

Computed tomography-guided percutaneous cholecystostomy: a single institution's 6-year experience

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Abstract

Background Acute cholecystitis (AC) is an emergency commonly managed by a surgical department. The interventional part of the standard treatment algorithm includes laparoscopic or open cholecystectomy. Percutaneous cholecystostomy (PC) under imaging guidance is recommended as the first-line approach in the subset of high-risk patients for perioperative complications, as a bridging therapy to elective surgery or as a definitive solution. The aim of the present study was to evaluate the mortality and morbidity of PC performed under computed tomographic (CT) guidance in patients at high surgical risk.

Methods Medical and imaging records from all consecutive patients who underwent a CTPC between 2015 and 2020 were reviewed. Adult patients with a definite indication for CTPC were recruited and mortality 7 and 30 days post-procedure was recorded. Variables potentially affecting those outcomes were retrieved and included in our analysis.

Results Eighty-six consecutive patients at high risk for surgical management were identified and included in the present study. Most patients (58.1%) were diagnosed with AC, while 14 (16.3%) had concurrent AC and cholangitis, 13 (15.2%) gallbladder empyema, and 9 (10.4%) hydrops. The 7- and 30-day mortality rates were 16.3% (14/86) and 22.1% (19/86), respectively, and were significantly associated with patients' hospitalization in the intensive care unit ($P < 0.05$). Other parameters investigated, such as age, sex, diagnosis, catheter diameter, and duration of hospital stay were not significantly associated with our primary outcome.

Conclusion PC is a safe alternative to surgery in patients with high perioperative risk, thus providing acceptable mortality rates.

Keywords Percutaneous cholecystostomy, computed tomography, acute cholecystitis, high-risk patients

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Introduction

Acute cholecystitis (AC) is a common emergency in a surgical department. Gallstones are the primary cause, affecting up to 15% of the population (calculus cholecystitis), whereas less commonly the gallbladder inflammation is attributable to diabetes, viral infection, chronic kidney disease or hemoglobinopathy (acalculous cholecystitis) [1-2]. The standard choice of treatment in AC remains the laparoscopic or open cholecystectomy [1]. However, a significant percentage of patients with many comorbidities, especially the elderly, are ineligible for surgery because of the high risk of perioperative complications [1-3].

According to the Tokyo guidelines (TG18) the severity of AC is graded as follows: grade 1 (mild), grade 2 (moderate), and grade 3 (severe), based on the laboratory and clinical findings and the involvement of other organs [4,5]. Isolated conservative treatment and elective intervention are only

recommended in mild cases, whereas the moderate and severe cases require surgical treatment [5]. However, urgent cholecystectomy in high-risk patients has been associated with high morbidity and mortality [6]. Nevertheless, percutaneous cholecystostomy (PC) was first suggested as a treatment option for AC in 2007 (TG07) [4,5,8]. To date, in the revised TG18, PC is recommended as the first-line treatment in the subset of patients ineligible for surgery, based on the American Society of Anesthesiologists (ASA) performance status score and the Charlson Comorbidity Index [4,5,8]. The safety advantage of this technique, which is performed under image guidance (computed tomography [CT], ultrasound, or fluoroscopy), is based on the fact that no general anesthesia is necessary and the patients avoid the physical stress of intra-abdominal manipulations [5,7,8].

PC can also serve as a bridging therapy to more elective surgery, or as a definitive treatment in patients who pose a high risk for cholecystectomy [1,8,9]. In this regard, the increased availability of imaging techniques and the establishment of interventional radiology departments facilitated the adoption of PC as an available option in day-to-day practice [1,7]. Nevertheless, despite its theoretical benefit in the management of critical ill patients with AC, there is a lack of evidence regarding the overall efficacy and adverse events of this technique. For example, in severe (grade III) AC, it is associated with higher mortality, longer hospital stay, and more readmissions, implying a need for further improvements in minimally invasive drainage of the gallbladder [9]. The aim of the present study was to evaluate the outcomes in terms of mortality and morbidity of CT-guided PC (CTPC) in patients with high surgical risk.

Patients and methods

A retrospective study was conducted using medical and imaging records from all patients at high risk for surgical management who underwent CTPC in a single interventional radiology department of a tertiary hospital between 2015 and 2020. Approval was obtained from the Ethical committee of the University Hospital of Larissa, Greece. Experimental therapeutic protocols were not applicable in this study. All data were collected in the context of routine diagnostic and therapeutic procedures and were analyzed anonymously using code numbers to preserve the patients' privacy. Moreover, the informed consent signed before the procedure included approval of future data use for research, given the academic nature of our institution.

