Early versus interval laparoscopic cholecystectomy for treatment of noncomplicated acute calcular cholecystitis

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Laparoscopic cholecystectomy (LC) is widely established as the standard treatment in uncomplicated acute calcular cholecystitis (ACC). Despite the relevant frequency of ACC, controversies remain regarding the timing of LC. Traditionally treatment for ACC included two stages with an initial conservative management followed by an interval LC. Early LC was avoided for ACC owing to concerns about potential hazards of complications and a high conversion rate. The aim of the study is to compare between patients with uncomplicated ACC treated with early LC (within 72 h) versus interval LC (after 6 weeks of conservative treatment) regarding primary and secondary outcomes. A total of 100 patients with uncomplicated ACC are divided randomly into two groups, group A, early LC, and group B, interval LC. From this study, we conclude that there is no significant difference between both groups regarding primary and secondary outcomes. Early LC is feasible and safe, and interval LC is not associated with a lower conversion rate. In group A, there is a significantly high rate of infection, with longer hospital stay in diabetics, and in group B as well, the bile leak and rate of conversion are high, with longer hospital stay in diabetics.

Keywords:
early versus delay, interval laparoscopic cholecystectomy, laparoscopic cholecystectomy

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Introduction

Laparoscopic cholecystectomy (LC) leads to a more rapid improvement in quality of life than open cholecystectomy. Thus, it has continued to gain widespread clinical acceptance and is now the gold standard procedure for cholecystectomy [1].

When LC began in the early 1990s, pregnancy, previous abdominal surgery, obesity, cirrhosis, and acute cholecystitis were considered absolute contraindications for performance of the laparoscopic procedure. As advances in laparoscopic skills and instrumentation have evolved, all these traditional absolute contraindications had changed to relative [2]. Gallstones are common and present as acute calculus cholecystitis (ACC) in 20% of patients with symptomatic disease with wide variation in severity. ACC often requires emergency admission to the hospital. The traditional treatment of ACC was conservative followed by interval cholecystectomy, usually 6–8 weeks after discharge, although early cholecystectomy in patients with ACC was shown to be safe and effective many years ago [3]. However, early reports of LC for ACC frequently showed a higher complication rate, a prolonged operation time, and a higher rate of conversion to open surgery because of perceived difficulties in dissection. Conservative treatment of acute cholecystitis followed by delayed-interval LC became a commonly accepted practice in the nuance of laparoscopy [4,5]. With the growing experience and improvement in laparoscopic skills, recent studies have demonstrated that LC is safe for ACC. Randomized trials have also shown that early LC (within 72 h of admission) for the treatment of ACC is safe, feasible, and associated with a shorter hospital stay. The feasibility of the laparoscopic technique in the condition of ACC was assessed and reported in several publications. It has been shown that laparoscopy for ACC was feasible, with conversion rates ranging from 0.5 to 30%. The conversion rate with LC for ACC was evidently greater than that for elective cases, which range from 3 to 7% [6,7]. In ACC, extensive inflammation, adhesions, and consequent increased oozing would make dissection of Calot's triangle and recognition of the biliary anatomy more hazardous and difficult. These factors were reported to be the most common reasons for complications and conversion [8]. Multiple randomized clinical trials report that early LC is safe with no difference in complications, mortality and conversion rate when compared with interval LC [9]. However, existing evidence regarding the clinical benefits of early LC for patients presenting with ACC remains elusive, and

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there is still controversy regarding the timing of surgery [10].

Most specialists perform an interval cholecystectomy owing to uncertainty regarding the efficacy and safety of an early cholecystectomy. Limitations to hospital resources, such as access to surgeons, operating room time, and postoperative intensive unit beds, may contribute to noncompliance to recommendations for early cholecystectomy [11]. The rationale for cholecystectomy during the same hospitalization, compared with interval cholecystectomy, is that it leads to a reduction in the frequency of recurrent biliary events (e.g. recurrent biliary pancreatitis, acute cholecystitis, symptomatic choledocholithiasis, and biliary colic) in these patients. It was noted that there is an increased risk of recurrence 2–4 weeks after discharge [12].

