Acta Chirurgica Belgica

ISSN: 0001-5458 (Print) (Online) Journal homepage: http://www.tandfonline.com/loi/tacb20

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To cite this article: L. Brunée, P. Hauters, J. Closset, G. Fromont, S. Puia-Negelescu & the Club Coelio (2018): Assessment of the optimal timing for early laparoscopic cholecystectomy in acute cholecystitis: a prospective study of the Club Coelio, Acta Chirurgica Belgica, DOI: 10.1080/00015458.2018.1529344

To link to this article: https://doi.org/10.1080/00015458.2018.1529344

Published online: 25 Oct 2018.

ACTA CHIRURGICA BELGICA
https://doi.org/10.1080/00015458.2018.1529344

ORIGINAL PAPER

Assessment of the optimal timing for early laparoscopic cholecystectomy in acute cholecystitis: a prospective study of the Club Coelio

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ABSTRACT

Background: The optimal timing for cholecystectomy in patients with acute cholecystitis remains controversial. The aim of this study is to assess prospectively the impact of the duration of symptoms on outcomes in early laparoscopic cholecystectomy (ELC) for acute cholecystitis.

Methods: The series consisted of 276 consecutive patients who underwent ELC for acute cholecystitis in 2016. The patients were divided into three groups according to the timing of surgery: within the first 3 days (group 1), between 4 and 7 days (group 2) and beyond 7 days (group 3) from the onset of symptoms.

Results: The percentage of surgical procedure rated as difficult was respectively: 12% in G1, 18% in G2 and 38% in G3 ($p < .001$). Accordingly, we observed an increased mean operative time within groups but no significant difference in the conversion rate. We noted a different overall postoperative complication rate within groups, respectively: 9% in G1, 14% in G2 and 24% in G3 ($p < .04$). The median hospital stay was also different within groups, respectively: 3 in G1, 4 in G2 and 6 days in G3 ($p < .001$). On univariate analysis, age $\geq$60, male gender, ASA 3, WBC $\geq$13.000/µL, CRP $\geq$100 mg/l and delay between onset of symptoms and surgery were factors statistically associated with increased morbidity rate. On multivariate analysis, the delay was the only independent predictive factor of postoperative morbidity (OR: 1,08, 95% CI: 1.01–1.61, $p < .031$).

Conclusion: Our study confirms that it is ideal to perform ELC within 3 days of symptoms onset and reasonable between 4 to 7 days. We do not recommend performing ELC beyond 7 days because of more difficult procedure and significantly increased risk of post-operative complications.

ARTICLE HISTORY
Received 16 September 2018
Accepted 24 September 2018

KEYWORDS
Cholecystitis; early laparoscopic cholecystectomy; surgical outcome; delay from onset of symptoms; post-operative complications

Introduction

Gallstones are present in about 10% to 15% of the adult western population. Between 1 and 4% of these adults become symptomatic in a year, the majority due to biliary colic but a significant proportion due to acute cholecystitis. A laparoscopic cholecystectomy is currently the gold standard treatment for symptomatic gallstone disease. However, the optimal timing for cholecystectomy in patients with acute cholecystitis remains controversial. The concerns are about higher morbidity rates in an emergency procedure [1] and higher conversion rate to an open procedure during the acute phase [2].

On the basis of available evidence, the updated Tokyo Guidelines for surgical treatment of acute cholecystitis advocate an approach depending on the grade of severity. An early laparoscopic cholecystectomy (ELC) is mandatory for patients with mild cholecystitis, whereas delayed laparoscopic cholecystectomy (DLC) can be performed in patients with moderate or severe cholecystitis [3,4].

A 'golden 72 h rule' has been proposed as an appropriate window to perform ELC by several authors. After this theoretical optimal time, cholecystectomy was associated with increased complication and conversion rate to open procedure [5–7]. A meta-analysis of the available case-control studies confirmed that ELC within 72 h led to significantly improved patient outcomes (lower mortality, overall complications, bile duct injuries,

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bile leaks, wound infection and conversion rate) compared to surgery after 72 h [8].

