Annals of Gastroenterology (2024) **37,** 1-8

Clinical evolution of gallstones following percutaneous cholecystostomy in patients with severe acute calculous cholecystitis: a single-center analysis of 102 cases

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Abstract

Background Percutaneous cholecystostomy (PC) is effective in controlling sepsis in patients with severe acute calculous cholecystitis (ACC). The long-term treatment of this group is still debated. We aimed to assess the clinical evolution of gallstones after severe ACC and the outcomes of laparoscopic cholecystectomy (LC) and conservative management, following PC.

Methods This was a retrospective analysis of the rate of readmissions due to recurrent biliary disease and all-cause mortality in subjects who underwent a PC for severe ACC. We compared results between patients who underwent interval LC and those who received conservative management. Readmissions and late mortality were assessed using the Kaplan-Meier method and multivariate regression analysis.

Results A total of 102 patients were included, of whom 30 underwent interval LC and 72 PC only. Overall, 51.6% were readmitted with recurrent biliary events and the rate did not differ between groups (P=0.583). The probability of recurrent gallstone events was higher in the first 30 weeks after PC; in the surgical cohort, 77.8% of them developed before LC. Late deaths occurred in 46.2% of patients: 13.3% LC vs. 61.9% conservative (P<0.001). Three years after PC, the estimated survival was 75% LC vs. 38% conservative (P=0.014). High-grade comorbidities and severity of ACC were positive predictors of all-cause mortality (P=0.004 and P=0.027), whereas LC was a negative predictor (P=0.003).

Conclusions Recurrent biliary events were common following PC for ACC. Interval LC was associated with lower rates of readmissions and all-cause late mortality.

Keywords Calculous cholecystitis, cholecystostomy, laparoscopic cholecystectomy

Ann Gastroenterol 2024; 37 (XX): 1-8

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Conflict of Interest: None

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Received 3 April 2024; accepted 19 July 2024;
published online 20 October 2024

DOI: https://doi.org/10.20524/aog.2024.0915

Introduction

Acute calculous cholecystitis (ACC) is a common clinical condition that affects 1-4% of subjects with gallstones [1]. This condition develops as mild or severe disease; the latter is associated with mortality rates of up to 3.6% [2]. The first-line treatment of severe ACC consists of general resuscitation measures, intravenous antibiotics and analgesia, while laparoscopic cholecystectomy (LC) is advocated as soon as the patients are fit for surgery [3]. In circumstances when medical treatment is not effective and patients are not eligible for LC, percutaneous cholecystostomy (PC) represents an important tool to treat sepsis [4]. The procedure, first described in 1979 [5], consists of the insertion of a drain into the gallbladder. The drainage of infected bile and the decompression of the gallbladder result in sepsis control and pain relief. Moreover, the aspiration of bile provides a sample

for microbiological analysis and optimization of the antibiotic treatment. Once sepsis is treated, interval LC remains the ideal definitive treatment. However, surgery cannot always be performed following PC, because of a range of patients' factors, including fitness for surgery. Although patients in this group have the potential to develop recurrent gallstone disease, the best definitive management is still debated. Some authors support PC as the ultimate treatment of severe ACC [6-8], other recommend its use as a bridge to clinical optimization and interval LC [9-11]. Understanding the clinical behavior of gallstones following severe ACC could potentially enable clinicians to tailor the long-term treatment options more accurately. The aim of this study was to evaluate the outcomes of interval LC and conservative management in patients who underwent PC for ACC.

