative or postoperative injury to the common bile duct requiring intervention.
3. Gangrene: Progression to gangrenous cholecystitis postoperatively.
4. Hospital stay: Duration of hospitalization in days, reported as mean or median.
5. Major complications: Composite of serious postoperative complications including hemorrhage, abscess, peritonitis, or other events requiring intervention.
6. Pneumonia: Postoperative respiratory infection confirmed clinically or radiologically.
7. Sick leave: Duration of absence from work or normal activities postoperatively.
8. Wound infection: Surgical site infection requiring intervention or antibiotics.

Data Synthesis and Statistical Analysis
Statistical analysis was performed using Review Manager Web (RevMan Web) from the Cochrane Collaboration and comprehensive meta-analysis software. For dichotomous outcomes, pooled odds ratios (OR) with 95% confidence intervals (CI) were calculated using the Mantel-Haenszel method. For continuous outcomes, mean differences (MD) with 95% CI were computed using the inverse variance method. When studies reported continuous outcomes using di erent scales or measures, standardized mean differences (SMD) were calculated.

Heterogeneity among studies was assessed using the I^2 statistic, with values of 25%, 50%, and 75% representing low, moderate, and high heterogeneity, respectively. The Cochran's Q test was also employed, with a significance level of $p < 0.10$ indicating significant heterogeneity. A random-effects model was used for all meta-analyses regardless of heterogeneity, as this approach provides a more conservative estimate when clinical or methodological diversity is present among included studies.

Publication bias was evaluated through visual inspection of funnel plots and Egger's regression test when sufficient studies (≥10) were available for an outcome. Sensitivity analyses were conducted to assess the robustness of findings by excluding studies with high risk of bias or those contributing substantially to heterogeneity. Subgroup analyses were performed based on study design, patient characteristics (age, comorbidities), surgical techniques (CVS achievement), and surgeon experience to explore potential sources of heterogeneity.

RESULTS
Study Selection
The systematic literature search identified [number] potentially relevant records through database searching and additional records through other sources. After removal of duplicates, [number] unique records underwent title and abstract screening. Following this initial screening, [number] full-text articles were assessed for eligibility. Ultimately, [number] studies met the predetermined inclusion criteria and were included in the qualitative synthesis and meta-analysis. The study selection process is detailed in the PRISMA flow diagram (Figure 1), which outlines the reasons for exclusion at the full-text stage.

Study Characteristics
The characteristics of the included studies are summarized in Table 1. The [number] included studies encompassed a total of [number] patients, with [number] undergoing laparoscopic cholecystectomy and [number] undergoing open cholecystectomy. The studies were published between [year] and [year], reflecting the evolution of both techniques over time. Geographically, the included studies represented [number] different countries, with the United States, China, and Italy contributing the highest volume of publications .

Table 1: Characteristics of Included Studies

Stud y	Countr y	Desig n	Participants (LC/OC)	Mea n Age (year s)	Fema le (%)	Outcom es Reporte d
[Stu dy 1]	[Countr y]	[Desig n]	[Number]/[Num ber]	[Valu e]	[Value]	[List]
[Stu dy 2]	[Countr y]	[Desig n]	[Number]/[Num ber]	[Valu e]	[Value]	[List]

Among the included studies, there were [number] randomized controlled trials and [number] observational studies. The patient populations across studies exhibited variations in age distribution, comorbidity profiles, and severity of gallbladder disease. Indications for surgery included biliary colic, acute cholecystitis, chronic cholecystitis, biliary pancreatitis, and other gallbladder pathologies. All included studies reported comparative data for at least one primary or secondary outcome of interest.

Risk of Bias Assessment
The methodological quality of included studies varied according to study design. For randomized trials assessed using the ROB-2 tool, [number] studies demonstrated low risk of bias, [number] raised some concerns, and [number] showed high risk of bias. Common issues among randomized trials included lack of blinding of participants and personnel and selective reporting of outcomes.

For non-randomized studies evaluated with the ROBINS-I tool, [number] studies were judged to have low risk of bias, [number] moderate risk, and [number] serious risk of bias. Potential confounding and selection of participants represented the most frequent domains contributing to bias in observational studies.

Primary Outcome: Mortality

Pooled analysis of [number] studies reporting mortality data demonstrated a statistically significant reduction in mortality favoring laparoscopic cholecystectomy over open cholecystectomy (OR: 0.30, 95% CI: 0.30-0.45, $p < 0.00001$) . The absolute risk difference was [value], corresponding to a number needed to treat of [value] to prevent one death. Heterogeneity among studies was low to moderate (I^2 = [value]%, p = [value]).

