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Original Research Article

A randomized controlled study on early and delayed laparoscopic cholecystectomy in acute calculus cholecystitis

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ABSTRACT

Background: Acute calculus cholecystitis, characterized by inflammation of the gallbladder due to gallstone obstruction, is a common emergency requiring effective management. Laparoscopic cholecystectomy is the gold standard treatment, but optimal timing remains debated. This study evaluates outcomes of early versus delayed laparoscopic cholecystectomy in patients with acute calculus cholecystitis.
Methods: A prospective, randomized controlled trial conducted at Srinivas Institute of Medical Sciences, Mangalore, from July 2022 to July 2023. Ninety-six patients diagnosed with acute calculus cholecystitis were randomized into early (surgery within 72 hours) or delayed (surgery after 6-12 weeks) laparoscopic cholecystectomy groups. Outcomes assessed included operative time, hospital stay, intraoperative bleeding, conversion to open surgery and complications.
Results: The early group had significantly longer mean operative time (95.47±11.41 minutes) compared to delayed group (73.69±17.67 minutes, p=0.04) but a shorter hospital stay (5.2±1.40 days vs. 7.8±1.65 days, p=0.04). The early group experienced higher intraoperative bleeding rates (38 (79.16%) versus 26 (54.16%, p<0.001). Conversion to open surgery 8 (16.66%) versus 3 (6.25%) p=0.156) and bile duct injuries (2 (4.16%) versus 0%, p=0.241) were slightly more frequent in the early group, though not statistically significant.
Conclusions: Early laparoscopic cholecystectomy is associated with longer operative time and higher bleeding rates but offers shorter hospital stay compared to delayed surgery. Both approaches are safe and the choice should be guided by individual patient factors and surgical expertise. Early surgery can be a viable option, potentially reducing hospital length of stay without significantly worsening postoperative outcomes.

Keywords: Acute calculus cholecystitis, Bile duct injuries, Gallbladder, Intraoperative bleeding, Laparoscopic cholecystectomy

INTRODUCTION

Acute calculus cholecystitis is a common and often severe condition characterized by the inflammation of the gallbladder due to the obstruction of the cystic duct by gallstones.[1] This obstruction leads to increased pressure within the gallbladder, secondary infection and subsequent inflammation. Acute calculus cholecystitis accounts for a significant number of emergency surgical admissions worldwide, making the management of this condition a critical concern in clinical practice.[2] Laparoscopic cholecystectomy is now considered the preferred treatment for acute calculus cholecystitis because it is minimally invasive, causes less postoperative pain, shortens hospital stays and leads to faster recovery compared to open cholecystectomy.[3] However, the optimal timing of laparoscopic cholecystectomy in the context of acute calculus

cholecystitis remains a subject of ongoing debate.[4] Current clinical guidelines offer differing recommendations regarding early versus delayed intervention. Early laparoscopic cholecystectomy, typically performed within 72 hours of symptom onset, aims to mitigate the risks of ongoing inflammation and complications, such as gallbladder perforation and peritonitis.[5] Conversely, delayed laparoscopic cholecystectomy, conducted after an initial period of conservative management, allows for the resolution of acute inflammation and potentially lowers the risk of surgical complications.[5,6]

Despite numerous studies investigating the timing of laparoscopic cholecystectomy in acute calculus cholecystitis, there remains no consensus on the optimal approach.[7] Proponents of early laparoscopic cholecystectomy argue that early intervention reduces the total duration of hospital stay, healthcare costs and the risk of recurrent biliary events. On the other hand, advocates of delayed laparoscopic cholecystectomy emphasize the potential for reduced surgical difficulty and complications associated with operating on an inflamed and potentially friable gallbladder. Furthermore, the timing of surgery must also consider the availability of surgical expertise, hospital resources and patient comorbidities.[7,8]

This randomized controlled study aims to provide a comprehensive comparison of early and delayed laparoscopic cholecystectomy in patients with acute calculus cholecystitis in a tertiary care setting. The findings of this study will contribute to the ongoing discourse on the management of acute calculus cholecystitis and potentially inform clinical guidelines to optimize patient care and resource utilization in healthcare settings.

METHODS

Study design and study settings

This prospective study was carried out at the Department of General Surgery, Srinivas Institute of Medical Sciences and Research Centre in Mangalore, Karnataka, India, from July 2022 to July 2023.

Study objectives

To compare the outcomes of early versus delayed laparoscopic cholecystectomy for treating acute calculus cholecystitis.

Ethics considerations

This study received approval from the Institutional Ethical Committee of Srinivas Institute of Medical Sciences and Research Centre, Mangalore. Prior to enrolment, informed consent was obtained from all participants.

