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Original Article

Role of Early Elective Cholecystectomy in Acute Mild-To-Moderate Biliary Pancreatitis

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ABSTRACT

Objective: To compare the outcomes of early versus delayed laparoscopic cholecystectomy (LC) in patients with mild/moderate acute biliary pancreatitis (ABP).

Study Design: Prospective comparative study.

Place and Duration of Study: General Surgery Department of Pak-Emirates Military Hospital, Rawalpindi, Pakistan, from Jun 23 to Feb 24.

Methodology: The target population included patients who were diagnosed with mild/moderate ABP. 138 participants were distributed equally into two groups:(1) Early LC Group (2) Delayed LC Group. Both groups were compared in terms of operation timing, operative difficulty, intra/post-operative complications, conversion to open cholecystectomy, mortality, total length of stay (LOS) in the hospital, and recurrent biliary events (RBEs).

Results: Mean LOS (days)in Early LC Group was 6.5±1.1 and in the Delayed LC Group was 9.7±1.8(*p*-value<0.001). No RBE occurred in Early LC Group, however, 15 patients in Delayed LC Group had RBEs (*p*-value<0.001). No statistically significant difference was observed between the two groups in terms of operative difficulty, intra/post-operative complications, and conversion to open cholecystectomy.

Conclusion: Early LC done for mild/moderate ABP is associated with reduced total LOS in the hospital and no RBEs. There was no statistically significant difference observed between Early LC and Delayed LC in terms of operative difficulty, intra/post-operative complications, and conversion to open cholecystectomy.

Keywords: Delayed Cholecystectomy, Early Cholecystectomy, Laparoscopic, Pancreatitis.

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INTRODUCTION

Acute pancreatitis is an acute inflammation of the pancreatic parenchyma that can lead to severe health problems.[1] Its annual global prevalence is 34 cases per 100,000 population, and its global incidence ranges from 15 to 42 cases per 100,000 population.[2] Gallstones are the leading cause of the disease worldwide, accounting for more than 50 % of the total cases.[3] Acute Biliary Pancreatitis(ABP) is caused by transient blockage of the ampulla of Vater by passing gallstones/sludge.[4] The outcome depends upon the severity of the disease, with less morbidity and mortality associated with mild /moderated attack.[5] Patients with ABP usually experience sudden, severe epigastric pain associated with nausea, vomiting, and retching.6 Diagnosis of ABP is made based on clinical presentation, raised serum amylase/lipase levels ≥3 times above normal, and radiological evidence of gallstones.[7]

All cases of ABP require laparoscopic cholecystectomy (LC) as a definite cure. The timing of LC can be either early or delayed. For mild cases, international guidelines recommend Early LC, preferably within the same hospital admission to prevent recurrent biliary events (RBE).[7] Timings of Early LC, however, vary between different guidelines. As per UK guidelines, LC should be performed preferably within the same admission or otherwise should not be delayed beyond two weeks after hospital discharge.[8] A study conducted in Canada concluded that due to delay in LC, 28.5% of the patients suffered from RBE at a median time of 34 days.[2] A study conducted in Saudi Arabia concluded that early LC is associated with reduced LOS in the hospital.[4] Furthermore, in developing countries like ours, where patients mostly don't have access to free healthcare facilities, once discharged from the hospital, they usually don't come back for Delayed LC despite thorough counseling by medical professionals.

Despite all these recommendations, Delayed LC is still being performed worldwide, usually 06 weeks after the episode of ABP.[2] The primary reason is that surgeons are mostly reluctant to do surgery in an acute edematous state of the organ, assuming that it will increase operative difficulty and perioperative

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complications. A study conducted in Italy documented that Early LC was performed only in 31% of the patients admitted with ABP. Another retrospective study conducted in California revealed that only 38.6% of the total patients admitted with ABP underwent Early LC.