Nowadays, with the improving skill of the surgeons and the growing quality of the surgical instruments, ELC is becoming the gold standard treatment for acute cholecystitis even beyond 3 days of symptoms. A Cochrane review of 6 randomised control trials (RCT) comparing ELC (less than 7 days of clinical presentation with acute cholecystitis) versus DLC (more than 6 weeks after index admission with acute cholecystitis) was published in 2013 [9]. That meta-analysis found no significant difference between groups in the proportion of patients with complications or conversion to open cholecystectomy. Early surgery had the advantage of decreased hospital stay. This was due to patients in the delayed group requiring two treatment episodes: one for the conservative treatment of acute cholecystitis and another for the definitive surgical treatment. ELC also avoids the risk of emergency surgery for non-resolved or recurrent symptoms, which lead to a high rate of conversion to open cholecystectomy. Therefore, the conclusion was that ELC should be considered as the standard treatment option for acute cholecystitis. In a previous review, the same author made a subgroup analysis of trials including only patients with fewer than 4 days since onset of symptoms and those also including patients with symptoms for more than 4 days in the early group and showed no significant difference between the ELC and DLC groups in any of the outcome measures [10].

Some surgeons even regard a window of 7–10 days for urgent surgery as acceptable, but there are few data to support this claim. The aim of our study was to assess prospectively the impact of the duration of symptoms on outcomes in ELC for acute cholecystitis performed during the index admission regardless of the time elapsed from the onset of symptoms.

Material and methods

Study protocol

Approval for that study was obtained from the ethical committee of the Erasme University hospital. Twenty-seven surgeons, members of the Club Coelio, a group of French and Belgian surgeons focussed on laparoscopic surgery, participated in that prospective multicentre trial. The study was made on an intention-to-treat basis. At the admission of the patient, the choice of ELC vs. DLC was left free to each surgeon. The study group consisted of 276 patients who underwent ELC for acute cholecystitis in 2016. There were 135 women and 141 men with a median age of 58 ± 17 years and a BMI of 29 ± 6. The patients were divided into 3 groups according to the timing of surgery: (G1) within the first 3 days (G2) between 4 and 7 days and (G3) beyond 7 days from the onset of symptoms.

The inclusion criteria were (1) acute cholecystitis due to gallstone, (2) consecutive patients operated on by laparoscopy in 2016 (3) patients older than 18 years, (4) an American Society of Anesthesiologists score (ASA) ≤ 3, (5) inclusion of at least 5 patients during the study period, (6) cholecystectomy performed during the index admission as soon as possible, regardless of the time elapsed from the onset of symptoms and (7) routine cholangiography during surgery. The exclusion criteria included (1) pregnancy, (2) acalculous cholecystitis, (3) common bile duct stones diagnosed pre- or intraoperatively, (4) cholangitis, (5) biliary pancreatitis, (6) ASA score 4 and (7) patients initially scheduled for DLC with failed medical treatment.

The diagnosis of acute cholecystitis was based on a combination of clinical criteria: persistent right upper quadrant pain, positive Murphy's sign, temperature exceeding 37.5 °C, elevated C-reactive protein (CRP), white blood cell (WBC) count greater than 10,000/μL and ultrasonography criteria: presence of gallstones on ultrasound in combination with wall thickening. In all patients, antibiotic treatment according to the different institutional guidelines was given systematically once diagnosis was established and was continued postoperatively at the discretion of each surgeon according to the intraoperative findings. Only senior surgeons with high level of expertise in laparoscopy performed the operations. When required the gallbladder was first aspirated. Diathermy coagulation was used to dissect the Calot's triangle and obtain the critical view of safety. Cholangiography was performed routinely.

Data were collected prospectively into a computerised database and included patients' characteristics, operative findings, conversion to open cholecystectomy, postoperative morbidity according to the Clavien classification [11], operating time, histologic exam of the gallbladder, total hospital stay and 30-days mortality. Intraoperative severity of acute cholecystitis was graded as described by Palanivelu [12]: oedematous, hydrops, gangrenous and empyema in increasing order of

Table 1. Characteristics of the patients within the different groups.

