Extending the optimal timing for early laparoscopic cholecystectomy among patients presenting with acute calculous cholecystitis

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Purpose
The optimal timing of early laparoscopic cholecystectomy (ELC) from the onset of acute calculous cholecystitis (ACC) attack remains controversial. The purpose of this study was to compare the outcomes of ELC within 72 h from the onset of symptoms versus that performed after 72 h and up to 10 days from the onset of symptoms.
Patients and methods
We performed a retrospective analysis for patients who received LC for ACC between August 1, 2018, and December 31, 2021. We compared patients who received very ELC within 72 h versus those who received ELC between 4 and 10 days from the onset of symptoms in terms of bailout procedure, postoperative complications, and postoperative hospital stay.
Results
We analyzed 90 patients, with 45 patients per group. There was no significant difference between ELC and very ELC groups regarding subtotal cholecystectomy (11 vs. 2.2%, *P*=0.2), conversion to open surgery (9 vs. 2.2%, *P*=0.36), postoperative bile leak (6.7 vs. 2.2%, *P*=0.62), and the length of postoperative hospital stay (24 h, *P*=0.12).
Conclusion
ELC is safe to perform for patients with ACC presenting beyond 3 days from the onset of symptoms, with no significant increased morbidity, provided that it is performed by well-experienced surgeons in well-equipped medical centers.

Keywords:
acute calculous cholecystitis, early laparoscopic cholecystectomy, timing of laparoscopic cholecystectomy, very early laparoscopic cholecystectomy

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Introduction

Gallstone disease remains one of the leading medical problems and requires surgical intervention. It affects ~10–15% of the general population, with women having four times higher risk than men during the reproductive age, which decreases in older ages to near equality [1]. Almost 40% of patients with gallstone disease will experience gallstone-related complications throughout their life, with acute calculous cholecystitis (ACC) being the first clinical presentation among 10–15% of them [2–4].

Although laparoscopic cholecystectomy (LC) is established to be the gold standard definitive treatment for ACC, the optimal timing of LC remains a matter of debate [5].

For years, delayed laparoscopic cholecystectomy (DLC) 6–8 weeks after onset of symptoms was the modality of treatment provided for patients with ACC for the concerns of higher morbidity rate that may be associated with early laparoscopic cholecystectomy (ELC), such as a higher rate of conversion to open surgery and postoperative bile leakage [6].

On the contrary, several meta-analyses including relevant studies have demonstrated that ELC performed during the initial admission of patients with ACC is preferred over delaying it after resolution of the acute phase for being associated with shorter postoperative hospital stay and lower hospital costs. Additionally, such meta-analyses failed to find any differences in overall morbidity, bile duct injury, and conversion rate between both sets of LC timings [7–13].

The definition of ELC has, however, been vague with controversy regarding the optimal timing to be considered early. LC was considered early when performed within 96 h following admission or 1 week following the onset of symptoms [9–15].

The updated World Society of Emergency Surgery (WSES) guidelines recommended ELC to be performed as soon as possible in the presence of adequate surgical expertise, within 7 days from hospital admission and within 10 days from the onset of symptoms [16]. Alternatively, the updated 2018 Tokyo guidelines (TG18) recommended performing ELC as soon as possible regardless of how much time has passed since the onset of symptoms of ACC provided that the patient is deemed operable with adequate performance status [17].

Accordingly, it was our aim to compare the outcomes of ELC performed within 72 h from the onset of ACC symptoms versus that performed beyond 72 h and up to 10 days from the onset of symptoms in terms of the rate of conversion to open, postoperative morbidity including postoperative bile leak, and the length of postoperative hospital stay.

Patients and methods

Study design and definitions

Before August 2018, LC was performed for patients with ACC presenting to us within 72 h from the onset of symptoms. For patients presenting beyond 3 days from onset of acute attack, conservative treatment followed by DLC 6–8 weeks later was our adopted management protocol. Upon failure of conservative treatment, open cholecystectomy was carried out. Starting August 2018, our policy was modified to be in accordance with 2016 WSES guidelines [18] and TG18 guidelines [17], where ELC was performed for patients presenting with ACC within 10 days from the onset of symptoms.