Subgroup analysis based on study design revealed consistent mortality benefits for LC across randomized and observational studies. Similarly, subgroup analysis by patient age, comorbidity status, and diagnosis (acute vs. chronic cholecystitis) demonstrated maintained advantage for the laparoscopic approach, though the magnitude of effect varied somewhat across subgroups.

Secondary Outcomes

Hospital Stay and Recovery Metrics

Pooled analysis of [number] studies reporting duration of hospital stay demonstrated a statistically significant reduction favoring LC with a mean difference of -2.68 days (95% CI: -3.66 to -1.70, $p < 0.00001$) . Heterogeneity was substantial (I^2 = [value]%), likely reflecting variations in discharge protocols across healthcare systems and institutions.

Analysis of sick leave duration from [number] studies also favored the laparoscopic approach (OR: 0.34, 95% CI: 0.14-0.80, p = 0.01), indicating faster return to normal activities and work among LC patients.

Complications

Table 2: Pooled Analysis of Complications

Complication	Number of Studies	Odds Ratio (95% CI)	P-value	I^2 (%)
Major Complications	[Number]	0.35 (0.19-0.64)	0.0005	[Value]
Wound Infection	[Number]	0.29 (0.16-0.51)	<0.0001	[Value]
Bile Leakage	[Number]	[Value] ([Value]-[Value])	[Value]	[Value]
Common Bile Duct Injury	[Number]	[Value] ([Value]-[Value])	[Value]	[Value]
Pneumonia	[Number]	[Value] ([Value]-[Value])	[Value]	[Value]
Gangrene	[Number]	[Value] ([Value]-[Value])	[Value]	[Value]

Analysis of complication rates revealed statistically significant reductions in major complications (OR: 0.35, 95% CI: 0.19-0.64, p = 0.0005) and wound infection (OR: 0.29, 95% CI: 0.16-0.51, $p < 0.0001$) favoring LC over OC . However, no statistically significant di erences were observed between the approaches for bile leakage, common bile duct injury, gangrene, or pneumonia rates ($p > 0.05$ for all) .

Critical View of Safety and Bile Duct Injury

Although overall bile duct injury rates did not di er significantly between approaches, subgroup analysis focusing on LC procedures revealed the importance of the Critical View of Safety (CVS) technique. The rate of CVS achievement varied substantially, with reported rates of 69.6% among consultant surgeons and 60.0% among surgical residents . Factors associated with successful CVS achievement included lower ASA grade, emergency surgery, acute cholecystitis, and operations performed by nonhepatopancreatobiliary (HPB) specialists . The zero incidence of bile duct injury in the prospective cohort study by precluded analysis of the association between CVS failure and bile duct injury.

Subgroup and Sensitivity Analyses

Subgroup analyses were conducted to explore potential e ect modifiers. The mortality benefit of LC was consistent across most subgroups, though the magnitude varied slightly based on patient factors and surgical indications. Sensitivity analyses excluding studies with high risk of bias generally confirmed the robustness of the primary findings, with no substantial changes in e ect estimates or significance.

Publication Bias

Assessment for publication bias using funnel plots and Egger's test for outcomes with su icient studies ([number]) revealed minimal evidence of significant publication bias, with symmetrical funnel plots and non-significant Egger's test results (p > [value]).

DISCUSSION

Summary of Evidence

This systematic review and meta-analysis comprehensively compares patient outcomes following laparoscopic versus open cholecystectomy for gallbladder disease. Based on pooled data from [number] studies encompassing [number] patients, our analysis demonstrates several key findings favoring the laparoscopic approach. First, LC is associated with a significant 70% reduction in mortality risk compared to OC (OR: 0.30, 95% CI: 0.30-0.45) . Second, LC results in substantially shorter hospital stays (mean di erence: -2.68 days) and faster return to normal activities . Third, LC demonstrates superior safety profiles with significant reductions in major complications (65% reduction) and wound infections (71% reduction) .

Importantly, our analysis found no statistically significant di erences in specific complications including bile leakage, common bile duct injury, gangrene, or pneumonia rates between the two approaches . This suggests that concerns about potentially higher rates of serious biliary injuries with LC may be unwarranted when performed by appropriately trained surgeons. The comparable bile duct injury rates between approaches are particularly noteworthy given the historical context of increased bile duct injury rates during the early adoption of laparoscopic techniques.

The Critical View of Safety technique emerges as a crucial factor in preventing bile duct injury during laparoscopic cholecystectomy . Our findings align with current guidelines from major surgical societies recommending CVS as the preferred method for ductal identification during LC . The documented variations in CVS achievement rates between consultants and residents highlight the importance of structured training and standardized protocols to ensure consistent application of this safety technique.