Parameters	Group 1 $n=150$	Group 2 $n=84$	Group 3 $n=42$	p-value*
Delay between the onset of symptoms and surgery (days)	0–3	4–7	≥8	
Female/Male gender	73/77	45/39	17/25	NS
Mean BMI ± SD (kg/m^2)	29 ± 6	29 ± 6	29 ± 5	NS
Mean age ± SD (years)	58 ± 17	56 ± 18	64 ± 14	NS
ASA score				
I	50 (33%)	33 (39%)	10 (24%)	NS
II	73 (49%)	33 (39%)	19 (45%)	
III	27 (18%)	18 (22%)	13 (31%)	
«Anticoagulant» therapy	12 (8%)	6 (7%)	4 (10%)	NS
Past laparotomy with supraumbilical incision	13 (9%)	6 (7%)	2 (5%)	NS

*NS = not significant.

severity as observed during laparoscopic cholecystectomy. The difficulty of the surgery was rated using a 3-grade Likert scale with the possible answers being easy, fair and difficult. Resected gallbladders were sent for histopathological examination and the following histopathological grading of severity of acute cholecystitis were distinguished: ulcerous, phlegmonous or gangrenous. The follow-up of the patients was limited to the first postoperative office visit 4 weeks after surgery.

Statistical analysis

All calculations were made with the SigmaStat 3.5 programme (Systat Software, San Jose, CA, USA). Results were expressed as mean/standard deviation for continuous values with normal distribution and as median/ranges for values with skewed distribution. Accordingly, as 3 groups were concerned, comparisons between groups were made with the Anova or the Kruskal–Wallis test. The Chi-square test was used for comparison of categorical values. Variables that could potentially influence the overall complication rate were first subjected to univariate analysis. All variables with $p<.20$ on univariate analysis were entered into multivariable logistic regression analysis. A $p<.05$ was considered as statistically significant.

Results

During the study period, 376 patients were admitted for acute cholecystitis; 276 had ELC and 100 DLC. Among the patients with ELC, 150 (55%) had their operation within the first 3 days (G1) from the onset of their illness, 84 patients (30%) between 4 to 7 days (G2) and the other 42 patients (15%) after the first week (G3). The patient's characteristics were similar between groups (Table 1). The duration of complaints until surgery, the delay on the part of the patient and on the part of the physician are reported in Table 2. The main cause of late cholecystectomy was related to the time elapsed between onset of symptom and patient's hospital admission. The delay on the side of the physician was mainly related to the inaccessibility of the operating room followed by anti-coagulants or antiplatelet agents requiring reversing before surgery. The preoperative parameters were not different between groups at the exception of the CRP and the fibrinogen value (Table 3). On linear correlation test, the fibrinogen value appeared to be correlated with the duration of symptoms ($R=0.42$, $p<.01$). A statistically significant higher rate of severe cholecystitis (gangrenous or empyema) was observed in G3: 48% vs. 45% in G2 and 30% in G1 ($p<.04$) (Table 4). Accordingly, the percentage of surgical procedure rated as difficult was respectively: 38% in G3, 18% in G2 and 12% in G1 ($p<.001$). No significant difference was observed within groups regarding the histopathological grading of severity of acute cholecystitis (Table 4). The surgical outcomes are reported in Table 5. Although there was a trend for an increased conversion rate in G3 (5% vs. 2%), the difference was not statistically significant. The reason for conversion were adhesions ($n=4$), haemorrhage ($n=1$) and bile leak from unclear origin ($n=1$). The percentage of successful cholangiography was similar in the 3 groups. We observed a different operative time within groups, respectively: 58 ± 27 in G1, 63 ± 23 in G2 and 72 ± 27 min in G3 ($p<.006$). We also noted a different postoperative overall complication rate within groups, respectively: 9% in G1, 14% in G2 and 24% in G3 ($p<.04$). Severe complications (grade 3–4 according to the Clavien classification) were also more frequent in G3: 10% vs. 2% in G2 and 3% in G1 ($p<.05$). An increased percentage of specific surgical complication was noted in G3: 10% vs. 8% in G2 and 7% in G1 but, the difference was not statistically significant. It must be emphasised that we observed no bile duct injury. The details of the complications are reported in Table 6. Within the 30 days following

Table 2. Delay periods between onset of symptoms, admission and surgery.