We performed a retrospective review of prospectively maintained patient database to analyze all LCs performed between August 1, 2018, and December 31, 2021. We excluded patients who received LC for chronic calculous cholecystitis. Patients presenting with ACC with concomitant obstructive jaundice were also excluded. We then compared the data of patients with ACC who received LC beyond 3 days and up to 10 days from onset of symptoms (the ELC group) to an equal number of the most recent consecutive patients who received LC for ACC within 3 days from onset of symptoms [the very early laparoscopic cholecystectomy (VELC) group]. The study was approved by the Ethics Committee and the Institutional Review Board of Alexandria Faculty of Medicine.

The diagnosis and severity of ACC was based on the criteria endorsed by TG18 [17]. The operative time was calculated from time of insertion of first trocar till the end of suturing of port-site skin incisions.

Study outcomes

The primary outcome of the study was to compare the rate of biliary complications among the two groups as well as the need for bailout procedure such as subtotal cholecystectomy or conversion to open surgery. Secondary outcomes included the length of postoperative hospital stay and the incidence of surgical site infection.

Surgical technique

All LCs included in the study were performed by a highly experienced surgeon in the field of laparoscopic hepatobiliary surgery to control for confounding bias in intervention. LC was performed using the standard four-port technique. Closed pneumoperitoneum was achieved using either Veress needle or optical trocar.

In case of difficulty to achieve the critical view of safety, we resorted to bailout procedures such as subtotal cholecystectomy or conversion to open surgery. Subtotal cholecystectomy was performed by dividing the gallbladder closest as possible to the Hartmann's pouch with extraction of all residual gallstones followed by suture-closing the remaining gallbladder cuff using absorbable suture materials. The gallbladder was then extracted through the epigastric port in a specimen bag. Drain insertion was not routinely used unless we opted for bailout procedures, in case of excessive adhesiolysis, or marked soiling of the field necessitating thorough irrigation.

Data collection

Preoperative patient variables included demographics, surgical and medical history, and preoperative laboratory workup [serum total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, C-reactive protein (CRP), total leukocyte count (TLC), and polymorphonuclear leukocyte count].

Operative variables included operative time, presence of tough adhesions masking the gallbladder upon gaining abdominal access, the condition of gallbladder wall (friable or gangrenous), gallbladder wall perforation during grasping or manipulation, presence of dense adhesions obscuring Calot's triangle, absent plane of dissection between gallbladder and liver bed, and the need for bailout techniques.

Postoperative outcomes included the length of postoperative hospital stay, incidence of biliary complications such as bile duct injury with leak or stricture, and the incidence of wound infection.

Statistical analysis

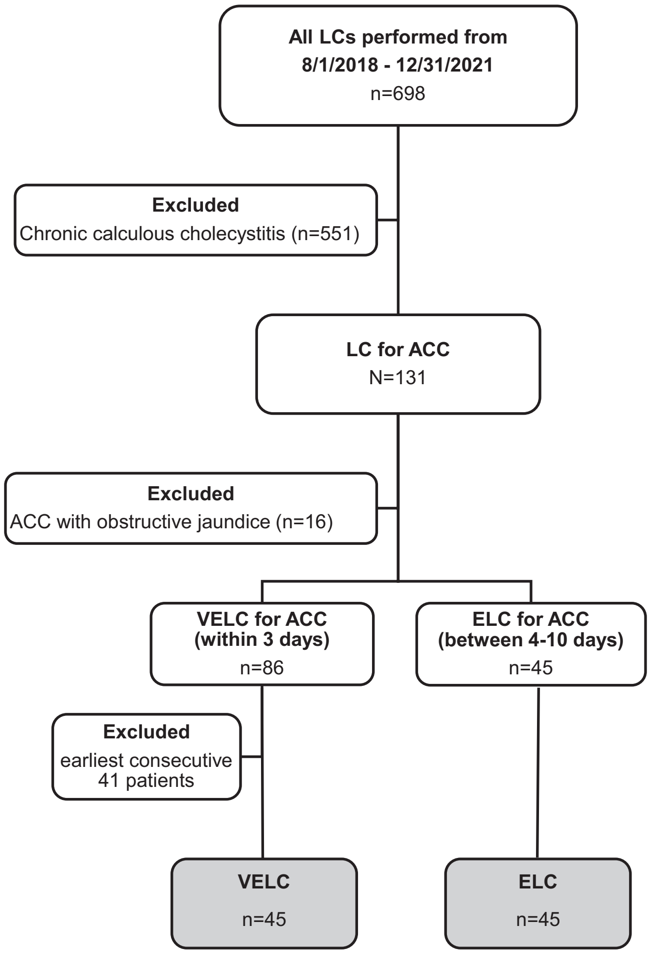
Descriptive statistics were reported for the entire study cohort. Categorical variables were summarized as numbers and percentages and continuous variables were summarized as medians and interquartile ranges. The groups were compared based on the timing of LC from the onset of acute attack (within 3 days versus between 4 and 10 days). Univariate analyses were performed using Pearson's χ^2/Fisher's exact test for categorical variables and Mann–Whitney *U* test for continuous variables. Statistical significance was considered at *P* value less than 0.05. All the analyses were performed using IBM SPSS Statistics, version 26 (IBM Corporation, Armonk, New York, USA).

