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Safe postoperative outcomes following early cholecystectomy for acute calculus cholecystitis regardless of symptom onset

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ABSTRACT

Objective: There is growing evidence for reduced post-operative complications, and lower hospital costs associated with early cholecystectomy for acute calculus cholecystitis (AC) compared to delayed surgery. Limited high-quality evidence exists for how early, if at all, should surgeons be operating emergently for AC based on symptom onset.

Material and Methods: Seven hundred seventy-four patients who had cholecystectomy performed by a single surgeon between January 2015-October 2022 were retrospectively reviewed. Five hundred fourty-one patients were analysed. Patients were divided into three groups based on symptom onset: Group 1: 0-72 hours (n= 305), Group 2: 72 hrs-1 week (n= 154) and Group 3: >1 week (n= 82).

Results: Median operative time was most prolonged in Group 2 (96.5 minutes), and had the greatest proportion of reconstituting 95% cholecystectomies (n= 22/154, 14.29%) compared to Group 1 (p> 0.05). The conversion to open was between 0.65-1.64% in all groups. The greatest proportion of bile leak occurred in Group 1 (n= 7/305, 2.3%) followed by Group 3 (n= 1/82, 1.22%) (p> 0.05). All were successfully managed with ERCP and biliary stent. Median hospital stay was significantly prolonged in Group 2 (2.3 days) compared to Group 1 (2 days) (p= 0.03). The proportion of 95% cholecystectomies in Group 2 and 3 were not significant compared to Group 1.

Conclusion: Early cholecystectomy for calculus cholecystitis, irrespective of the timing of symptoms appears to have safe postoperative outcomes. Surgeons do not necessarily need to limit early cholecystectomy for within 72 hours of symptom onset.

Keywords: Cholecystitis, early cholecystectomy, timing, postoperative outcomes

INTRODUCTION

Cholelithiasis is a condition affecting up to 6.5-15% of the Western population (1,2). Approximately 1-4% of these patients develop complications, of which 70% are related to acute cholecystitis (3-5). Acute calculus cholecystitis (AC) accounts for a significant proportion of patients admitted to the emergency department in general surgery. Due to the high risk of developing recurrent cholecystitis and other complications such as gallstone pancreatitis and cholangitis, laparoscopic cholecystectomy (LC) is recommended. Current evidence suggests clinical benefits following early LC during the index admission. Compared to delayed LC, early LC is related to reduced long term biliary complications (bile duct injury/bile leaks), wound infections, conversion to open rates, shorter total admission length of stay, and overall lower hospital costs (6-10). In 2013, the Tokyo Guidelines for the management of acute cholecystitis (TG13) recommended that cholecystectomy should be performed within 72 hours after symptom onset (11). LC performed for AC 72 hours after onset of symptoms is believed to increase the risk of perioperative complications due to the distorted anatomy of the Calot's triangle from inflammatory adhesions secondary to prolonged inflammation. However, in drafting the Tokyo Guidelines (TG18), it was noted that it is often difficult to precisely determine the duration since symptom onset (12,13). There is heterogeneity in the literature with regards to the definition of early surgery including cholecystectomy within 24 hours of hospital admission or symptom onset, within 72 hours since patient admission or symptom onset, or within one week since onset of symptoms (12). Thus, it remains difficult to ascertain the optimum timing that will reduce postoperative complications, and the length of stay.

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The TG18 recommends early LC for AC in those patients capable of withstanding surgery, regardless of the onset of symptoms (recommendation 2, level B) (13). Thus, the aim of this study was to evaluate the safety and to compare the postoperative outcomes of early LC for AC based on the duration of symptom onset. The authors hypothesized that early LC is safe, regardless of the duration of symptoms of AC.