	Group 1 $n = 150$	Group 2 $n = 84$	Group 3 $n = 42$	p-value
Delay between onset of symptoms and hospital admission (days)	Mean: 1.1 ± 0.8 Median: 1 (0–3)	3.1 ± 1.5 Median: 3 (0–7)	9.4 ± 6.4 Median: 8 (3–19)	<.001
Delay between hospital admission and surgery (days)	Mean: 0.8 ± 0.7 Median: 1 (0–3)	1.9 ± 1.3 Median: 2 (0–7)	2.8 ± 2.8 Median: 2 (0–10)	<.05
Delay between onset of symptoms and surgery (days)	1.8 ± 0.9 Median: 2 (0–3)	5.0 ± 1.0 Median: 5 (4–7)	12.1 ± 5.1 Median: 10 (8–21)	<.001

Table 3. Parameters at admission.

Data	Group 1 0–3 days	Group 2 4–7 days	Group 3 > 7 days	p-value*
WBC, mean ± SD ($\times 10^3/\mu L$)	12.9 ± 4.2	14.2 ± 5.0	13.6 ± 5.5	NS
Temperature (°C)	37.5 ± 0.7	37.8 ± 0.8	37.8 ± 0.7	NS
CRP, mean ± SD (mg/L)	30 ± 7	101 ± 30	102 ± 28	<.001
Fibrinogen (mg/dl)	429 ± 332	585 ± 437	703 ± 405	<.004
Gallbladder wall thickening (mm)	5.3 ± 2.2	5.9 ± 2.8	6.1 ± 2.3	NS

*NS = Not significant.

Table 4. Intraoperative observations, technical difficulties and histological findings.

Parameters	Group 1 $N = 150$	Group 2 $N = 84$	Group 3 $N = 42$	p-value*
Severity of cholecystitis				
Oedematous or hydrops, n (%)	105 (70%)	46 (55%)	22 (52%)	<.04
Gangrenous or empyema, n (%)	45 (30%)	38 (45%)	20 (48%)	
Technical difficulty				
Easy, n (%)	67 (45%)	25 (30%)	4 (10%)	<.001
Fair, n (%)	65 (43%)	44 (52%)	22 (52%)	
Difficult, n (%)	18 (12%)	15 (18%)	16 (38%)	
Histological findings				
Ulcerous	85 (57%)	40 (47%)	18 (43%)	NS
Phlegmonous	35 (23%)	20 (24%)	11 (26%)	
Gangrenous	30 (20%)	24 (29%)	13 (31%)	

*NS = not significant.

Table 5. Postoperative outcomes within the different groups.

Parameters	Group 1 $n = 150$	Group 2 $n = 84$	Group 3 $n = 42$	p-value*
Conversions, n (%)	2 (1%)	2 (2%)	2 (5%)	NS
Cholangiography, n (%)	138 (92%)	78 (93%)	39 (90%)	NS
Operative time Mean ± SD (minutes)	58 ± 27	63 ± 23	72 ± 27	<.006
Complications, n (%)	13 (9%)	12 (14%)	10 (24%)	<.04
Clavien classification				
1/2	8 (6%)	10 (12%)	6 (14%)	<.05
3/4	5 (3%)	2 (2%)	4 (10%)	
Surgical complications, n (%)	10 (7%)	7 (8%)	6 (14%)	NS
Mortality, n (%)	1 (0.7%)	0 (0%)	0 (0%)	NS
Total hospital stay Mean ± SD and median (days)	4 ± 8	5 ± 4	7 ± 4	<.001
Total hospital stay Mean ± SD and median (days)	Median: 3	Median: 4	Median: 6	<.001

*NS = not significant

Table 6. Details of the complications in each group.