Results

Over a 41-month period, 698 consecutive LCs were performed for patients with symptomatic gallstone disease. A total of 551 patients with chronic calculous cholecystitis were excluded and 16 patients were excluded for having ACC with concomitant obstructive jaundice. The remaining 131 patients received LC for ACC; 86 of these patients received LC within 3 days of onset of symptoms. A total of 45 patients received LC between 4 and 10 days from the onset of symptoms and constituted the ELC group. They were matched with the latest consecutive 45 of 86 patients who received LC within 3 days of onset of symptoms to constitute the VELC group. A total of 90 patients (45 patients per group) represented our study cohort (Fig. 1).

The median age was 48 years [interquartile range (IQR) 40–53]. The majority were females (*n*=60, 66.7%), and the median BMI was 31 kg/m^2 (IQR=29–33). A total of 18 (20%) patients were diabetic, 12 (13%) were hypertensive, five (5.6%) patients had bilharzial hepatic fibrosis, and two (2.2%) patients had chronic hepatitis C virus infection. In addition, three (3.3%) patients had prior upper abdominal surgery in the form of open splenectomy via left paramedian incision, laparoscopic sleeve gastrectomy, and longitudinal pyloromyotomy via small upper right transverse abdominal incision. According to TG18 classification for severity of acute cholecystitis, 41 (45.6%) patients were grade I, 48 (53.3%) patients were grade II, and only one (1%) patient was grade III. The median time to LC from the onset of ACC symptoms was 3.5 days (IQR=2–7). Successful completion of LC was achieved in 85 (94%) patients, whereas five (5.6%) patients required conversion to open surgery due to occurrence of bleeding difficult to control laparoscopically in two (2.2%) patients, presence of dense and tough adhesions between gallbladder and duodenum and/or colon precluding safe dissection in two (2.2%) patients, and the presence of frozen Calot's triangle that interfered with successful creation of the critical view of safety in one (1.1%) patient.

Figure 1



Flow chart showing study design and the population of patients included in the analysis over 41 month-period. ACC, acute calculous cholecystitis; ELC, early laparoscopic cholecystectomy; LC, laparoscopic cholecystectomy; VELC, very early laparoscopic cholecystectomy.

Table 1 shows the comparison between VELC and ELC groups regarding demographic data, patient comorbidities, and preoperative lab values. The median time from onset of symptoms till LC was 2 days (IQR=1–3) for patients who received VELC compared with 7 days (IQR=5–8) for patients in the ELC group.

Table 2 shows the intraoperative data for the two groups. The median operative time was significantly longer among patients who received ELC compared with those who received VELC (100 vs. 70 min, *P*<0.001), as shown in Fig. 2.