Due to this discrepancy observed in the timings of LC for mild/moderate ABP, a study needed to be conducted to compare various intra/post-operative outcomes associated with Early LC versus Delayed LC, with a special focus on our local population. Therefore, we conducted a study in our institution, comparing Early versus Delayed LC for ABP, in terms of operative difficulty, intra/post-operative complications, conversion into open surgery, LOS in hospital, and RBEs.

METHODOLOGY

This prospective comparative study took place at the General Surgery Department of Pak-Emirates Military Hospital, Rawalpindi, Pakistan, from Jun 23 to Feb 24 after obtaining approval from the hospital's ethical review board (Serial no # A/28/ERC/549/23. For the calculation of sample size, the WHO Sample Size Calculator was used. To calculate sample size, the following parameters were used: 90% power of the test, 5% level of significance, anticipated complications in Early LC =22.2%, and anticipated complications in Delayed LC = 48.1%.[9] Based on these, the total sample size of 138 patients was calculated.

Inclusion Criteria: We included patients aged between 20 and 60 years, either of the male or female genders, diagnosed with mild/moderated ABP, having American Society of Anesthesiologists (ASA) grade I/II.

Exclusion Criteria: Patients having persistent organ failure > 48 hours, Glasgow score within 48 hours ≥ 3, choledocholithiasis, ascending cholangitis, and having local/systemic complications of pancreatitis that would need intensive care unit or high dependency unit admission were excluded from the study. Furthermore, patients with ASA grade III/IV/V and having any severe/uncontrolled systemic disease like Diabetes Mellitus, Hypertension, Asthma, COPD, and cardiovascular disease were excluded. Patients with impaired immunity, chronic liver disease, known coagulation disorder, chronic renal failure, and diagnosed malignancy were also excluded.

Before inclusion into the study, patients were informed about the two treatment groups and possible complications that could occur in either group. A sequential allocation method was adopted to assign participants to two groups. Moreover, patients' personal choice was also considered while dividing them into two groups. All participants provided written informed consent.

Diagnosis of ABP was made based on the following aspects: (1) Clinical signs of acute pancreatitis. (2) Serum amylase and/or serum lipase levels ≥ 3 times of normal value. (3) Radiological confirmation of gallstones/ biliary sludge. Other possible causes of acute pancreatitis were excluded by taking a careful relevant history. Mild/ moderate pancreatitis was diagnosed based on the following features: (1) Glasgow Score within 48 hours<3. (2) Absence of single/multiple organ failure for more than 48 hours. (3) No local/systemic complication that would require intensive care unit or high dependency unit admission.

Age, gender, ASA grade, and Glasgow score of all participants were recorded. All patients were managed initially using a conservative approach with intravenous fluid administration and frequent observation of vital signs. Patients with significant vomiting were advised to have a brief period of oral fasting. Oral fluids were continued as soon as the patient started tolerating oral intake. Analgesic and antiemetic medications were advised; however, no antibiotics were administered. Blood complete picture was blood, liver function tests, serum amylase, and C-reactive protein were repeated daily.

Patients in the Early LC Group underwent LC during index admission within 10 days after the acute attack. Patients in the Delayed LC Group were discharged after ABP was resolved, and Delayed LC was planned after 06 weeks. All surgeries were performed using the standard four-port technique. Operative difficulty was assessed using the Nassar Operative Difficulty Scale.[12] The decision to convert to open surgery was based on the difficult dissection and unanticipated operative complications. Patients in each group were compared in terms of LOS and incidence of recurrent biliary events (recurrent pancreatitis, acute cholecystitis, choledocholithiasis, ascending cholangitis). Furthermore, various intra/post-operative parameters among the two groups were also compared, including operation time, operative difficulty, intra/post-operative complications, and conversion rate to open surgery. When discharged after LC, follow-up visits were

planned at 10 days, 20 days, and 30 days post-surgery Figure.