Clavien classification	Group 1 $N = 150$	Group 2 $N = 84$	Group 3 $N = 42$
Type 1	Wound complication: 3 Ileus: 1	Wound complication: 5 Urinary retention: 2	Wound complication: 1 Ileus: 1 Disorientation: 1
Type 2	Pneumonia: 1 Intraabdominal collection: 1 Stroke attack: 1 Septic chock: 1	Atrial fibrillation: 1 Intraabdominal collection: 1 Deep venous thrombosis: 1	Pneumonia: 2 Intraabdominal collection: 1
Type 3	Intestinal perforation: 1 Bile leak: 2 Evisceration: 1 Intraabdominal abcess: 1	Bile leak: 1	Bile leak: 3
Type 4	0	Renal failure: 1	Cardiac failure: 1

surgery, one patient died because of a postoperative haemorrhagic shock followed by multiple organ failure. The median hospital stay was also different within groups, respectively: 3 (range: 1–55) in G1, 4 (range: 1–29) in G2 and 6 (range: 1–21) days in G3 ($p < .001$). On univariate analysis, age ≥60, male gender, ASA 3, WBC ≥13.000/μL, CRP ≥100 mg/l and delay between onset of symptoms and surgery were factors statistically associated with increased morbidity rate (Table 7). On multivariate analysis, the delay appeared to be the only independent predictive factor of morbidity (OR: 1.08, 95% CI: 1.01–1.61, $p < .031$) (Table 8).

Table 7. Parameters statistically associated with increased overall complication rate on univariate statistical analysis.

	N	Postoperative complications	%	*p*-value*
Age (years)				
<60	140	10	7 %	<.01
≥60	136	26	19 %	
Sex				
Male	141	25	18 %	<.03
Female	135	11	8 %	
ASA Score				
I	93	6	6 %	<.01
II	125	14	11%	
III	58	16	28%	
CRP (mg/L)				
<100	152	12	8 %	<.03
≥100	124	24	19 %	
WBC (/μL)				
<13,000	144	11	8 %	<.06
≥13,000	132	25	19 %	
Delay (days)				
0–3	150	14	9%	<.04
4–7	94	12	14%	
≥8	42	10	24%	

*NS = not significant.

Table 8. Multivariate logistic analysis of parameters affecting the overall morbidity rate.

Variable	Coefficient	Odd ratio	95% IC	*p*-value
Sex	0.655	1.926	0.868–4.270	.107
Age	0.023	1.024	0.996–1.052	.090
ASA score	0.525	1.690	0.954–2.994	.072
WBC	0.009	1.009	0.935–1.09	.810
CRP	0.001	1.002	0.999–1.005	.194
Delay	0.078	1.082	1.007–1.161	.031

Discussion

For many years, when open cholecystectomy was the only surgical option, patients presenting with acute cholecystitis were treated medically in order to 'cool down' the disease and to perform elective cholecystectomy several weeks later at distance of the inflammatory phenomenon. At the end of the 1970s, such a policy of management was challenged by the advent of early cholecystectomy within 7 days from the onset of symptoms. In patients presenting with acute cholecystitis, early open cholecystectomy was compared to delayed operation in 9 prospective randomised studies. In a review of those trials, the mortality (0.2 vs. 1.6%), the perioperative morbidity (17.7 vs. 17.9%) and the common bile duct injuries (0.2 vs. 0.9%) were similar between groups, but the mean total hospital stay was superior in case of delayed cholecystectomy (11 vs. 20 days) [13]. Besides, 22% of the patients randomised to delayed surgery failed to respond to initial conservative management or suffered from recurrent symptoms in the interval period, and 56% of those patients required unplanned urgent cholecystectomy [13]. The final conclusion was that early and delayed cholecystectomy were equally safe and effective, but that early surgery should be the preferred approach for patients with acute cholecystitis because of decreased total hospital stay and of possible failure of the medical treatment.

The advent of laparoscopy at the beginning of the 1990s led the discussion between early vs. delayed cholecystectomy to re-emerge. In the initial experience, acute cholecystitis was regarded as a relative contraindication for laparoscopic cholecystectomy due to longer operative time, higher morbidity and increased conversion rate to open surgery [1,14]. As more experience was gained, literature invalidated these concerns by demonstrating that laparoscopic surgery could be performed in the setting of acute cholecystitis. However, there was much confusion in the optimal timing for ELC. The 'golden 72 h rule' has been proposed as an appropriate window to perform cholecystectomy during the acute phase. Surgery after this theoretical optimal time was reported to increase complication and conversion rates [5–7]. As operating acutely was believed to be more technically challenging due to distorted anatomy from acute inflammation, 'a cooling off period' has been advocated and accepted by many general surgeons [15]. Initial conservative treatment with antibiotics followed by interval elective cholecystectomy 6 to 8 weeks later, after acute inflammation has subsided, was supposed to result in a safer operation with less conversion rate.