Regarding postoperative outcomes, the median length of postoperative hospital stay was similar in both groups (24 h, *P*=0.12). In terms of postoperative complications, none

Table 1 Demographic data, patient comorbidities, and preoperative laboratory findings among very early laparoscopic cholecystectomy and early laparoscopic cholecystectomy groups

Variables	VELC (*N*=45)	ELC (*N*=45)	*P*
Demographic data			
Age (years)	47 (39–53)	48 (42–54)	0.54
Sex, female [*n* (%)]	33 (73.3)	27 (60)	0.18
BMI (kg/m^2)	31 (29–33)	31 (30–33)	0.81
Comorbidities			
Diabetes	6 (13)	12 (26.7)	0.11
Hypertension	6 (13)	6 (13)	1
HCV infection	1 (2.2)	1 (2.2)	1
Bilharzial hepatic fibrosis	2 (4.4)	3 (6.7)	1
Prior upper abdominal surgery	3 (6.7)	0	0.24
Preoperative laboratory workup			
Total bilirubin (mg/dl)	0.7 (0.6–0.9)	0.8 (0.6–0.9)	0.52
Direct bilirubin (mg/dl)	0.2 (0.1–0.3)	0.2 (0.1–0.3)	0.71
AST (U/l)	23 (21–28)	27 (21–29)	0.08
ALT (U/l)	29 (24–34)	31 (25–38)	0.09
ALP (U/l)	109 (99–120)	114 (100–126)	0.1
Hb (g/dl)	13.1 (12–14.5)	13.4 (12.2–14.6)	0.57
Total leukocyte count (×10^3/μl)	9.4 (7.9–10.9)	11.7 (10.4–13.4)	<0.001*
PMNL count (×10^3/μl)	7.1 (5.9–8.3)	9.3 (8.5–10.6)	<0.001*
CRP (mg/l)	13.5 (8.7–21)	39 (23.5–60)	<0.001*
Severity of acute cholecystitis			
Grade I	41 (91)	0	
Grade II	3 (6.7)	45 (100)	<0.001*
Grade III	1 (2.2)	0	

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CRP, C-reactive protein; ELC, early laparoscopic cholecystectomy; HCV, hepatitis C virus; PMNL, polymorphonuclear leukocyte; VELC, very early laparoscopic cholecystectomy.
Continuous data are reported as median (interquartile range).
Categorical data are reported as *n* (%).
*Statistical significance at *P* value less than 0.05.

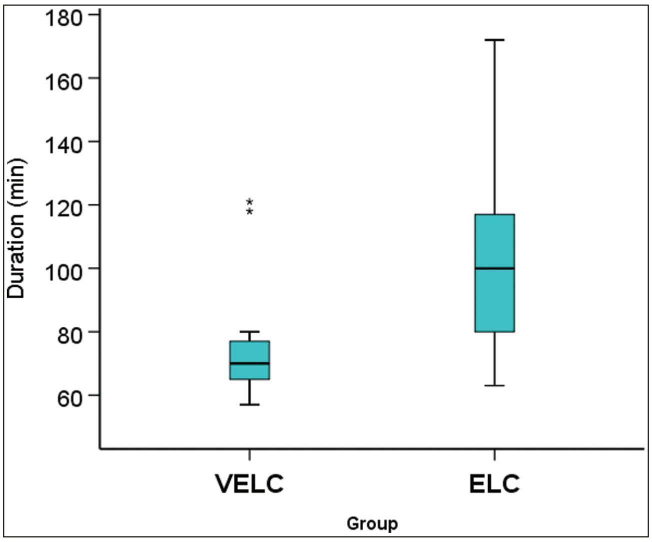
Table 2 Operative data among very early laparoscopic cholecystectomy and early laparoscopic cholecystectomy groups