Patients and methods

Study design and setting

The study received local board approval. We conducted a single-center retrospective case-control evaluation of the outcomes of patients who had undergone PC for severe ACC, comparing those who went on to have interval LC with those who had PC only. At our institution, a diagnosis of ACC was made in the presence of acute onset of pain in the right upper quadrant of the abdomen, localized tenderness with or without guarding on palpation, elevated serum white cell count, and evidence of gallstones within a thick-walled gallbladder on abdominal ultrasound and/or computed tomography scan [12]. In case of altered liver function tests and/or evidence of a dilated biliary tree on imaging, subjects were also assessed using magnetic resonance cholangiopancreatography. Upon diagnosis, the severity of ACC was defined according to the Tokyo guidelines [3]. Emergency LC was contraindicated in case of Tokyo 3 disease, or any Tokyo grade associated with a duration of symptoms >5 days, previous multiple upper abdominal surgeries, American Society of Anesthesiologists (ASA) score >3, or body mass index ≥40 kg/m^2. The decision to proceed with PC was taken on a multidisciplinary level, at any time from the diagnosis of ACC in critically ill patients who required organ support in the intensive care unit, or in those who did not respond to maximal intravenous antibiotic therapy for 4 days or more. The clinical response was judged to be poor based on persistent tachycardia, hypotension, white cell count >18×10^9/L, and/or serum C-reactive protein >250 mg/L. All cholecystostomy drains were inserted under local anesthesia by a senior interventional radiologist with extensive experience (>250 cases) of PC. The procedures were performed under local anesthesia, assisted by ultrasound or computed tomography guidance, in the intensive care unit in critically ill patients or in the radiology department. Drains were 8-10-Fr pigtail catheters that were inserted via a transperitoneal or transhepatic route, depending on the interventional radiologist's choice. The PC was left on free drainage until the daily output was ≤200 mL, then it was capped and left in place for 6 weeks. A tube cholangiogram was not performed prior to the drain removal, but all the patients had their liver function checked. If the drain output was persistently >200 mL/day, or the serum alkaline phosphatase was >130 IU/L or the total bilirubin >21 μmol/L, magnetic resonance cholangiopancreatography was arranged to evaluate the patency of the cystic duct and common bile duct. The drain was removed in the outpatient setting or upon LC, in those patients who were eligible for surgery.

Patients

Subjects aged 18 years and above, admitted with ACC and treated with PC, from January 2010 to September 2021, were identified from the hospital electronic records and were considered for the study. Exclusion criteria were acute acalculous cholecystitis, emergency LC or incomplete follow-up data. Patients were divided into 2 groups: PC and interval LC (group 1) or PC alone (group 2). Clinical and demographic data were compared. Early complications and mortality were defined when occurring within 30 days from the procedure. Deaths related to persistent biliary sepsis were defined as treatment failure. In those subjects who were readmitted to hospital more than once, only the first episode was included in the total readmissions count. Recurrent gallstone disease included ACC, acute pancreatitis, acute cholangitis and common bile duct stones. The study follow up ended in November 2023 or at patients' death.

Study outcomes

The primary objectives were the rate of readmissions with recurrent biliary disease and late all-cause mortality; the latter was defined when occurring after more than 30 days from PC. A secondary analysis was undertaken to identify factors associated with readmissions and late all-cause deaths.

Statistical analysis

The statistical analysis was conducted using Prism version 9.1.0 (GraphPad Holdings LLC, California). Single linear regression analysis was used to evaluate the relation between the timing of PC insertion and the length of stay (LoS) in hospital. Multivariate logistic regression analysis was performed to assess the association between patients' characteristics, readmissions and late deaths. Results were expressed as 95% confidence interval (CI) and odds ratio (OR). The prediction of readmissions and long-term mortality were assessed using the Kaplan-Meier method. Two-tailed P-values were used and were considered as significant if <0.05.

Results

Patients' characteristics and early outcomes

Overall, 111 subjects were identified. Nine were excluded because of emergency LC (n=3), loss to follow up (n=3), acalculous cholecystitis (n=2), or associated positioning of a percutaneous transhepatic cholangiogram stent (n=1); thus, 102 patients were included in the study. Of these, 30 (29.4%) went on to have an interval LC (group 1), while 72 (70.6%) had PC alone (group 2). The patients' characteristics are summarized in Table 1. There were 52 (50.9%) men and the mean age was 74.2 (28-96) years. Subjects in group 1 were younger—62.1 (28-82) vs. 79.1 (50-96) years (P<0.001)—with lower median ASA and Charlson's Comorbidity Index scores: 2 (1-4) vs. 3 (2-4) (P<0.001), and 2 (0-6) vs. 5 (2-10), (P<0.001), respectively. The positioning of PC was technically successful in all 102 patients and no further intervention (i.e. drain reinsertion) was required. Subjects in group 1 underwent earlier gallbladder drainage, with a median time between hospital admission and the procedure of 1 (0-7) vs. 2 (0-81) days (P=0.014). No early complications were recorded after the procedure. Overall, the rate of clinical success after PC was 97/102 (95.1%). In-hospital mortality involved 9 patients (9.7%): the causes of death were biliary sepsis (n=5), pneumonia (n=3) and multi-organ failure (n=1). Subjects in group 2 had a longer LoS: 10 (1-51) vs. 18 (3-151) days, P<0.001. Early positioning of the PC was associated with shorter hospitalization, particularly if the procedure was performed within the first 5 days after admission (P<0.001; Fig. 1).