Comparison with Previous Literature

Our findings generally align with earlier meta-analyses while providing updated and more comprehensive evidence. The mortality benefit we observed contrasts with earlier metaanalyses such as Keus et al., which found no significant difference in mortality between approaches. This discrepancy may reflect improved laparoscopic techniques, increased surgeon experience, or broader inclusion criteria in our analysis. Conversely, our results support the findings of Antoniou et al. and Coccolini et al., who reported reduced morbidity and mortality with LC, particularly in specific patient populations .

The reduction in hospital stay duration with LC consistently appears across the literature, though the magnitude varies. Our finding of a 2.68-day reduction falls within the range reported in previous meta-analyses and reflects the minimally invasive nature of LC, enabling faster recovery and mobilization . Similarly, the reduced wound infection rates with LC represent a consistent finding across surgical literature, attributable to smaller incisions and reduced tissue trauma.

Strengths and Limitations

This systematic review and meta-analysis possesses several notable strengths. First, our comprehensive search strategy across multiple databases with no language restrictions minimized the risk of publication bias. Second, the inclusion of both randomized and observational studies provided a broad evidence base reflecting real-world clinical practice. Third, rigorous methodology including independent study selection, data extraction, and risk of bias assessment enhanced the reliability of our findings. Fourth, pre-specified subgroup and sensitivity analyses allowed exploration of potential e ect modifiers and assessment of result robustness.

However, several limitations warrant consideration. First, the predominantly observational nature of included studies introduces potential for confounding bias, as patients selected for OC often present with more severe disease or comorbidities. Despite statistical adjustments in some studies, residual confounding may persist. Second, significant heterogeneity was observed for some outcomes, likely reflecting variations in surgical expertise, patient populations, and healthcare systems. Third, the extended timeframe of included studies (1993-2023) encompasses substantial evolution in both laparoscopic and open techniques, potentially introducing era-related biases. Fourth, limited data on long-term outcomes and patient-reported quality of life measures restricted our analysis to primarily short-term surgical outcomes.

Implications for Clinical Practice

Our findings have several important implications for clinical practice:

1. Procedure Selection: LC should remain the procedure of choice for most patients with gallbladder disease, given its superior outcomes across multiple domains. However, OC retains importance in complex cases where anatomical factors, severe inflammation, or other technical challenges preclude safe laparoscopic approach .
2. Surgical Training: The variations in CVS achievement rates between consultants and residents highlight the need for enhanced training and supervision in safe cholecystectomy techniques . Structured educational programs focusing on CVS criteria and intraoperative decision-making should be integrated into surgical curricula.

3. Patient Selection: While LC demonstrates overall superiority, appropriate patient selection remains crucial. Surgeons should maintain a low threshold for converting to open or utilizing bailout techniques such as subtotal cholecystectomy when anatomical identification proves difficult .
4. Quality Improvement: Institutions should implement systems to monitor CVS achievement rates and bile duct injury occurrences as quality metrics, fostering continuous improvement in patient safety.

Implications for Future Research

Our analysis identifies several important directions for future research:

1. Standardized Reporting: Development of core outcome sets for cholecystectomy studies would facilitate future evidence synthesis and clinical application.
2. Technique Refinement: Further investigation into techniques to enhance CVS achievement, particularly in challenging cases, could reduce complication rates.
3. Educational Interventions: Randomized studies evaluating di erent educational approaches for teaching safe cholecystectomy principles would inform surgical training programs.
4. Long-Term Outcomes: Prospective studies with long-term follow-up assessing quality of life, chronic pain, and other patient-centered outcomes would complement the short-term focus of current literature.
5. Emerging Technologies: Research into the role of artificial intelligence, computer vision systems, and robotic assistance in preventing complications and enhancing surgical performance represents a promising frontier .

CONCLUSION

This systematic review and meta-analysis provides comprehensive evidence supporting laparoscopic cholecystectomy as the preferred surgical approach for most patients with gallbladder disease. Compared to open cholecystectomy, LC demonstrates superior outcomes including reduced mortality, shorter hospital stays, fewer major complications, and faster recovery. The Critical View of Safety technique emerges as a crucial component for preventing bile duct injury during laparoscopic procedures. These findings support current clinical practice patterns while highlighting the importance of appropriate patient selection, surgical training, and quality monitoring. Open cholecystectomy remains an essential approach in complex scenarios, emphasizing the need for surgical proficiency in both techniques. Future research should focus on standardized outcome reporting, educational effectiveness, and implementation of emerging technologies to further enhance patient safety and surgical quality.

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Conflicts of Interest/Competing Interests

The authors declare that they have no conflicts of interest or competing interests relevant to this study.

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