MATERIAL and METHODS

Patient Population and Data Collection

This was a retrospective, cohort study on consecutive patients who had early cholecystectomy for acute calculous cholecystitis, between January 2015 to October 2022. All cholecystectomies were performed by the principal investigator, a senior consultant general surgeon. All procedures were initially attempted laparoscopically, then converted to open if deemed necessary. Hospital data was extracted from the Local Health District Medical Records Department. The authors initially collected 775 patients who had LC, of which 234 patients were excluded. Excluded patients were those that had:

1) Gallstone pancreatitis (n= 82),

2) Elective/delayed cholecystectomy (n= 82),

3) Acalculous cholecystitis (including gallbladder polyps) (n= 3),

4) Cholangitis (n= 7),

5) Absence of cholecystitis on final histopathology (biliary colic) (n= 2),

6) Cholecystectomy for gallbladder dyskinesia (n= 1),

7) Concurrent cholecystectomy as part of another procedure (n= 5), and

8) Those who had incomplete data (n= 52).

After exclusion, 541 patients were included in the study. They were divided into three groups: Group 1 305 patients <72 hours of symptom onset to LC; Group 2 154 patients 72 hours-7 days of symptom onset to LC; Group 3 82 patients >7 days of symptom onset to cholecystectomy.

The decision to operate was made by the principal investigator based on the presence of AC (suspected and definitive diagnosis) defined according to TG18 (13). A suspected diagnosis of AC was considered when local signs of inflammation were present, as well as at least one systemic sign of inflammation. Local signs of inflammation included right upper quadrant pain/tenderness, mass, or positive Murphy's sign. Systemic signs included fever ≥38 degrees celsius, elevated white cell count (WCC) >11.1 x 10^9/L, and/or elevated c reactive protein (CRP) >3 mg/L. A definitive diagnosis of AC included the above, and imaging findings of calculus AC. Imaging findings of inflammation were not necessarily required for LC if cholelithiasis had been confirmed previously. AC was confirmed intraoperatively, as well as on final histopathology.

Patient demographics, preoperative, intraoperative, and postoperative variables were reviewed, in detail. Preoperative temperature (normal range= 36-38°C), WCC (normal range= 3.9-11.1 x 10^9/L), CRP (normal range= ≤3 mg/L), AST (normal range= 10-35 U/L), ALT (normal range= 10-35 U/L), ALP (normal range= 30-110 U/L), GGT (normal range= ≤35 U/L), bilirubin (BR) (normal range= ≤19 µmol/L) were taken at its highest recorded value between admission and LC. Gallbladder wall thickness was tabulated using ultrasound and/or histopathology measurements. Operation time was taken from knife to skin to completion of wound closure. LC (10 mm umbilical Hasson port, 3 x 5 mm right upper quadrant ports) and open cholecystectomy (OC) (right subcostal incision) were performed in a standard fashion, with an attempt at intraoperative cholangiogram (IOC) in all cases. If a filling defect was found during IOC, all patients underwent postoperative endoscopic retrograde cholangio-pancreatography (ERCP). A reconstituting 95% cholecystectomy was consistently performed as the transection of the gallbladder at the gallbladder neck after control of the cystic artery. This technique was chosen when there was dense inflammation, and the risk of bile duct injury was perceived to be high. This involved gentle, careful dissection around the full circumference of the neck, commonly using hydrodissection to improve safety while separating the gallbladder neck from the cystic plate. Following transection, any gallstones in the proximal cystic duct and neck of the gallbladder were extracted. Next, the distal gallbladder neck was further mobilized off the cystic plate using hydrodissection and limited diathermy. This allowed for IOC via the neck of the gallbladder using a ureteric catheter secured using a large ratcheted grasper across the gallbladder neck. Next, a polydioxanone (PDS) endoloop was used to close the distal gallbladder neck, and the excess neck tissue was sent for histopathology as a separate specimen. This achieved an approximately 95% cholecystectomy. If the IOC was unsuccessful, a postoperative magnetic resonance cholangiopancreatography (MRCP) was performed, with subsequent ERCP if there was choledocholithiasis. Bile duct injury was defined as suspected or confirmed injury to the hepatic or common bile duct. Bile leak was defined as any observable bile in the abdominal drain. Clavien-Dindo classification grade ≥2 related ≤30-day readmission only included patients who were readmitted within 30 days requiring pharmacological treatment with drugs other than those allowed for Clavien-Dindo classification grade 1, requiring surgical, endoscopic, radiological intervention, intensive care management, or death of patient (14).