All included patients had an ASA score equal to IV. In all cases with AC, the diagnosis was based on clinical, laboratory and imaging findings, fitting the TG criteria. In addition, further indications for CTPC (hydrops, empyema) were assessed for eligibility. The exclusion criteria included patients under 18 years old, with coagulation disorders (platelets <50,000/ μ L, INR >1.2), and an indication for more complex manipulations than CTPC, or concomitant percutaneous transhepatic cholangiography.

After identifying the eligible cases from our reports, data on age, sex, catheter diameter, diagnosis, intensive care unit (ICU)

stay and length of stay were retrieved after collaboration with the surgical and gastroenterological units. The variable values were recorded by the primary investigator (IKS) in an Excel Sheet (Office 2019, Microsoft, USA) and confirmed by the surgeon (AS) and gastroenterologist (FF).

In our department, PC procedures are guided by CT and performed in patients with grade 3 (severe) cholecystitis according to TG, without clinical improvement after 24 h of receiving conservative treatment. Other indications, such as hydrops due to malignant obstruction, or empyema, are discussed in a multidisciplinary group to provide the optimal management. CTPC procedures were performed by a total of 2 different attending physicians during the study period, with assistance from a resident (2 in total), while 7 clinicians (4 general surgeons and 3 gastroenterologists) acted as patients' supervisors. In our cases we used a transhepatic approach.

The Seldinger technique was used in all patients and local anesthesia was used in all cases [10]. The patient was placed in a supine or semilateral position and the gallbladder was punctured with a 21-G needle under CT guidance. Bile was aspirated through the needle for gallbladder decompression and was sent for microbiological examination. A 0.035" guidewire was used to exchange the needle for a dilator and an 8-, 10-, or 12-Fr pigtail drain was placed within the gallbladder. The pigtail drain was immobilized with skin sutures. All patients had been receiving pre-procedure antibiotic prophylaxis for at least 24 h. The primary outcome was to define the 7- and 30-day mortality following CTPC. Other variables that could potentially affect those outcomes were also investigated. Technical success was defined as successful intubation of the gallbladder.

Statistical analysis

Data were tested for a normal distribution using the Kolmogorov-Smirnov test. The parametric *t*-test and the non-parametric Mann-Whitney *U* test were used to determine if a statistically significant difference existed in quantitative data. Comparisons of the qualitative variables were performed using a chi-square test. A *P*-value <0.05 was considered statistically significant. Statistical calculations were performed using SPSS v.26 software (IBM Chicago, IL, USA).

Results

In total, 86 consecutive patients at high risk for surgical management were identified and included in the present study. The mean age was 72.2 years and 52 (60.4%) patients were male. Most of the patients (58.1%) were diagnosed with AC, 14 (16.3%) with concurrent AC and cholangitis, 13 (15.2%) with gallbladder empyema and 9 (10.4%) with hydrops. An 8-Fr catheter was preferred when it was available and was used in 59 (68.6%) of cases, a 10-Fr catheter in 21 (24.4%) cases, and a 12-Fr in 6 (7%) cases. Furthermore, 19 (27.9%) patients were admitted to the ICU during their hospital stay.

Regarding CTPC-related outcomes, technical success was achieved in all cases. The 7-day mortality rate was 16.3% (14/86) and the 30-day mortality rate was 22.1% (19/86). All patients died from underlying sepsis and bacteremia as a result of AC. Table 1 displays the data regarding 7-day mortality. There was no statistically significant associations between 7-day mortality and age ($P=0.522$), sex ($P=0.781$), diameter of the inserted catheter ($P=0.921$), diagnosis ($P=0.412$), or length of hospital stay ($P=0.098$). However, the need for an ICU stay showed a significant association with 7-day mortality ($P=0.02$).

The results regarding 30-day mortality are provided in Table 2. There was no statistically significant association with age ($P=0.563$), sex ($P=0.186$), diameter of the catheter ($P=0.932$), diagnosis ($P=0.354$), or length of hospital stay ($P=0.426$). Again, the only statistically significant factor associated with 30-day mortality was the need for an ICU stay ($P<0.001$).

Regarding the morbidity rates attributed to the procedure, tube dislodgment was the most commonly reported adverse event (9 cases; 10.5%), followed by minor local bleeding (7 cases; 8%), and abscess formation (5 cases; 6%). Other less commonly reported complications included pneumothorax (2 cases; 2.5%), 1 case of peritonitis (1.5%), and 1 case of bowel perforation (1.5%). There were no method-attributed deaths recorded and reintervention was not performed in any case. In total, surgical intervention was performed in 6 cases (7%).

According to our protocol, the drainage catheter was removed 3 weeks after the placement, on the condition that the patient remained asymptomatic following the 48 h of catheter closure.