Percutaneous gallbladder drainage (PGBD) in the group of a severely ill patient with empyema of the gallbladder has been used increasingly in patients with ACC as a diagnostic and therapeutic procedure, with a success rate of 100%. PGBD did not significantly improve; however, the outcome of LC for ACC as assessed by conversion and morbidity rates and hospital stay [13,14].

A controversy still exists in between local guidelines questioning which is preferable, early versus interval cholecystectomy. Hence, in the USA, the standard of care is LC within 48–72 h, whereas in the UK, National Institute for Health and Care Excellence guidelines, implemented in 2011 and updated in 2017, state LC should be performed within 1 week of presentation, but despite a drive toward providing early surgery, many patients in the UK are still initially managed conservatively with planned delayed cholecystectomy 6–8 weeks following discharge [15,16]. In this study, we implement our experience in a trial to have guidelines toward early cholecystectomy compared with delayed cholecystectomy in patients with mild to moderate ACC in an attempt to reduce recurrent biliary events without a higher perioperative complication rate.

Patients and methods

Between January 2017 and December 2017, one hundred patients with a diagnosis of ACC admitted to the Department of Surgery, Kasr Alainy Hospital were included in the study. The diagnosis of ACC was based on a combination of clinical criteria (acute right upper quadrant tenderness, temperature exceeding 37.5°C, and white blood cell count >10 000/ml) and ultrasonographic criteria (thickened, edematous distended gallbladder; positive sonographic Murphy's sign; presence of gallstones; and pericholecystic fluid collection). Patients with symptoms for more than 72 h, previous upper abdominal surgery, coexisting common bile duct stones, obstructive jaundice, or significant medical disease rendering them unfit for laparoscopic surgery were excluded from the study. Informed consent was obtained. Patients were then randomized into either the 'early' group, with 50 patients, or the 'delayed' group, with 50 patients. Randomization was accomplished manually by alternating cases. In the early group, LC was performed within 24 h of randomization, whereas in the interval group, conservative treatment with intravenous fluids and antibiotics including ampicillin, gentamicin, and metronidazole was given. The patients who responded to conservative treatment underwent an elective LC 6–8 week after the acute episode had subsided. The patients who failed conservative treatment were treated with emergency open cholecystectomy. All patients were fully investigated in the form of CBC, FBS, serum amylase, serum bilirubin, liver enzymes, bleeding profile, and abdominal ultrasound. Patients were assessed primary for bleeding; injury to bile duct, bowel, or vessel; and the rate of conversion to open surgery. Then, they were followed up for secondary outcomes, which were postoperative complications and hospital stay. Laparoscopy was performed with standard four-port and two-handed techniques in the American position. Open Hasson's technique was used to provide direct visualization.

Dissection of Calot's triangle and the gallbladder from the liver bed was accomplished by using monopolar electrocautery and sometimes hydrodissection. Critical-view dissection was used to prevent any bile duct injury. No clipping was carried out until all anatomic structures had been identified. Gallbladder was extracted through the epigastric port site. Often the epigastric wound had to be extended for the extraction of the gallbladder when its wall is considerably thickened. Drains were routinely placed. Postoperatively two more doses of intravenous broad-spectrum antibiotics were used. All patients could eat and drink when tolerating. All patients were discharged after 24 h except patients with complications. Drains were removed after 24 h, except in patients with complications. In addition, all patients who underwent surgery had histologic confirmation of ACC.

Statistical analysis

Comparisons between groups were on an intention-to-treat basis. All continuous variables were expressed as median (range) and compared using the Mann–Whitney

U-test. χ^2-Test and Fisher's exact test were used to compare discrete variables. Statistical calculations were performed with the help of SPSS/PC+ (SPSS Inc., Chicago, Illinois, USA), and a *P* value of less than 0.05 was considered to indicate statistical significance.

Results

Demographic and clinical profile of the 100 patients in the study shows that 50 patients in the early group and 50 in the interval group completed the study and were suitable for analysis. There were four males and 46 females with a mean age of 44.96 years (range: 26–67 years) in the early group, whereas there were four male and 46 female patients, with a mean age of 43.88 years (range: 26–67 years), in the interval group. There is no significant difference between the two groups in age and sex demographics. In the study, 14 patients were diabetic: six (12%) in the early group and eight (16%) in the interval group.