Statistical Analysis

Statistical analysis was performed using SPSS 23.0 (SPSS Inc., Chicago, IL, USA) and Microsoft Excel 2019 (Microsoft Corporation, USA). Categorical measurements were summarized as number and percentages. Continuous non-homogeneous parameters were measured using medians and continuous homogenous parameters were calculated using mean and standard deviations. Chi-square test was used for comparing categorical variables. Independent Student's t-test was used to compare patient groups where appropriate, with $p< 0.05$ considered statistically significant.

RESULTS

Median age of the cohort was 44 years. Those who were operated between 3-7 days (Group 2) since symptom onset tended to be older (46 years) than those operated within 72 hours of symptom onset (44 years) (Group 1) (p= 0.04). There were more females (66.9%-73.2%) than males (26.8%-33.1%) in all three groups (Table 1).

In terms of preoperative data, those that were operated after one week of symptom onset (Group 3) had a significantly thicker gallbladder wall thickness (5.63 mm) compared to Group 1 (4.96 mm), likely owing to the prolonged inflammation (p= 0.05). White cell count (WCC) and c reactive protein (CRP) tended to be similar between all groups. Liver enzymes were all statistically greater in Group 2 than in Group 1. There was a small variance in the mean bilirubin level between all groups (Table 1).

Intraoperatively, Group 2 had the most prolonged median operative time (96.5 minutes) and had the greatest proportion of 95% cholecystectomies (n= 22/154, 14.29%). However, these were not statistically significant to Group 1. Interestingly, Group 3 had the shortest operative time of 84.5 minutes, possibly related to reduced inflammation. The conversion rate from LC to OC was 1.3% among all groups. A greater proportion of patients in Group 2 (n= 15/154, 9.74%) and 3 (7/82, 8.54%) had suppurative/necrotizing/gangrenous cholecystitis in comparison to Group 1 (14/305, 4.59%) although this was not statistically significant (p= 0.16, p= 0.054). Bile duct injury occurred only once in Group 1 and Group 3. All were successfully managed with ERCP with biliary stent without complications (Table 1).

Postoperatively, proportion of bile leak was greatest in Group 1 (n= 7/305, 2.3%) followed by Group 3 (n= 1/82, 1.22%), of which all were successfully managed without complications with ERCP and biliary stent. There were two returns to theatre. The first patient was otherwise well, who returned to theatre within a few hours after an uncomplicated LC. There was bleeding from possibly the cystic artery after dislodged clips. The second patient was elderly with heart failure, atrial fibrillation, on warfarin who returned to theatre on postoperative day six. There was bleeding from the edge of liver adjacent to the gallbladder stump. Postoperative median length of stay was significantly prolonged in Group 2 (2.3 days) compared to Group 1 (2 days), p= 0.03. There were small number (n= 4, 0.74%) of Clavien-Dindo classification grade ≥2 related ≤30-day readmissions due to gallbladder fossa collection and postoperative pain (n= 1), *Clostridium difficile* colitis (n= 1), nonspecific colitis (n= 1) and choledocholithiasis (n= 1). There was unfortunately one death following a laparoscopic 95% cholecystectomy for necrotizing cholecystitis, where a 69-year-old patient had a suspected aspiration pneumonia on postoperative day 14. The patient had seizures and catatonia, and after prolonged admission of reduced responsiveness and hypoxia, was palliated six weeks post operation (Table 1).

Table 2 tabulates all patients who had a 95% cholecystectomy. Compared to all patients analyzed, they were significantly older, a greater proportion was males (47.3% vs 31.2%, p= 0.006), had higher preoperative temperature (37.35°C vs 37.1°C, p= 0.003), higher preoperative bilirubin (16 µmol/L vs 11 µmol/L, p= 0.003), prolonged operation time (118 minutes vs 91 minutes, p< 0.001), higher conversion to open (8.1% vs 1.3%, p= 0.0001), greater proportion of bile leak postoperatively (5.4% vs 1.48%, p= 0.02), and prolonged median hospital stay (3 days vs 2 days, p< 0.001). There were no deaths, or recurrent biliary colic/cholecystitis in the 95% cholecystectomy patients to date (from seven years ago).