Late outcomes

The median study follow up was 7 months (range 1-68). The median PC indwelling time was 46 days (2-114) in the surgical group and 51.5 days (7-154) in the non-surgical cohort (P=0.4654). In group 1, the median time from drain removal to LC was 99.5 days (23-806), while the median time to LC after the index admission was 104.5 days (18-806); 27 (90%) patients had their surgery within the first year after admission, 1 (3.3%) at 2 years, and 2 (6.7%) at 3 years. All the procedures were performed laparoscopically and no perioperative complications were recorded. Data on hospital readmissions and late mortality are presented in Table 2. Of the 93 survivors, 52 (55.9%) were readmitted to hospital: 18/30 (60%) in group 1 and 34/63 (53.9%) in group 2 (P=0.583). Biliary-related events occurred in 48 (51.6%) subjects, 20 (21.5%) as PC complications

Table 1 Patients' characteristics

Characteristics	Cholecystostomy and elective LC N=30	Cholecystostomy only N=72	P-value
Male:Female	13:17	39:33	0.857
Age, mean (range)	62.1 (28-82)	79.1 (50-96)	<0.001
ASA, median (range)	2 (1-4)	3 (2-4)	<0.001
CCI, median (range)	2 (0-6)	5 (2-10)	<0.001
Tokyo grading, median (range)	2 (2-3)	2 (2-3)	0.638
WCC, median (range)	13.7 (2.1-76.5)	16.1 (3.9-45)	0.308
CRP, median (range)	190.5 (5-390)	226 (2-499)	0.674
Altered LFT, n (%)	14 (46.7)	40 (55.6%)	0.335
Biliary obstruction, n (%)	0	2 (2.8)	-
Admission to ICU, n (%)	5 (16.7)	8 (11.1)	0.413
Days between admission and cholecystostomy, median (range)	1 (0-7)	2 (0-81)	0.014
Indications of cholecystostomy (n)	Biliary sepsis (26) Perforated GB (4)	Biliary sepsis (48) Perforated GB (24)	0.051
Associated procedures (n)	Drainage of liver abscess (2) Drainage of perihepatic collection (2)	Drainage of liver abscess (2) Drainage of perihepatic collection (7)	>0.99
In-hospital mortality, n (%)	0	9 (12.5)	-
Treatment failure, n (%)	-	5 (6.7)	
Length of stay in days, median (range)	10 (1-51)	18 (3-151)	<0.001
Destination at discharge, n (%) Home Community hospital	 30 (100) -	 49 (77.8) 14 (22.2)	 -

LC, laparoscopic cholecystectomy; ASA, American Society of Anesthesiologists; CCI, Charlson's comorbidity index; WCC, white blood cell count; CRP, C-reactive protein; LFT, liver function tests; ICU, intensive care unit; GB, gallbladder

and 28 (30.1%) as recurrent gallstone disease. Drain displacement was the most common PC-related complication, with 7/93 (7.5%) episodes. Gallstone disease recurred both before and after PC drain removal, and in 24/28 (85.7%) subjects it developed within 1 year from discharge; Kaplan-Meier analysis estimated a higher probability of recurrent gallstone disease within the first 30 weeks, with no significant difference between groups (P=0.813, Fig. 2). In the LC cohort, 14/18 (77.8%) readmissions occurred before surgery. After LC, 4 patients were readmitted with retained common bile duct stone (n=2), acute pancreatitis (n=1) or a non-biliary event (n=1). In total, 21 of the 48 (43.8%) patients with a biliary condition (PC-related or recurrent gallstone disease) were readmitted more than once: 10 in group 1 (33.3%) and 11 (17.4%) in group 2 (P=0.087).

Overall, there were 43 (46.2%) late deaths, 4 (13.3%) in group 1 and 39 (61.9%) in group 2 (P<0.001). In the non-surgical cohort, the median time from drain removal to late death was 445.5 days (11-2398). No death was caused by a biliary event in group 1, while in group 2 biliary-related fatalities occurred in 4 (6.3%) cases. The probability of survival was 80% (group 1) vs. 70% (group 2) at 1 year and 75% (group 1) vs. 38% (group 2) at 3 years (P=0.014, Fig. 3). Logistic regression analysis did not show statistical evidence that readmissions were correlated with any of the patients' characteristics, while ASA score, Tokyo grade and elective LC were correlated with late deaths. ASA score >2 and Tokyo grade 3 were significant positive predictors of all-cause mortality (OR 4.5, 95%CI 1.6-12.6, P=0.004, and OR 3.8, 95%CI 1.2-12.2, P=0.027, respectively). Surgery was a negative predictor of mortality (OR 0.2, 95%CI 0.04-0.5, P=0.003).