The clinical symptoms were comparable between the two groups. In the early group, the pain was constant in eight patients and colicky in 42, whereas the pain was constant in 10 patients and colicky in 40. The time mode interval between the onset of symptoms and admission to the hospital was 1–3 days. Approximately a third of the patients (32%) complained of upper quadrant pain for 3 days before admission.

Laboratory data are shown in Table 1. No patients with jaundice were included in this study. SGOT was similar in the two groups (25 vs. 23), and alkaline phosphatase was significantly higher in the interval group (206183) than the early treated group (*P*=0.023). Mean total leucocytic count (TLC) in group 1 is 7.82±1.410, which is higher than in group 2 (5.40±1.069) (*P*<0.001).

Ultrasonographic evidence of thickened gallbladder wall, edematous gallbladder wall, distended gallbladder, presence of gallstones, ultrasonographic Murphy's sign, and pericholecystic fluid collection were all positive in all patients in the study groups. Ultrasonographic findings during the acute phase were nearly similar, except for a significantly higher proportion of patients with edematous gallbladder wall in the early group (Table 2).

As shown in Fig. 1, group 1 patients had GB wall thickness more than 3 mm, with four patients having pericholecystic collection, and group 2 patients had GB wall thickness less than 3 mm.

The results of operative procedure and operating time show no modifications in the operative technique, but a longer operation time was required in the early group than in the interval group. The mean operative time was 104 min (range: 40–210 min) in the early group and 93 min (range: 35–200 min) in the interval group. The difference in operative time was not statistically significant (*P*=0.433).

The rate of conversion to open cholecystectomy was equal in both groups with only one case converted of 50 cases in each group. The operative and postoperative complications are more prevalent in the early group, as there was bleeding (4%), infection (2%), bile leak (4%) and common bile duct (CBD) injury (2%). The average blood loss was 228 ml in the early group and 125 ml in the delayed group (*P*=0.006). No patient in either group required blood transfusion (Fig. 2).

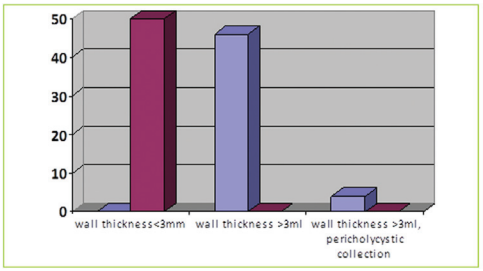
Table 1 Laboratory results of early and interval groups on admission

	Early (*n*=50)	Interval (*n* 50)	*P*
Hemoglobin (g/dl)	13.6±2.4	12.4±3.2	0.812
WBC (10^9/l)	7.82±1.410	5.40±1.069	0.542
Platelet count (10^9/l)	242.7±19.1	295±24.7	0.606
Albumin (g/l)	4.3±2.1	4.6±3.2	0.805
Total bilirubin (μmg/l)	0.7±0.13	0.6±0.14	0.955
Alkaline phosphatase (IU/l)	91.00±30.7	99.6±43.8	0.518
Aspartate aminotransferase (IU/l)	40.7±20	30.8±14	0.393
Alanine aminotransferase (IU/l)	35.3±18	25.4±13	0.344