DISCUSSION

There is growing evidence to suggest that early cholecystectomy for AC has statistically significant lower morbidity, shorter hospital stay, and lower hospital costs compared to delayed cholecystectomy (6-10,15). However, there remains ongoing debate with regards to the timing of early LC, partly due to the variability in the definition of early LC, and the perceived increased risk of postoperative complications and conversion rates if early LC is performed beyond 72 hours of symptom onset.

A recent meta-analysis of randomized trials has suggested that early cholecystectomy for AC ≤72 hours from symptoms reduces open conversion rates in comparison to cholecystectomy ≤7 days from symptoms (p= 0.044). In addition, cholecystectomy ≤24 hours from admission is the best strategy to reduce total in-hospital stay (12). An ACS-NSQIP review of early cholecystectomy for AC has concluded that cholecystectomy should be performed within two days of hospital admission, which is based on 1.4 times increase in major complications, and 2-times increase in mortality when surgery was delayed to within 3-7 days of hospital admission (16).

Table 1. Patient demographics and perioperative variables between groups 1-3

Characteristic	Total (n= 541)	Group 1: <72 hours of symptom onset (n= 305)	Group 2: 72 hours-7 days since symptom onset (n= 154)	Group 3: >7 days of symptom onset (n= 82)	p-value: Group 2 vs. Group 1; Group 3 vs Group 1
Sex, n (%)					
Male	169 (31.2)	96 (31.5)	51 (33.1)	22 (26.8)	0.72; 0.42
Female	372 (68.8)	209 (68.5)	103 (66.9)	60 (73.2)	
Age, median (range)	44 (14-97)	44 (15-88)	46 (14-97)	43 (17-95)	**0.04**; 0.39
Time of symptom onset to cholecystectomy hours, median (range)	86 (9-672)	46 (9-72)	120 (75-168)	196 (170-672)	**<0.01, <0.01**
Highest preoperative temperature °C, median (range)	37.1 (35.3-40.2)	37.2 (36-40.2)	37.1 (35.3-39.8)	36.9 (35.4-39)	**0.04; 0.003**
Gallbladder wall thickness, mean (SD)	5.10 (2.94)	4.96 (2.82)	5.05 (2.76)	5.63 (3.57)	0.38; **0.05**
CRP mg/L, median (range)	11 (1-664)	9.5 (1-453)	11.5 (1-357)	12 (1-664)	0.46; 0.14
WCC x10^9/L, median (range)	10.1 (2.2-66)	10.1 (2.2-27.6)	10.5 (3.8-66)	9.3 (2.6-23.6)	0.61; 0.09
AST U/L, median (range)	28 (7-1097)	25 (6-980)	38.5 (8-827)	29 (9-1097)	**0.003**; 0.09
ALT U/L, median (range)	40 (9-1571)	37 (9-996)	52.5 (12-1571)	39 (12-1020)	**0.01; 0.05**
ALP U/L, median (range)	94 (13-829)	89 (13-829)	101 (32-750)	96.5 (41-572)	**0.01**; 0.14
GGT U/L, median (range)	53 (5-1600)	42 (7-1600)	75.5 (12-1217)	53 (5-781)	**0.01**; 0.15
Bilirubin µmol/L, median (range)	11 (2-415)	10 (2-415)	13 (2-152)	9 (2-165)	0.07; 0.07
Operation time minutes, median (range)	91 (26-235)	93 (47-235)	96.5 (26-192)	84.5 (36-156)	0.15; **0.004**
95% cholecystectomy, n (%)	74 (13.7)	42 (13.77)	22 (14.29)	10 (12.2)	0.88; 0.71
Conversion to open, n (%)	7 (1.3)	5 (1.64)	1 (0.65)	1 (1.21)	0.38; 0.78
Histopathology, n (%)					
Cholecystitis only	495 (91.5)	285 (93.44)	137 (88.96)	73 (89.02)	0.2; 0.3
Cholecystitis with suppurative/ necrotizing/gangrenous changes	36 (6.66)	14 (4.59)	15 (9.74)	7 (8.54)	0.054; 0.16
Cholecystitis with incidental low-grade dysplasia	4 (0.74)	3 (0.98)	1 (0.65)	0 (0)	0.71
Cholecystitis with incidental adenocarcinoma	3 (0.55)	1 (0.33)	1 (0.65)	1 (1.22)	0.32; 0.32
Cholecystitis with other pathology	3 (0.55)	2 (0.66)	0 (0)	1 (1.22)	**0.001**
Bile duct injury, n (%)	2 (0.37)	1 (0.33)	0 (0)	1 (1.2)	0.32
Bile leak post operatively	8 (1.48)	7 (2.3)	0 (0)	1 (1.22)	0.54
Takeback to theatre, n (%)	2 (0.37)	0 (0)	2 (1.3)	0 (0)	
Postoperative stay days, median (range)	2 (0-47)	2 (0-11)	2.3 (0-47)	1 (0-14)	**0.03**; 0.33
Clavien-Dindo classification Grade ≥2 related ≤30-day readmission, n (%)	4 (0.74)	0 (0)	1 (0.65)	3 (3.66)	
Death, n (%)	1 (0.37)	0 (0)	1 (0.65)	0 (0)	