Study population

Patients over 18 years with a diagnosis of acute calculus cholecystitis from July 2022 to July 2023, based on the Tokyo guidelines.[5]

The diagnosis of acute calculus cholecystitis was made based on the Tokyo guidelines, which include the following criteria:

Local signs of inflammation

Murphy's sign, pain or tenderness in the right upper quadrant

Systemic signs of inflammation

Fever (greater than 38°C), Elevated C-reactive protein (CRP), elevated white blood cell count (WBC >10,000/mm³)

Imaging findings

Imaging results consistent with acute calculus cholecystitis.

Study procedure

All patients received intravenous infusion, antibiotics (Injection Cefaperazone+Sulbactam 1.5 gm intravenous), analgesics and antiemetics. The antibiotic treatment was discontinued when clinical responses were positive and inflammatory markers returned to normal levels. Any additional measures, such as endoscopic interventions, were documented. Patients in the early group underwent laparoscopic cholecystectomy within 72 hours of admission. In contrast, patients in the delayed group were discharged after rehabilitation of acute calculus cholecystitis and scheduled for interval laparoscopic cholecystectomy 6-12 weeks later.

All laparoscopic cholecystectomies were performed by experienced surgeons with the assistance of a resident doctor. The procedure began with the insertion of trocars into the abdominal cavity to gain access. The gallbladder was then carefully dissected from the liver using monopolar electrocautery, with the cystic duct and artery secured using Trutie ligating clips 300 and 400 and applicator (Healthium Medtech, India). After removal of the gallbladder through a port or an enlarged incision, the abdominal cavity was inspected and the ports were closed using antimicrobial triclosan coated trusynth plus neo sutures (Healthium Medtech, India). The procedure was modified as needed, including steps like gallbladder decompression, using an additional port, securing the cystic duct with sutures, employing endoscopic pouches for specimen retrieval, enlarging the sub-umbilical incision for specimen extraction and placing a closed suction drain in the subhepatic space. The gallbladder

was dissected from the liver using monopolar electrocautery.

Inclusion criteria

In early group

Diagnosed acute calculus cholecystitis. Persistence of symptoms (nausea, vomiting, pain) despite conservative therapy. Palpatory sensitivity below the right rib arch. Elevated leukocyte values.

In delayed group: (in addition to the general criteria)

Significant reduction or complete absence of symptoms following conservative treatment. Reduced palpatory sensitivity below the right rib arch. Decreased leukocyte values.

Exclusion criteria

Symptoms lasting longer than 72 hours prior to confirmation of acute cholecystitis, jaundice, common bile duct stones, malignancies, preoperatively diagnosed acute pancreatitis caused by biliary calculus, patients who refused laparoscopic surgery, severe sepsis, immunosuppression, perforated cholecystitis, biliary peritonitis, cholangitis, pregnancy, previous abdominal surgery.

Study outcomes

To assess intraoperative and postoperative complications (such as bile duct injuries, bile leaks and wound infections), as well as morbidity, mortality and hospital stay duration. To evaluate the average duration of surgery, mean blood loss, additional complications (like subhepatic collections and postoperative pneumonia) and the rate of unsuccessful nonoperative management.

Statistical analysis

Data were analysed using SPSS software (IBM Corp. Released 2023. IBM SPSS Statistics for Windows, Version 29.0.2.0 Armonk, NY: IBM Corp). Continuous variables were reported as mean±SD and compared using the t-test or Mann-Whitney U test, as appropriate. Categorical variables were assessed with the chi-square test or Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

Randomization

Patients were evaluated for eligibility at the emergency department by the on-call surgeon after the diagnosis of acute calculus cholecystitis was confirmed. A dedicated study nurse randomly assigned patients to either the early or delayed laparoscopic cholecystectomy (LC) group by selecting and opening a sealed opaque envelope from a box. The envelopes contained cards indicating the allocated treatment, either "early" or "delayed." These envelopes were pre-prepared in a 1:1 ratio, thoroughly shuffled and placed in the box by the study nurse. Blinding was not implemented in this process.

RESULTS

Out of 115 participants assessed for eligibility, 19 were excluded, with 14 not meeting the inclusion criteria and five refusing to participate. The remaining 96 participants were randomized into two groups of 48 each. Early group was scheduled for early laparoscopic cholecystectomy within 72 hours of admission, while Delayed Group received initial conservative treatment, followed by surgery after a 6–12-week interval. There was no loss to follow-up in either group and all participants were included in the final analysis (Figure 1).