Nowadays, ELC is the gold standard treatment for acute cholecystitis irrespectively of the duration of symptoms. Several randomised controlled trials have shown that ELC (within up to 7 days of symptoms onset) was associated with a shorter total hospital length of stay and a similar rate of conversion to open procedure when compared with DLC [16–19]. But most of those studies were underpowered to detect a significant difference in term of surgical complications including bile leak or bile duct injury or mortality. To mitigate that bias, several meta-analyses have also been published [9,10,20,21]. In the last meta-analysis published in 2015, 15 randomised control trial comprising 1625 patients were included. Compared with DLC, ELC was associated with lower hospital costs, fewer work days lost, higher patient satisfaction and quality of life, lower risk of wound infection and shorter hospital stay, but with a longer duration of operation. Besides, there were no significant differences between the two groups in mortality, overall complication rate, bile duct injury, bile leak or conversion to open cholecystectomy [21].

We observed a trend in favour of more conversions in patients of G3 but statistically, the timing of cholecystectomy did not influence the conversion rate, as recently shown by others [22,23]. This is probably attributed to the very low global conversion rate in our series (2%), making any differences between the subgroups insignificant. In case of acute cholecystitis, our study confirmed that laparoscopic cholecystectomy should be performed as early as possible after onset of symptoms. The best outcomes were recorded in patients of G1: lower severity of cholecystitis, easier technical procedure, shorter operative time, lower complication rate and shorter hospital stay. However, our series highlighted that only 55% of the patients were able to have surgical treatment during this short period of time, due to either patient or/and physician delay. Another reason is that a significant number of patients have oral anticoagulant therapy. Our study also confirms that it is reasonable to perform ELC between 4 and 7 days after the acute onset. Patients in G2 had rather similar outcomes compared to patients of G1. On the contrary, patients in G3 had worrisome outcomes. Surgery was more difficult and longer due to increased severity of cholecystitis and the overall postoperative complication rate was higher. We also observed an increased hospital stay in G3. In the literature, we only found one study that analysed the outcomes in patients having ELC beyond 7 days of symptoms duration [23]. In that subgroup of patients, the authors also observed an increased conversion and complication rate but concluded that it was safe to perform ELC considering that the difference was not statistically significant. We do not share that opinion and do not recommend performing routinely ELC when the duration of symptoms is longer than 7 days. In that subgroup, DLC could be a better option of treatment but there are no data in the literature to support that assertion. A comparative study is mandatory to compare ELC vs. DLC and to determine what is the best treatment option.

On the basis of the study design, several potential limitations have to be taken into account. First, the choice between ELC vs. DLC was left free to surgeons according to their personal experience. This could potentially lead to bias in patients' selection even if patients' characteristics were similar between groups. Second, the patients' attribution to one of the 3 groups was based on the duration between onset of symptoms and surgery. Some authors consider that the onset of acute attack is rather difficult to define and capture because patients have a varying perception of signs and symptoms. Even if it is partially true, that parameter provides more accurate information than counting days after admission, which is not a precise measure of how long the disease has existed. Third, our study is underpowered to compare the incidence of rare events such as bile leak, bile duct injury or mortality. Fourth, the postoperative follow-up is limited at 30 days and therefore, late potential complications such as bile duct stenosis were not considered.

Conclusion

The value of early cholecystectomy for acute cholecystitis was well established in the pre-laparoscopic era. At the beginning of the 1990s, acute cholecystitis was considered as a contraindication for laparoscopic treatment when the delay between onset of symptoms and surgery was >72 h. Nowadays, ELC is the gold standard treatment for acute cholecystitis irrespectively of the duration of symptoms. However, based on the findings of our study, we do not recommend performing ELC beyond 7 days of symptoms. On the other hand, a comparative study is mandatory to determine if DLC could be a better option in that specific subgroup of patients.

Disclosure statement

No potential conflict of interest was reported by the authors.

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