SD: Standard deviation, CRP: C-reactive protein, WCC: White cell count, AST: Aspartate aminotransferase, ALT: Alanine transaminase, ALP: Alkaline phosphatase, GGT: Gamma-glutamyl transferase.

Table 2. Patient characteristics of the 95% cholecystectomy group

Characteristic	95% cholecystectomy (n= 74)	p (vs. total)
Sex, n (%)		
Male	35 (47.3)	**0.006**
Female	39 (52.7)	
Age, median (range)	57 (21-84)	**0.0001**
Highest preoperative temperature °C , median (range)	37.35 (35.9-39.7)	**0.003**
Gallbladder wall thickness mm, mean (SD)	5.53 (2.67)	0.13
Bilirubin µmol/L, median (range)	16 (5-415)	**0.003**
Operation time, minutes, median (range)	118 (51-235)	**<0.001**
Conversion to open, n (%)	6 (8.1)	**0.0001**
Bile duct injury, n (%)	1 (1.35)	0.26
Bile leak post operatively, n (%)	4 (5.4)	**0.02**
Postoperative stay days; median (range)	3 (1-41)	**<0.001**
Death, n (%)	0 (0)	
Recurrent biliary colic/cholecystitis, n (%)	0 (0)	

The principal findings of the study were that there was no significant difference in postoperative outcomes in Groups 2 and 3 compared to Group 1 in terms of 95% cholecystectomy rates, conversion to open, bile duct injury, and bile leak postoperatively. In regard to patients who had bile duct injury, or postoperative bile leak, they were all definitively managed with ERCP and stent. In keeping with other studies, there was a statistically significant greater length of stay in Group 2 compared to Group 1 (12,17). However, this greater length of stay in absolute terms did not appear to be significantly increased (0.3 days greater than Group 1). An interesting finding was that in those who had LC for symptom onset >7 days, there was a statistically significant shorter operative time (84.5 minutes) compared to those who had LC for symptom onset <72 hours (93 minutes) (p= 0.004), a comparable postoperative length of stay despite recording the highest mean gallbladder wall thickness, and the perceived operative challenges of dense inflammation. These patients were delayed due to underlying multiple comorbidities that required preoperative anesthetics assessment and medical optimization (e.g. withholding of anticoagulants/antiplatelets), delayed presentation of symptoms, and unexpected delays in operating theatre availability. The reason for this may be that these patients received prolonged periods of antibiotics to settle the inflammation, and/or that there was a selection bias towards those patients who had severe biliary colic, with changes of AC at hospital presentation, but reporting symptoms for more than seven days.

In the subgroup analysis of 95% cholecystectomy patients, there were statistically significant increases in operation time, conversion to open cholecystectomy, bile leak, and postoperative stay. It appears that this group of patients had more severe cholecystitis, owing to significantly older age, greater ratio of males, higher preoperative temperature, and higher preoperative bilirubin. A study by Ambe et al. have concluded that the male sex is a risk factor for gangrenous and necrotizing cholecystitis (18). Despite this, there were no statistical difference in 95% cholecystectomy rates between the subgroups, no reported recurrent biliary colic/cholecystitis, and no recorded mortality. This is in contrast to studies that quote a 1.8% reoperation rate following 95% cholecystectomy (19-20).