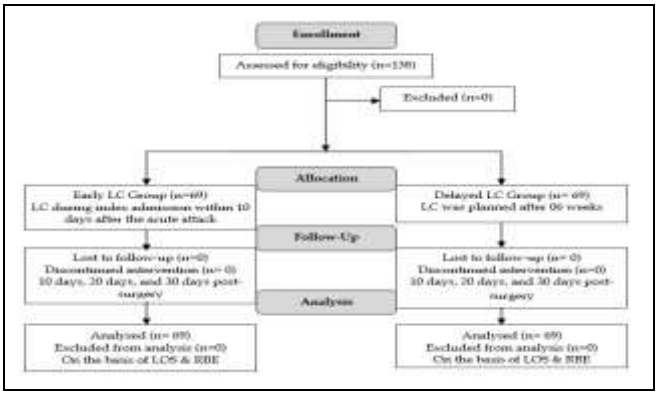

Figure: Patient Flow Diagram

The Statistical Package for Social Sciences (SPSS) vaersion 24:00 software was used for statistical data analysis. Quantitative variables were represented using Mean±SD. The normal distribution of data was assessed using the Shapiro-Wilk Test. Frequencies and percentages of categorical variables were calculated. The Chi-Square test was used to compare categorical variables and the Independent Samples t-Test was used for quantitative variables. A *p*-value of ≤0.05 was considered significant.

RESULTS

Patients were segregated into two groups, each comprising 69 patients. Mean age of the participants was 44.2±0.54 years, including 50(36.2%) males and 88(63.8%) females. The comparison of demographic features, ASA grade, and Glasgow score between the two groups is tabulated below in Table-I.

Table-I: Comparison of demographic features, ASA grade, and Glasgow score between the two groups (n =138)

Variables	Early LC Group (n = 69)		Delayed LC Group n = 69)	*p*-value
Gender (%)	Male	22(31.8%)	28(40.5%)	0.280
	Female	47(68.1%)	41(59.4%)	
Mean age±SD, years	44.5±7.2		43.9±5.4	0.610
ASA grade(%)	I	38(55.0%)	42(60.8%)	0.490
	II	31(44.9%)	27(39.1%)	
Glasgow score (%)	1	38(55%)	37(53.6%)	0.860
	2	31(44.9%)	32(46.3%)	

Nassar difficulty scale was used to assess operative difficulty during LC. This comparison is tabulated in Table-II.

During LC, a total of 06 participants (04 from Early LC Group and 02 from Delayed LC Group) developed intraoperative complications, including injury to abdominal viscera and damage to the bile duct/vessel [*p*-value 0.40, odds ratio 2.0, 95% confidence interval 0.36 – 11.6]. Conversion to open cholecystectomy occurred in 3 patients from Early LC Group and 1 patient from Delayed LC Group. 07 participants (03 from Early LC Group and 04 from delayed LC Group) had postoperative complications; 05 had superficial surgical site infection, and 02 had subhepatic bile collection, all of which were managed and resolved conservatively. No mortality occurred among study participants. No patient from Early LC Group developed RBE; however, 15 patients from Delayed LC Group developed RBE (biliary colic, acute cholecystitis, and recurrent ABP). LOS in hospital was less in Early LC Group (*p*-value<0.001). A comparison of intra/post-operative variables is shown in Table-III.

Table-II: Comparison of Operative Difficulty Between the two Groups (n=138)

Nassar operative difficulty grade	Early LC Group(n=69)	Delayed LC Group (n=69)	*p*-value
Nassar grade I(%)	19(27.5%)	14(20.2%)	0.400
Nassar grade II(%)	39(56.5%)	48(69.5%)	
Nassar grade III(%)	9(13.0%)	6(8.6%)	
Nassar grade IV(%)	2(2.8%)	1(1.4%)	

Table-III: Comparison of intra/post-operative variables (n=138)