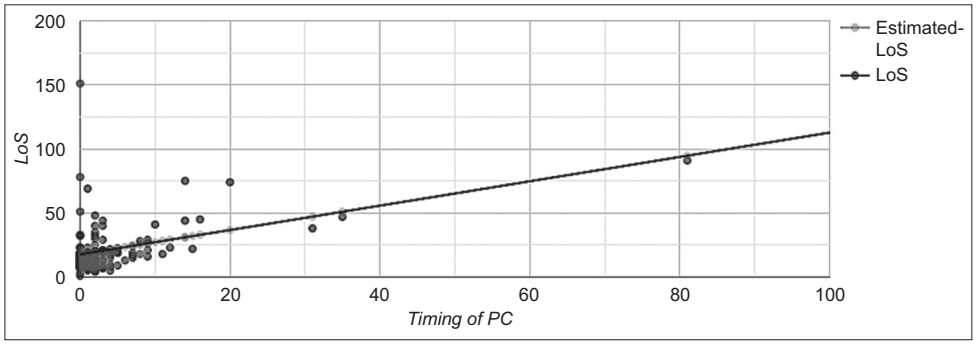

Figure 1 Relation between timing of insertion of the cholecystostomy and length of stay. Linear regression, with length of stay as dependent variable and timing of percutaneous cholecystostomy as independent variable. Gallbladder drainage performed within the first 5 days predicted a shorter hospital stay (P<0.001)
LoS, length of stay; PC, percutaneous cholecystostomy

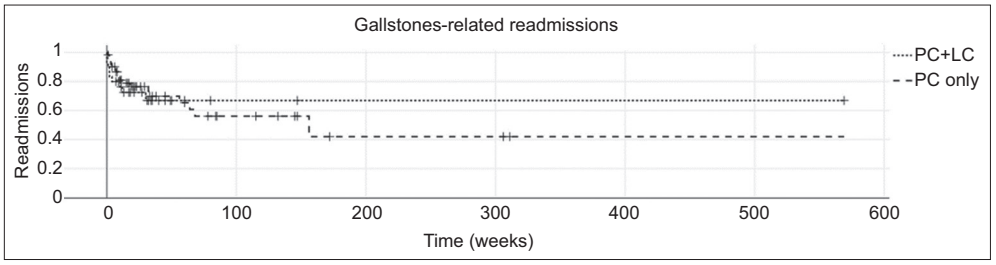

Figure 2 Analysis of biliary-related readmissions. The probability of readmission was highest in the first 30 weeks (Log-rank test: P=0.813)
LC, laparoscopic cholecystectomy; PC, percutaneous cholecystostomy

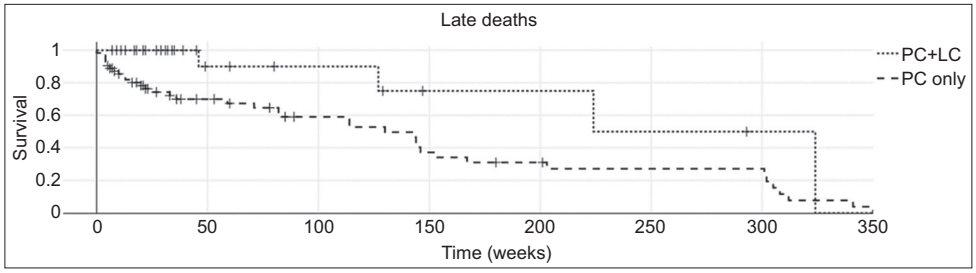

Figure 3 Survival analysis (long-term all-cause mortality). The probability of survival in group 1 and group 2 was 80% vs. 70% at 1 year, 75% vs. 38% at 3 years (log-rank test: P=0.014)
LC, laparoscopic cholecystectomy; PC, percutaneous cholecystostomy