Table 2 Ultrasound findings for the patients

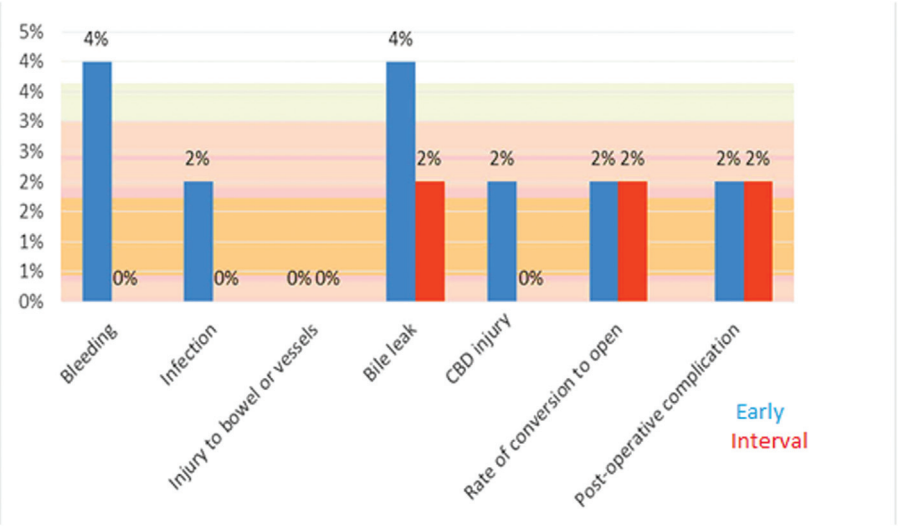
	Early (*n*=50) [*n* (%)]	Delayed (*n* 50) [*n* (%)]	*P*
Thickened edematous gallbladder	40 (80)	27 (54)	0.436
Distended gallbladder	43 (86)	37 (74)	0.901
Presence of gallstones	50 (100)	50 (100)	0.890
Ultrasonography Murphy's sign positive	46 (92)	44 (88)	0.769
Pericholecystic fluid	11 (22)	10 (20)	0.543

Figure 1



Difference in gallbladder wall thickness between the two groups.

Figure 2



The rate of operative and postoperative complications.

Early operated patients had a shorter hospital stay with a mean of 1.20±0.632 days, whereas the mean in the interval operated patients was 1.26±0.587 days. None of the patients of the interval group experienced another acute attack during the interval period and required readmission. Although there was no significant difference in the postoperative pain score, patients in the early group required fewer analgesics than those in the delayed group.

Histopathologic examination of the gallbladder confirmed the presence of acute inflammation in all patients undergoing cholecystectomy in the early group. There were 41 specimens in the delayed group that showed acute-on-chronic cholecystitis.

Discussion

LC has been well received by surgeons and patients since its introduction in 1985, owing to its perceived lower incidence of postoperative pain, morbidity, and shorter length of hospital stay [17,18].

Until the recent past, LC 6–8 weeks after the episode of ACC has been a standard protocol owing to the belief that chances of hemorrhage, CBD/Gastrointestinal (GIT)/liver injuries, and conversion rate are high if surgery is attempted in acutely inflamed tissue. As the experience and confidence of surgeons in LC have increased, several randomized clinical trials, though samples were small, proved that early LC in ACC is feasible, safe, and cheaper, with shorter hospitalization stay and with a more or less the same conversion rate as the interval LC [19].

It is widely accepted now that LC for acute cholecystitis should be done at the index admission as interval LC is associated with 25% of the patients remaining symptomatic, requiring readmission before the elective surgery [20].

In this study, we compared early operated patients (within 72 h) versus interval operated patients (after 6–8 weeks) regarding the primary outcome (bleeding, infection, CBD injury, bowel injury, bile leak, and conversion to open surgery) and the secondary outcome (hospital stay and postoperative complications) in diabetic and nondiabetic patients.

One hundred patients are randomly divided into two groups: group 1 included early operated versus group 2 interval operated patients.

The sex distribution in this study is 92% females, which is similar to a study stating that gallstones are more prevalent in females, and that the female to male ratio reported was 4.5 : 1 [1].

In this study, 14% of the studied population are diabetics. The mean age in group 1 is 44.96 years, whereas mean age in group 2 is 43.88 years. The mean TLC in group 1 is 7.82, whereas the mean TLC in group 2 is 5.40. The mean hospital stay in group 1 is 1.28, whereas it is 1.36 in group 2.

Equally, there was no statistically significant difference in the rates of conversion and morbidity between both groups. All cases of conversion were owing to the inability to clearly identify the structures within the space of calot, and not owing to complications.

In a study was done by Al-Salamah [1], the mean age was 43.7 years. In another study reported by Cheema *et al.* [21], the range of patients age was 22–70 years, with a mean age of 41.4 year.