Variable	Early LC Group (n = 69)	Delayed LC Group (n = 69)	*p*-value
Mean operative time ±SD (mins)	52.4±11.5	51.3±11.3	0.560
Operative complication	4 (5.7%)	2 (2.8%)	0.400
Conversion to open surgery	3(4.3%)	1(1.4%)	0.310
Postoperative complications	3(4.3%)	4(5.7%)	0.690
LOS mean ±SD (days)	6.5±1.1	9.7±1.8	<0.001
RBE (%)	0 (0.0%)	15(21.7%)	<0.001

**LOS = Length of Stay, RBE = Recurrent Biliary Event*

DISCUSSION

This comparative analysis reports that Early LC performed within index hospital admission for ABP is associated with reduced LOS in hospitals and no RBE. Our study included 138 patients divided equally into Early and Delayed LC groups. 63.8% of our participants were female gender. Similar female gender predominance for ABP was also documented by Blundell et al., who reported that management of ABP varies, depending upon the severity of the disease.10 While comparing operative difficulty in the two groups, no noteworthy difference was found. In contrast to our findings, Sumbizi et al., documented that increased operative difficulty was associated with delayed LC.[11] Furthermore, in terms of intra/post-operative complications and conversion to open surgery, no difference was found between the two groups.

The authors used the operating difficulty Index to reduce the influence of the cofounders in the data. Operation difficulty was assessed for both groups.[12,13] In studies involving surgical procedures, one of the primary outcomes is length of stay (LOS) of patients postoperatively. Additionally, in biliary pancreatitis, the recurrence of the disease is also a noteworthy outcome. In view of these aspects, Bergeson *et al*., reported longer mean hospitalization in the early group, different from our results.[14] Alburakan *et al*., conducted a similar study and concluded that early LC for mild/moderate ABP is associated with short LOS in hospital and reduced risk of RBEs.[15] In this study, patients with early LC had reduced total LOS in the hospital, and no RBE occurred in this group. As per international recommendations, Early LC is to be performed within the index hospital admission, yet many surgeons are reluctant to practice this approach because of the fear of anticipated difficult dissection and the possibility of operative complications.[16,17] Moreover, the existing literature lacks sufficient data to accurately depict the incidence and timing of RBEs that might occur if surgery is delayed.[18] In our country, the local population, once discharged from the hospital, mostly fails to report back for scheduled LC.

The 2023 meta-analysis by Qi *et al*., evaluated the optimal timing for laparoscopic cholecystectomy (LC) following endoscopic retrograde cholangio-pancreatography (ERCP). It compared early LC (typically within 72 hours) to delayed LC (3 or more days).[19] Similar results have been reported by the author. Seppanen *et al*., reported that out of the total, 59% of the idiopathic pancreatitis may prevent recurrent acute pancreatitis by addressing etiological factors and addressing early LC as the treatment plan.[20]

Leppäniemi et al recommend intensive care unit/ high-dependency unit admission and aggressive resuscitation to prevent complications associated with severe pancreatitis.[21] For mild/moderate ABP, a more conservative and non-invasive approach is recommended for initial management, followed by LC as a definitive treatment. In our routine surgical practice, we have witnessed a great ambiguity in the timing of LC. Walayat *et al*., in a meta-analysis study, in a prospective randomized study, concluded similar results that align with those of this study.[22]

The study supports the proposition that early LC for mild/moderate ABP done within index hospital admission is a safe surgical practice associated with reduced total LOS in the hospital and no RBEs without increasing operative difficulty and complications.

LIMITATIONS OF STUDY

This study has limitations such as single-center design, relatively small sample size, and short follow-up duration, which may restrict the generalizability of the findings.

CONCLUSION

Early LC performed within index hospital admission for ABP is associated with reduced LOS in hospitals and no RBE. Moreover, there is no statistically significant disparity between early and delayed LC regarding the operation duration, intraoperative/postoperative complications, and switching to open surgery.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MUS & NMW: Data acquisition, data analysis, critical review, approval of the final version to be published.

H & TMK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MN & AM: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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