Variables	VELC (*N*=45)	ELC (*N*=45)	*P*
Time from onset of symptoms to LC (days)	2 (1–3)	7 (5–8)	<0.001*
Concealed gallbladder upon abdominal entry	4 (9)	21 (46.7)	<0.001*
Friable gallbladder wall	1 (2.2)	12 (26.7)	0.001*
Perforation of gallbladder	4 (9)	18 (40)	0.001*
Dense adhesions obscuring Calot's triangle	7 (15.6)	21 (46.7)	0.001*
Gangrene of gallbladder wall	0	4 (9)	0.12
Absent gallbladder/liver plane of dissection	4 (9)	14 (31)	0.008*
Abdominal drain insertion	3 (6.7)	13 (29)	0.006*
Bailout techniques			
Subtotal cholecystectomy	1 (2.2)	5 (11)	0.2
Conversion to open surgery due to	1 (2.2)	4 (9)	0.36
Bleeding	1 (2.2)	1 (2.2)	
Adhesions with colon/duodenum	0	2 (4.4)	
Frozen Calot's triangle	0	1 (2.2)	

ELC, early laparoscopic cholecystectomy; VELC, very early laparoscopic cholecystectomy.
Continuous data are reported as median (interquartile range).
Categorical data are reported as *n* (%).
*Statistical significance at *P* value less than 0.05.

of the patients had iatrogenic bile duct injury; however, four (4.4%) patients experienced postoperative bile leak [three (6.7%) patients in the ELC group vs. one (2.2%) patient in the VELC group, *P*=0.62]. Three (3.3%) of them required bailout through subtotal cholecystectomy, and the leak was evident within the first 24 h after surgery through abdominal drain output. Magnetic resonance cholangio-pancreatography was performed to exclude missed bile duct injury or injured accessory bile duct. All such cases were managed conservatively, and the drains were kept in place until no further bile output was encountered. Regular follow-up was typically

Figure 2



Operative time among both groups. ELC group has significantly longer operative time compared to VELC group.

performed using serial abdominal ultrasonography to exclude any undrained intraabdominal collection before drain removal. The fourth patient with bile leak presented to the emergency department 5 days after discharge with right hypochondrial pain, fever, and vomiting. His TLC was $21.8 \times 10^3/\mu l$. Urgent abdomino-pelvic contrast-enhance computed tomography was performed, which revealed the presence of sizable loculated fluid collection in the subhepatic region. Percutaneous drainage of the collection was performed under computed tomography guidance, and the drained fluid was bilious in nature. Accordingly, the patient was subjected to endoscopic retrograde cholangiography, which showed minor leak from the cystic duct stump immediately distal to the applied clip. Sphincterotomy and stenting were performed, which helped to steadily reduce the bilious output from the pigtail drain until it completely ceased after 9 days and was removed after confirming the absence of undrained intraabdominal collections via abdominal ultrasonography.

Among the entire cohort, 10 (11%) patients developed postoperative superficial wound infection, which was similar among both groups [six (13%) patients in the ELC group vs. four (9%) patients in the VELC group, P=0.5]. They all presented with serous and/or purulent wound discharge few days postoperatively. They were all successfully managed conservatively after prescribing the corresponding antibiotic therapy. None of the patients developed incisional hernia at the 3-month follow-up.

Discussion

LC is considered the optimal treatment modality for patients with moderate to severely symptomatic acute cholecystitis in otherwise fit patients as well as those with mildly symptomatic acute cholecystitis who prefer surgery over conservative management with fluids, analgesia, and antibiotics for fear from recurrent gallstone-related complications [19–21].

The majority of the patients in our study had ACC of grade II severity, followed by grade I, which conforms with the findings reported in the literature [22,23]. It was not surprising, however, that there were more diabetic patients among those who received ELC compared with those who received VELC, which may be explained by neuropathy and the higher pain threshold experienced with diabetes, which may predispose to delayed presentation of patients with ACC. Similarly, Bundgaard *et al.* [22] in their study found that diabetes was significantly higher among the groups of patients who received LC beyond 3 days compared with those who received LC within 3 days of symptom onset. We found patients within the ELC group to have significantly higher TLC, polymorphonuclear leukocyte count, and CRP, which is in partial accordance with the results reported by Brunee *et al.* [24], who found significantly higher CRP levels among patients who received LC done beyond 3 days compared with those who received LC within 3 days of ACC. However, elevated white cell count was not demonstrated in other studies among patients who received LC beyond 3 days [24–26]. This may be explained by the fact that in our newly implemented policy, we did not offer initial medical treatment with intention-to-treat for patients who presented with ACC beyond 3 days of onset of attack who were deemed operable pertaining to their performance status and laboratory investigations in an attempt to offer them ELC as soon as possible within the initial hospital admission. This could have played a key role in keeping their white cell count at significantly higher levels related to the relatively longer time of inflammatory response compared with those who presented within 1–3 days of the acute attack.