Chang [22] reported that although early LC is associated with a higher rate of wound infections compared with interval intervention, it shortens the length of hospital stay and reduces the risk of repeated cholecystitis and biliary complications. In a randomized, controlled trial including 75 patients, early LC (<24 h) was found to decrease the morbidity during the waiting period for elective LC, the rate of conversion to open cholecystectomy, operating time, and hospital stay [22,23].

It is important to realize that the need for conversion to laparotomy is neither a failure nor a complication, but an attempt to avoid complications and ensure patient safety [24].

It was concluded that there is no advantage to delay cholecystectomy for ACC based on outcomes in complications, rate of conversion to open surgery, and mean hospital stay. There is strong evidence that early LC for acute cholecystitis offers an advantage in the length of hospital stay without increasing the morbidity or mortality. The operating time in earlylaparscopic cholecystectomy (ELC) can be longer; however, the incidence of serious complications (i.e. common bile duct injury) is comparable to the delayedlaparscopic cholecystectomy (DLC) group. Larger randomized studies are required before solid conclusions are reached [25,26].

In a meta-analysis including seven trials with 1106 patients, there was no significant difference between the two groups in terms of bile duct injury or conversion to open cholecystectomy. The total hospital stay was shorter by 4 days for early LC. Intraoperative bleeding may occur during the dissection of Calot's triangle or be related to a wound of the liver. This risk is even more if there are adhesion and severe locoregional inflammation. Interval cholecystectomy is more often complicated with intraoperative bleeding (299 vs. 81 ml, $P<0.05$) [27,28].

A study of 45 patients of acute cholecystitis showed two cases of wound infection in patients of early LC. In another study, in early LC group, there was only one (2%) case of wound infection [29].

Another study found 2.94% wound infection in the early group against 2.02% in the interval group ($P=0.755$). However, in diabetics, a significant increase in the rate of surgical site infection is shown in case of interval cholecystectomy (4.93 vs. 2.77%, $P=0.034$) [30].This study shows that in group 1 the bleeding is 4%, infection is 2%, bile leak 4%, CBD injury (2%), rate of conversion to open is 2%, whereas in group 2, CBD injury is 2%, and the rate of conversion to open is 2%, with no bleeding, infection, or bile leak. This study shows no significant difference between the two groups in primary outcome.

Moreover, this study shows a significant difference in group 1 regarding wound infection, with 16.7% in diabetics, whereas zero in nondiabetic ($P=0.006$).

There is a significant difference regarding bile leak in group 1, with 12.5% in diabetics whereas zero in nondiabetics ($P=0.02$). Moreover, there is a significant difference between diabetics and nondiabetics in group 2 regarding the rate of conversion to open, as it is higher in diabetics than in nondiabetics ($P=0.021$).

In a recent survey evaluating surgical approaches for acute gallbladder disease between 1989 and 2006 in Sweden, the total hospital stay was found to be shorter for patients who had emergency cholecystectomy at first admission compared with patients with elective cholecystectomy [31].

In this study, there is no statistically significant difference between both groups regarding secondary outcome. The postoperative complications are similar, with 2% in both groups, whereas the mean hospital stay was 1.28±0.757 in group 1 and 1.36±0.722 in group 2.

Moreover, this study shows a significant difference in group 2 between diabetics and nondiabetics regarding hospital stay. Mean hospital stay is 1.88±1.126 in diabetics, which is longer than in nondiabetics value at 1.26±0.587 (0.026).

Mental stress on the patients in the interval group, with 6–8 weeks waiting interval for surgery, is an additional disadvantage not considered by the studies.

Conclusion

Early LC is a feasible and safe for treatment of uncomplicated ACC with economic benefit to the patient and health care system. Interval LC is not associated with a lower conversion rate.

There is no significant difference between early (first 72 h) and interval (after 6 weeks) operated patients regarding primary and secondary outcomes. However, in the early operated patients, there is a significantly high rate of infection and longer hospital stay in diabetics more than nondiabetics. Moreover, in the interval operated patients, the bile leak and rate of conversion to open are higher, with longer hospital stay in diabetics than nondiabetics.

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Conflicts of interest
There are no conflicts of interest.

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