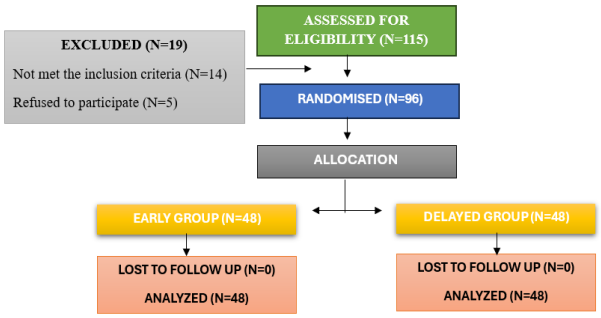

Figure 1: Enrolment and allocation CONSORT diagram.

Intraoperative and postoperative complications

Distribution based on gender

The Table 1 presents the gender distribution of patients in the early and delayed laparoscopic cholecystectomy groups. In the early group, 13 (27%) patients were male and 35 (72.9%) were female, while in the delayed group, 17 (35.4%) were male and 31 (64.5%) were female. Overall, most participants in both groups were female 66 (68.75%). The comparison between the two groups showed no statistically significant difference in gender distribution (p=0.334), indicating that the gender composition was similar across both groups.

Bile duct injuries

The table summarizes the incidence of bile tract injuries in the early and delayed laparoscopic cholecystectomy groups. In the early group, two (4.16%) patients experienced bile tract injuries, while no injuries were reported in the delayed group. Overall, 94 (97.91%) patients did not suffer bile tract injuries. Although bile tract injuries were slightly more common in the early group, the difference between the groups was not statistically significant (p=0.241), suggesting that the

timing of surgery did not significantly affect the risk of bile tract injuries (Table 2).

Duration of surgery and hospitalization

The table compares the operative time and the number of hospitalization days between the early and delayed laparoscopic cholecystectomy groups. The mean operative time was significantly longer in the early group (95.47±11.41 minutes) compared to the delayed group (73.69±17.67 minutes), with a p value of 0.04, indicating statistical significance. Additionally, patients in the early group had a shorter hospital stay (5.2±1.40 days) compared to those in the delayed group (7.8±1.65 days), with this difference also being statistically significant (p=0.04). This suggests that while early surgery may take longer, it is associated with a shorter duration of hospitalization (Table 3).

Conversion to open surgery

The table shows the distribution of patients who required conversion from laparoscopic to open surgery in the early and delayed laparoscopic cholecystectomy groups. In the early group, eight (16.66%) of patients required conversion, compared to 3 (6.25%) in the delayed group. Overall, 11 (11.45%) of all patients required conversion to open surgery. Although a higher percentage of conversions occurred in the early group, the difference between the two groups was not statistically significant (p=0.156), indicating that the timing of surgery did not significantly impact the likelihood of conversion (Table 4).

Mean blood loss

The Table compares the incidence of intraoperative bleeding between the early and delayed laparoscopic cholecystectomy groups. In the early group, 38 (79.16%) patients experienced bleeding, whereas in the delayed group, 26 (54.16%) patients had bleeding. Overall, 64 (66.66%) of all patients experienced bleeding. The difference between the groups was statistically significant (p<0.001), indicating that patients in the early group were significantly more likely to experience bleeding during surgery compared to those in the delayed group (Table 5). There were no reported incidences of bile leaks, wound infections, morbidity, mortality or other complications such as subhepatic collections, postoperative pneumonia or unsuccessful nonoperative management.

Table 1: Distribution of patients based on gender.

			Group (%)		Total	P value
			Early (n=48)	Delayed (n=48)		
Gender	Male	Number	13 (27)	17 (35.4)	30 (31.2)	0.334*
	Female	Number	35 (72.9)	31 (64.5)	66 (68.75)	

*Pearson's chi-square test, %-Percentage, N-Number of patients

Table 2: Distribution of patients in relation to biliary tract injuries.

			Group (%)		Total	P value
			Early (n=48)	Delayed (n=48)		
Bile duct injuries	No	Number	46 (95.83)	48 (100)	94 (97.91)	0.241*
	Yes	Number	2 (4.16)	0	2 (2.04)	

* Fisher's exact test; %: Percentage; N: Number of patients

Table 3: Duration of surgery and hospitalization among patients following surgery.

	Early group (Mean±SD)	Delayed group (Mean±SD)	P value
Operative time in minutes	95.47±11.41	73.69±17.67	0.04*
No. of hospitalization days	5.2±1.40	7.8±1.65	0.04#

* t-test; # Mann-Whitney U test; SD: Standard deviation

Table 4: Distribution of patients based on conversion to open surgery.

			Group (%)		Total	P value
			Early (n=48)	Delayed (n=48)		
Conversion to open surgery	No	Number	40 (83.33)	45 (93.75)	85 (88.5)	0.156*
	Yes	Number	8 (16.66)	3 (6.25)	11 (11.45)	

* Fisher's exact test; %: Percentage; N: Number of patients

Table 5: Bleeding frequency in the early and delayed group of patients.