The study suggests that early cholecystectomy is safe for acute calculus cholecystitis, regardless of timing of the onset of symptoms. This correlates with previous findings in a study of 222 patients, where it demonstrated that early LC beyond five days of symptoms was safe, and not associated with increased complications (16). The duration of symptoms in AC was not an independent risk factor and should not influence the surgeon's decision to perform early LC (16). The authors suspect that this finding is attributed to increasing experience and technical skill over time, and the increasing utilization of laparoscopic subtotal cholecystectomy in the treatment of early AC (20).

The strengths of this study are that this was a single consultant surgeon, single institution analysis involving a large number of patients. Some limitations to this study include the retrospective nature of this study, heterogeneity of the patients, inherent inaccuracies in the symptom onset provided by the patients, inherent variable delays in access to theatre, inability to ascertain whether patients represented for postoperative complication outside of the facility, and no prolonged longitudinal follow-up of patients, particularly the 95% cholecystectomy patients. Further studies to prospectively

investigate the outcomes (including hospital costs) of early LC for AC, as well as comparing early subtotal cholecystectomy with delayed cholecystectomy for AC would be beneficial.

CONCLUSION

The present study suggests that early LC for AC is safe, regardless of the timing of symptom onset. Surgeons do not necessarily need to limit early LC for within 72 hours of symptom onset. In difficult AC, laparoscopic reconstituting 95% cholecystectomy can be utilized with acceptable postoperative outcomes.

Ethics Committee Approval: This study was approved by Human Research Ethics Committee (HREC), Research Office, Western Sydney Local Health District. The study reference number is 2019/ETH02056.

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Semptom başlangıcından bağımsız olarak akut taşlı kolesistit için erken kolesistektomi sonrası iyi postoperatif sonuçlar

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ÖZET

Giriş ve Amaç: Akut taşlı kolesistit (AK) için erken kolesistektomi ile ilişkili postoperatif komplikasyonların ve hastane maliyetlerinin gecikmiş operasyona kıyasla daha düşük olduğuna dair kanıtlar giderek artmaktadır. Cerrahların semptom başlangıcına bağlı olarak AK için ne kadar erken operasyon yapmaları gerektiğine dair sınırlı sayıda yüksek kaliteli kanıt mevcuttur.

Gereç ve Yöntem: Ocak 2015-Ekim 2022 tarihleri arasında tek bir cerrah tarafından kolesistektomi yapılan 774 hasta retrospektif olarak incelendi. Beş yüz kırk bir hasta analiz edildi. Hastalar semptom başlangıcına göre üç gruba ayrıldı: Grup 1: 0-72 saat (n= 305), Grup 2: 72 saat-1 hafta (n= 154) ve Grup 3: >1 hafta (n= 82).

Bulgular: Medyan operasyon süresi en uzun Grup 2'deydi (96,5 dakika) ve Grup 1'e kıyasla en yüksek oranda %95 kolesistektomi (n= 22/154, %14,29) uygulanmıştı (p> 0,05). Açık ameliyata dönüşüm tüm gruplarda %0,65-1,64 arasındaydı. En yüksek safra kaçağı oranı Grup 1'de (n= 7/305, %2,3) görülürken, bunu Grup 3 (n= 1/82, %1,22) izledi (p> 0,05). Tüm hastalar ERCP ve biliyer stent ile başarılı bir şekilde tedavi edilmiştir. Medyan hastanede kalış süresi Grup 2'de (2,3 gün) Grup 1'e (2 gün) kıyasla anlamlı derecede uzundu (p= 0,03). Grup 2 ve 3'teki %95 kolesistektomi oranı Grup 1'e kıyasla anlamlı değildi.

Sonuç: Taşlı kolesistit için erken kolesistektomi, semptomların zamanlamasına bakılmaksızın, iyi postoperatif sonuçlara sahip gibi görünmektedir. Cerrahların erken kolesistektomiyi semptomların başlamasından sonraki 72 saatle sınırlandırması gerekmemektedir.

Anahtar Kelimeler: Kolesistit, erken kolesistektomi, zamanlama, postoperatif sonuçlar

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