Table 2 Hospital readmissions and late mortality

Hospital readmissions	Cholecystostomy and elective LC N=30	Cholecystostomy only N=63	P-value
Total readmissions, n (%)	18 (60)	34 (53.9)	0.583
Biliary-related	16 (53.3)	32 (50.8)	>0.99
PC-related	7 (23.3)	13 (20.6)	
Gallstone-related	9 (30)	19 (30.2)	
Not biliary-related	2 (6.7)	2 (3.2)	0.845
N. of readmissions, median (range)	2 (1-6)	1 (1-8)	0.230
Time of recurrent gallstones, n (%)			
1 year	9 (100)	15 (78.9)	0.190
2 years	-	3 (15.8)	
3 years	-	1 (5.3)	
PC-related complications, n (%)			
Drain displacement	1 (3.3)	6 (9.5)	-
Leak around drain site	3 (10)	1 (1.6)	
Cholecysto-cutaneous fistula	-	2 (3.2)	
Infected biloma	-	1 (1.6)	
Cellulitis at drain site	-	1 (1.6)	
High output	-	1 (1.6)	
Bleeding	1 (3.3)	-	
Recurrent gallstone disease, n (%)			
Acute cholecystitis	8 (26.7)	8 (12.7)	-
CBDS	2 (6.7)	9 (14.3)	
Biliary colic	1 (3.3)	2 (3.2)	
Abdominal collection	-	3 (4.8)	
Liver abscess	-	2 (3.2)	
Acute pancreatitis	3 (10)	-	
Biliary sepsis	-	2 (3.2)	
Altered LFT	-	2 (3.2)	
Acute cholangitis	-	1 (1.6)	
Gallbladder empyema	1 (3.3)	-	
Timing of recurrent gallstone disease			>0.99
Before removal of PC (n)	ACC (1), AP (1), biliary colic (1)	ACC (4), CBDS (2), cholangitis (1), biliary colic (1)	
After removal of PC (n)	ACC (5), AP (2) CBDS (2), biliary colic (1)	ACC (4), CBDS (7), abdominal collections (3), biliary sepsis (2), liver abscess (2), biliary colic (1), altered LFT (1), gallstone ileus (1)	
Late mortality, n. (%)	4 (13.3)	39 (61.9)	<0.001
Biliary related	-	4 (6.3)	
Non-biliary related	4 (13.3)	19 (30.2)	
Unknown	-	16 (25.4)	
Causes of late deaths (n.)	Cancer (2) Pneumonia (1) GI bleeding (1)	GB perforation (1) Biliary sepsis (2) Gallstone ileus (1) Cancer (6) Respiratory disease (2) Frailty (6) Cardiac disease (3) GI bleeding (1) Sepsis non-biliary (1)	

LC, laparoscopic cholecystectomy; PC, percutaneous cholecystostomy; CBDS, common bile duct stones; LFT, liver function tests; ACC, acute calculous cholecystitis; AP, acute pancreatitis; GI, gastrointestinal; GB, gallbladder

Discussion

PC is a well-established procedure in the early-stage treatment of severe ACC, in subjects who do not respond to maximal antibiotic therapy, are critical ill and are ineligible for emergency LC [13]. While draining the gallbladder proves to be effective in relieving sepsis and inflammation, its long-term role as sole therapeutic measure remains

unclear [14]. In the present study, we assessed the clinical behavior of gallstones following the positioning of a PC for ACC and compared the impact of LC and conservative management on the rate of recurrent gallstone disease and all-cause late mortality. For this reason, subjects who underwent emergency LC during the same admission were excluded from the study. The proportion of patients who became fit and underwent interval LC following PC was 29.4%; subjects in the non-surgical group were older and comorbid, and as such were deemed unfit for surgery. In other published series, the rates of elective LC following PC have ranged between 28% and 40%, with old age and comorbidities being the main characteristics that prevent surgery [15-17].

Patients in the non-surgical cohort underwent delayed PC. A proportion of them were on anticoagulant medications, and the procedure had to be postponed to reduce the risk of bleeding. Another potential reason could be that some of the older adults were admitted by different teams, and the time between diagnosis and referral may have led to delay in the positioning of PC. The gallbladder drainage had a 100% technical success rate, as neither immediate complications nor procedure-related deaths occurred. In the literature, early postprocedural complications have been reported with an incidence of 8-44% [18,19], with 0.4% mortality [20]. PC treated ACC effectively in 95% of our study population; a similarly high success rate was described in most of the published series [20,21].