Discussion

PC is a minimally invasive procedure that allows gallbladder decompression without the need for general anesthesia [11-20]. The present study illustrates the experience of a tertiary center from CTPC during a 6-year period, for patients with a high perioperative risk for cholecystectomy.

AC is a common condition that occurs in up to 20% of all patients with symptomatic gallstone disease and is best treated with early cholecystectomy (24-48 h from the onset of symptoms) [21,22]. The incidence of gallstone disease, which is the primary risk factor for AC, increases with age [23]. The standard reference treatment for patients with AC is laparoscopic cholecystectomy. One recent prospective randomized trial showed that laparoscopic cholecystectomy within 24 h of hospital admission was superior to a conservative approach with regard to morbidity and cost, although there was no significant difference in mortality [15]. Generally, laparoscopic cholecystectomy is considered to be acceptable and safe, and is associated with low rates of morbidity and mortality [21,22]. However, in patients operated for acute calculous cholecystitis, conversion is required in up to 25% of subjects [24-28]. Furthermore, conversion from laparoscopic to open cholecystectomy substantially increases both morbidity and mortality [24-28]. The risk for conversion increases with the duration of symptoms [27]. Thus, surgical intervention can carry significant morbidity and mortality in patients with a

Table 1 Seven-day mortality

Variants/ 7-day mortality	Yes (14) N (%)	No (72) N (%)	P-value
Age (mean, SD)	73.9 (15.3)	71.4 (12.3)	0.522*
Male sex	8 (57.1%)	44 (61.1%)	0.781 [†]
Catheter diameter			
8 Fr	9 (64.2%)	50 (69.4%)	0.921 [†]
10 Fr	4 (28.6%)	17 (23.6%)	
12 Fr	1 (7.2%)	5 (6.9%)	
Diagnosis			
Cholecystitis	6 (42.9%)	44 (61.1%)	0.412 [†]
Cholecystitis and cholangitis	3 (21.4%)	11 (15.3%)	
Gallbladder hydrops	3 (21.4%)	6 (8.3%)	
Gallbladder empyema	2 (14.3%)	11 (15.3%)	
ICU stay			
Yes	8 (57.1%)	6 (8.3%)	0.020 [‡]
No	6 (42.9%)	66 (91.7%)	
Length of stay (mean, SD)	3,14 (1.88)	9.87 (7.66)	0.098 [‡]

*t-test, [†]chi-square test, [‡]Mann-Whitney test

SD, standard deviation; ICU, intensive care unit

Table 2 Thirty-day mortality

Variants/ 30-day mortality	Yes (19) N (%)	No (67) N (%)	P-value
Age (mean, (SD))	73.9 (13.9)	71.15 (12.6)	0.563*
Male sex	9 (47.4%)	43 (64.2%)	0.186 [†]
Catheter			
8 Fr	13 (68.4%)	46 (68.7%)	0.932 [†]
10 Fr	5 (26.3%)	16 (13.9%)	
12 Fr	1 (5.3%)	5 (7.5%)	
Diagnosis			
Acute cholecystitis	8 (42.1%)	42 (62.3%)	0.354 [†]
Acute cholecystitis and cholangitis	5 (26.3%)	9 (13.4%)	
Gallbladder hydrops	3 (15.8%)	6 (9.0%)	
Gallbladder empyema	3 (15.8%)	10 (14.9%)	
ICU stay			
Yes	13 (68.4%)	6 (9.0%)	<0.001 [†]
No	6 (31.6%)	61 (91.0%)	
Length of stay (mean, SD)	8.47 (9.97)	9.4 (7.02)	0.426 [‡]

*t-test, [†]chi-square test, [‡]Mann-Whitney test

SD, standard deviation; ICU, intensive care unit

prolonged duration of symptoms and those who are critically ill and unfit for surgery [12,13,21,22].

PC represents an alternative approach in this group of patients. It was first described in 1979 as a treatment for obstructive jaundice and later, in 1980, it was proven to be effective in patients with AC who were at high risk of surgical morbidity and mortality [16-19,29,30]. However, no study has reported the optimal timing for PC in patients with AC who are not suitable for surgery [31]. Its technical success is extremely high and approaches 100%, specifically 98.9% [7].

For these patients, PC can be used either as a bridging procedure to subsequent elective cholecystectomy or as a definitive treatment modality [9,12,14]. However, a recent study shows that, compared with percutaneous drainage, laparoscopic cholecystectomy is the preferred treatment strategy from both a clinical and economical point of view, with lower morbidity and fewer readmissions [32].