Although it is already established that ELC is safe and not different from DLC in terms of intraoperative conversion to open and postoperative morbidity and mortality, the optimal time for performing ELC remains elusive [16]. This is attributed in most cases to the heterogeneity regarding the definition of early LC and whether surgery is considered from the timing of onset of acute attack or the timing of patient presentation/admission irrespective of the duration of the acute attack. Most studies in the literature advocate toward performing LC within the 'golden 72 h' from onset of symptoms [9,10,27]. Other authors sought to expand the window for ELC up to 7 or even 10 days from the onset of symptoms after demonstrating no significant added morbidity or mortality [5,13,14,16].

The updated 2020 WSES guidelines tried to clear such ambiguity by recommending LC for acute cholecystitis to be performed as soon as possible within 7 days from hospital admission and within 10 days from the onset of symptoms [16]. Nonetheless, the TG18 updated guidelines proposed performing ELC for patients with ACC as soon as possible regardless of the time elapsed from the onset of acute attack as long as the patient is deemed suitable for surgery [5].

In this study, our primary aim was to compare the outcomes of ELC performed between 4 and 10 days with VELC performed within 3 days from the onset of symptoms. Although the ELC group had significantly longer operative time compared with the VELC group, both groups were similar in terms of rate of conversion to open surgery, subtotal cholecystectomy, and postoperative complications such as bile leak and wound infection. Additionally, the length of postoperative hospital stay was comparable among the two groups including those who were converted to open surgery. Such findings are in accordance with the data reported in several studies, which demonstrated that patients with ACC who received LC beyond 72 h from onset of symptoms have comparable length of postoperative hospital stay and were not associated with increased risk of operative conversion or postoperative biliary complications despite the longer operative time in comparison with those operated within 72 h [22,25,28,29]. Such findings highlight the safety and feasibility of offering ELC cautiously to patients who may present later than 72 h from the onset of ACC attack without the increased risk of operative conversion or postoperative complications. Brunee *et al.* [24] in their study supported the reasoning for performing ELC beyond 3 days of onset of ACC; however, they did not recommend ELC after 7 days of onset owning to increased operative difficulty and longer operative time despite no bile duct injury was experienced. On the contrary, conflicting data were reported by other authors who argued that strict adherence to performing ELC within 72 h from onset is safer as it offers significantly better outcomes in terms of reduced conversion rates and postoperative biliary complications, shorter length of postoperative hospital stay, and lower overall costs [30–32].

The primary limitation of this study is being a single-center retrospective cohort study with relatively small number of patients included. Although our results were in accordance with the data from literature advocating the benefit and highlighting the safety of performing ELC for patients presenting with ACC beyond 3 days of onset without added significant morbidity, we did not perform external validation for our results.

In conclusion, although it remains optimal to perform VELC within 3 days from onset of ACC symptoms, there is growing evidence toward expanding this golden 72-h window to grant ELC for patients presenting with ACC regardless of the duration from onset of symptoms. This is attributed to the absence of significant difference in conversion rate, subtotal cholecystectomy rate, postoperative complications, as well as the length of postoperative hospital stay among patients who underwent ELC beyond 3 days compared with those who received VELC within 3 days from onset of symptoms. Accordingly, we can argue that the duration of acute attack alone should not be considered a major factor to influence surgeon's decision to proceed with LC. Nonetheless, such conclusion should be drawn cautiously where ELC could be offered for properly selected patients presenting with ACC beyond 3 days from onset of symptoms provided that they are performed in specialized and well-equipped medical centers and operated by competent surgeons with adequate surgical expertise in laparoscopy and biliary surgery to deal with the challenges and complex nature of such demanding surgeries wisely to guarantee safety of patients and optimize outcomes while ameliorating postoperative morbidity.

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Conflicts of interest

There are no conflicts of interest.

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