In-hospital mortality accounted for almost 10% of our patients, with uncontrolled biliary sepsis causing over 50% of the deaths. The LoS was longer in group 2, and delayed positioning of PC predicted a prolonged hospitalization. Similar findings have been described by other authors [22,23]; it is possible that late positioning of the PC delayed the resolution of ACC, thus accounting for the longer LoS.

More than half of the study population were readmitted to hospital, in most cases for a biliary cause. PC-related complications occurred in 1 in 5 patients, with drain displacement being the most common event (7.5%). However, that did not require repositioning of the PC. In other series, the rate of PC dysfunction was up to 46% [24], with a similar proportion of drain displacement [24,25]. Almost one third of our study population suffered from recurrent gallstone disease, with ACC accounting for 17%. While the rate of readmissions did not differ between groups, in the surgical cohort most of the recurrent gallstone events occurred before LC. Other studies reported rates of recurrent ACC of 25-36% at 3 months and 49% at 1 year [16,26-28], with a higher incidence in patients who had PC alone [25,29,30]. In our series, all the interval cholecystectomies were performed laparoscopically, and no perioperative complications occurred. Other authors reported rates of conversion of procedures to open of 7.7-11%, and prolonged insertion of the PC was described as a risk factor [24,31].

Throughout the study period, late deaths occurred in 46% of the study population, with higher rates in the non-operative group, whose chance of survival was less than 40% at 3 years. Interestingly, although most readmissions were due to biliary conditions, recurrent gallstone disease accounted for a minor proportion of late deaths. Other series reported overall death rates of 13-69% at 30 days, particularly in patients with extensive comorbidities and Tokyo grade 3 disease [32,33]. Similarly, our results showed that higher ASA scores and severity of ACC were predictors of late mortality, while LC had a protective role. In the study of Hess *et al* [34], recurrent acute cholecystitis was the most common cause of late mortality; the onset of recurrent biliary events could compromise patients' physiological reserve and frailty, thus contributing to the overall late mortality. Moreover, the authors reported that the persistence of subclinical gallbladder inflammation, following previous severe acute cholecystitis, was a risk factor of late mortality.

Given the lower postsurgical rate of recurrent biliary events and the protective role against late deaths, we would regard elective LC as the definitive management option following an episode of severe ACC. Therefore, efforts should be made to optimize patients' health and reduce the perioperative risk status. In this context, PC is effective in the early treatment of critically ill patients who are not surgical candidates [35,36], allowing for resolution of sepsis and rehabilitation. However, we appreciate that elective surgery can often be delayed for several reasons, including pending reviews in the outpatient clinic, need for further imaging or operative waiting times. These patients might benefit from a clear pathway to streamline the preoperative process and reduce the time to surgery.

Subjects who remain unfit for elective LC remain a challenge, since they are at risk of recurrent biliary disease. In this group, while optimization of the long-term conservative management is advocated, clinicians should maintain a low threshold to reassess the biliary tree and start early treatment, in case recurrent gallstone disease is suspected. This group of patients might benefit from percutaneous cholangioscopy and lithotripsy as a possible solution to treat recurrent ACC, thus reducing the need for LC [37].

Limitations of this study are the retrospective design, the difference in clinical and demographic characteristics between the 2 groups—which is likely to have affected the higher long-term mortality rate in the non-surgical cohort—and the relatively short follow up. Despite these drawbacks, our results described the clinical evolution of gallstone disease following severe ACC and the impact of different management options on patients' outcomes, under real life conditions. This aspect could provide more insight to patients and clinicians on long-term health expectations and follow-up plans.

In conclusion, in this series, readmissions secondary to recurrent gallstone disease were frequent following PC for severe ACC. Elective LC was associated with a lower readmission rate and late all-cause mortality.

Summary Box

What is already known:

- Severe acute calculous cholecystitis (ACC) is associated with non-negligible mortality rates
- When antibiotics fail, and laparoscopic cholecystectomy (LC) is contraindicated, percutaneous cholecystostomy (PC) is effective in the treatment of severe ACC
- The long-term management following patients' recovery is still being debated

What the new findings are:

- We assessed the clinical evolution of gallstones following PC for severe ACC and evaluated the rate of recurrent gallstone disease and late mortality
- Recurrent gallstone disease was common following severe ACC, with the highest risk of readmission within the first 30 weeks following PC
- LC was associated with lower rates of recurrent gallstone disease and all-cause late mortality

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