Technically, PC is generally carried out under imaging guidance, using fluoroscopy, ultrasound, CT, or a combination of these [10]. The PC catheter may be placed directly into the gallbladder (trocar technique) or by initially using a smaller catheter with exchange over a wire for placement of the larger diameter PC catheter (Seldinger technique) [10]. The PC course may be transhepatic, or may be, transperitoneal without crossing the intervening liver [30]. The choice of approach may be dictated by the location of the gallbladder, the degree of gallbladder distention, the presence of intervening bowel, and patient body habitus [30]. However, in many cases both the transhepatic and transperitoneal routes may be available to the operator [30]. Despite small series in the literature showing similar outcomes between the techniques, most authors and textbooks continue to state that the transhepatic approach is preferred [30]. In a recent study, no significant differences were observed for the transperitoneal versus transhepatic route in complications such as pain, clogging, skin infection, bleeding, biloma, cholangitis, abscess or leakage during placement or removal, according also to catheter size [30].

An emerging alternative to PC includes the use of endoscopic ultrasound to internalize the gallbladder content into the alimentary tract, using plastic or lumen apposing metal stents [33]. After the gallbladder has been identified, through the stomach or the duodenal bulb, and in the absence of intervening structures, transmural insertion of a needle is the first step to obtain access to the gallbladder and create the anastomosis [33]. Recent data concluded that this technique provides comparable results with PC, but with a lower incidence of adverse events [33]. More specifically, in their meta-analysis Luk *et al* indicated that the difference in the pooled rates of technical and clinical success between those modalities was not statistically significant, with optimal to moderate heterogeneity among included studies ($I^2=0\%$ and 44% respectively) [33]. On the other hand, ultrasound-guided drainage was associated with a shorter inpatient period (pooled mean difference: -2.53 , 95% confidence interval -4.28 to -0.78 ; $P=0.005$; $I^2=98\%$) and fewer indications for reintervention and readmission compared to PC [33]. Nevertheless, this approach requires specific training and an advanced level of endoscopic expertise, thus limiting its broad availability [33].

According to recent studies, in patients with AC who were at high surgical risk and underwent PC, the early intervention group had a shorter hospital stay due to earlier decompression of the gallbladder [31]. This may reverse the inflammation process earlier, consequently contributing to a faster improvement and a shorter hospital course [31].

The most common complications are minor, including drain dislodgment (range 7.2-29.6%), bleeding (range 2.4-7.2%), bile leakage (range 1.1-10.4%), and tube blockage (range 0.6-7%) [32,34]. The dislocations could be avoided using drains

with a locking system [35]. The overall procedure-related complication rates vary in broad intervals; the majority of articles report the incidence to be under 20% [23,36]. Cases of other complications, such as hemobiliary fistula, liver abscess, bowel injury or pneumothorax, are rarely reported [35, 36].

In a recent review only four PC-related mortalities were reported among 312,085 patients, with mortality 0.001% [34]. Another systematic literature review concluded that the mortality rate directly resulting from PC was 0.4% [35,36,37]. Several studies have reported that the 30-day mortality rates in patients undergoing PC ranged from 0-25% [35,36,37]. In our current study, although mortality was higher, none of the patients died as a direct result of procedure-related complications. Nonetheless, the significant association with ICU stay is indicative of the patient's already critical condition and the use of CTPC as a salvage measure.

Our study had some limitations. First, its retrospective design and the inclusion of a single intervention cohort incorporates a potential bias regarding the comparison with potential alternatives, such as surgery. Second, further parameters affecting survival, such as hospital-related infections, or differences in conservative measures between clinics, were not assessed. Finally, our sample was limited, although comparable with previous studies in this field.

In conclusion, CTPC was related with a short-term mortality of 16.3%, and with a rate 6% greater 1 month later, when selected as a salvage modality to treat patients with gallbladder emergencies and accompanying comorbidities. The necessity for ICU hospitalization was the unique factor associated with those rates, thus probably reflecting the background critical condition. Future comparative studies, evaluating the entire range of available minimally invasive drainage techniques, are required to provide the optimal choice for this subgroup of patients.

Summary Box

What is already known:

- Acute cholecystitis (AC) is a common emergency in a surgical department
- Percutaneous cholecystostomy (PC) under image imaging guidance is recommended in the subset of high-risk patients for perioperative complications
- There is a lack of evidence considering the overall efficacy and adverse events of this technique in the management of critically ill patients with AC

What the new findings are:

- Regarding computed tomography-guided PC-related outcomes, technical success was achieved in all cases
- The 7-day mortality rate was 16.3%, whereas the and 30-day mortality rate was 22.1%
- PC is a safe alternative to surgery in patients with high perioperative risk, thereby providing acceptable mortality rates

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