			Group (%)		Total	P value
			Early (n=48)	Delayed (n=48)		
Bleeding	No	Number	10 (20.83)	22 (45.83)	32 (33.33)	<0.001*
	Yes	Number	38 (79.16)	26 (54.16)	64 (66.66)	

* Fisher's exact test; %: Percentage; N: Number of patients

DISCUSSION

The aim of this study was to compare the outcomes of early versus delayed laparoscopic cholecystectomy in patients with acute calculus cholecystitis. The findings offer valuable insights into the optimal timing of laparoscopic cholecystectomy in managing this common and potentially severe condition.

Our results indicate that early group was associated with a significantly longer operative time compared to delayed group. The mean operative time for the early group was 95.47±11.41 minutes, notably longer than the 73.69±17.67 minutes observed in the delayed group. This finding aligns with the study by Agarwal R et al, which reported a mean operative time of 69.4±29.59 minutes for the early group and 66.4±15.97 minutes for the delayed group 9. Despite the longer operative time, early group demonstrated a clear advantage in terms of hospital stay duration.

Patients undergoing early laparoscopic cholecystectomy had a significantly shorter mean hospital stay of 5.2±1.40 days, compared to 7.8±1.65 days for those in the delayed laparoscopic cholecystectomy group. This is consistent with Agarwal et al,'s findings of a mean hospital stay of 4.16±1.21 days for early laparoscopic cholecystectomy and 8.6±2.04 days for delayed laparoscopic cholecystectomy.[9] Thus, while early laparoscopic cholecystectomy may involve a longer surgical duration, it potentially reduces the overall length of hospital stay, which could enhance patient outcomes and lower healthcare costs.

However, our study also observed a higher conversion rate from laparoscopic to open surgery in the early group it was eight patients (16.66%) compared to the delayed group, three patients (6.25%). This suggests that early surgery may present greater challenges due to the inflamed state of the gallbladder. Nonetheless, the conversion rates were within acceptable limits, reflecting the surgical team's proficiency and supporting the feasibility of early laparoscopic cholecystectomy, even in acute cases. These findings are consistent with Rather ZM et al, who reported similar conversion rates in their study, with 3 conversions in the early group and 2 in the delayed group.[10]

In terms of complications, we noted a slightly higher incidence of bile duct injuries in the early group, two patients (4.16%), compared to none in the delayed group. Although this difference was not statistically significant, it highlights the potential risks associated with early intervention. In a related study by Madhura et al, bile duct injuries occurred in one case (4%) in the early group and three cases (12%) in the delayed group, underscoring the need for meticulous surgical technique in both early and delayed procedures.[11]

A significant finding in our study was the higher incidence of intraoperative bleeding in the early group 38 (79.16%) compared to the delayed group 26 (54.16%). This trend is corroborated by Janjic et al, who observed intraoperative bleeding in 26 (61.9%) of the early group versus 34 (81%) in the delayed group.[12] Similarly, Rather et al, reported bleeding in four patients in the early group and three patients in the delayed group.[10] The increased risk of bleeding during early laparoscopic cholecystectomy highlights the necessity for careful intraoperative management.

Despite the increased bleeding risk, our study did not find significant differences in postoperative complications such as bile leaks, wound infections or subhepatic collections between the two groups. There were no variations in morbidity, mortality or other complications such as postoperative pneumonia or unsuccessful nonoperative management. This suggests that although early laparoscopic cholecystectomy may be associated with certain intraoperative challenges, it does not necessarily result in worse postoperative outcomes.

This study's strength lies in its prospective randomized design and comprehensive comparison of early versus delayed laparoscopic cholecystectomy for acute calculus cholecystitis, providing robust data on operative time, hospital stay and complications. The detailed documentation of intraoperative and postoperative outcomes enhances its clinical relevance. However, limitations include the relatively small sample size and single-center setting, which may affect the generalizability of the findings. Additionally, the lack of blinding could introduce bias in outcome assessment.

CONCLUSION

This study indicates that while early laparoscopic cholecystectomy for acute calculus cholecystitis is associated with longer operative times and higher rates of intraoperative bleeding compared to delayed laparoscopic cholecystectomy, it offers the advantage of a shorter hospital stay. Despite the increased challenges during early laparoscopic cholecystectomy, such as a higher conversion rate and risk of bile duct injuries, these did

not translate into significantly worse postoperative outcomes. The decision between early and delayed surgery should consider the individual patient's condition and the surgical team's expertise. Overall, early laparoscopic cholecystectomy can be a viable option with potential benefits in reducing overall hospital length of stay.

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