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Original Research

Is Interval Cholecystectomy Necessary After Percutaneous Cholecystostomy in High-Risk Acute Cholecystitis Patients?

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Abstract

Objectives: Percutaneous cholecystostomy (PC) for acute cholecystitis (AC) is frequently performed in high-risk surgical patients as an alternative treatment modality. However, debate remains over whether or not an interval cholecystectomy for these patients should be performed. The aim of this study was to investigate the outcomes of PC in high-risk surgical patients with AC.

Methods: Between September 2013 and June 2016, 27 of 952 patients with AC were treated with PC. The data collection included demographic variables, including comorbidities, the timing of the PC, the length of the hospital stay, the follow-up period, the complications related to PC, and readmission to hospital.

Results: There were 16 female and 11 male patients, with a mean age of 73±12.4 years (range: 49-97 years). Comorbid diseases included ischemic heart disease (n=6), diabetes mellitus (n=5), chronic obstructive pulmonary disease (n=6), and others (n=10). The mean timing of PC was 2.2±1.4 days (range: 1-3 days). The mean length of hospital stay was 9.6±2.1 days (range: 7-14 days), and the catheter was removed after the first month. The mean follow-up period after the PC catheter removal was 19.6±8.6 months (range: 10-38 months). Only 6 patients (22.2 %) were readmitted to the hospital. Cholecystectomy was performed in 4 cases, and 2 responded to medical treatment.

Conclusion: Despite ongoing controversy about the management of AC in high-risk surgical patients, PC is an adequate and safely applicable procedure in this group of patients. However, an interval cholecystectomy should be considered in persistent cases, which account for a small percentage. Longer-term follow-up studies with a larger sample size are needed to support our results.

Keywords: Acute cholecystitis; interval cholecystectomy; percutaneous cholecystostomy.

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Acute cholecystitis (AC) is a commonly seen disease in daily surgical practice, and emergent laparoscopic cholecystectomy (LC) is the standard treatment modality.[1] However, the rate of complications of LC, such as bile duct, vascular, or bowel injury, is high in cases of severe AC.[2] Emergency surgical treatment of AC in critically ill patients has a high mortality rate. Likewise, the operative mortality in elective LC can be as much as 30% in elderly patients with comorbidities.[3]

The wide range of clinical presentation and comorbidities of patients with AC makes the therapeutic management quite difficult to standardize. The Tokyo guidelines are cur-

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rently one of the most common approaches in the diagnosis and management of AC.[4] According to the guidelines proposed in 2013, the severity of AC is classified into 3 grades according to the physical examination results and laboratory tests that diagnose and predict organ failure, disease duration, and imaging studies.[5, 6]

Since the early 1980s, percutaneous cholecystostomy (PC) has been used as an alternative treatment to AC. It is considered a life-saving option for patients who are a high risk for open or LC. PC is a minimally invasive technique, which can safely be performed with local anesthesia under ultrasound (US) guidance with a satisfactory outcome.[7, 8] Patients with comorbidities who are diagnosed with severe AC can be treated with PC during the acute phase of AC. Elective surgery for high-risk patients is suggested in the best possible general condition.[9, 10] In the event of unsuitability for elective surgery, PC not only helps patients recover fully from the acute phase, but also keeps the inflammatory processes latent, preventing the status from worsening.[11] The clinical management of high-risk surgical patients with AC remains controversial, despite modern surgical techniques, as well as advances in anesthesiology and intensive care medicine. Definitive surgical intervention is still debated. The aim of this study was to investigate whether an interval cholecystectomy is routinely required after PC in high-risk surgical patients.

Methods

Between September 2013 and June 2016, all patients diagnosed and treated for AC were retrospectively reviewed. Of these, the data of 952 patients were analyzed, after receiving the approval of the institutional review board (registration number 807).

Patients who were diagnosed with AC and treated with PC due to (a) no symptomatic improvement despite appropriate medical management, including third-generation cephalosporin (Ceftriaxone, Novosef, 1000 mg intravenous; Zentiva Sağlık Ürünleri Sanayi ve Ticaret A.Ş., Istanbul, Turkey) or (b) plausible high-risk surgical patients (American Society of Anesthesiologists [ASA] classification III or IV) were included in the study.

Those excluded from the study were patients (a) who underwent surgery after PC due to gall bladder perforation, ineffective PC, failure of endoscopic retrograde cholangiopancreatography for choledocholithiasis, (b) with a diagnosis of surgery requiring entities such as previous history of gall bladder polyp or suspicious malignancy, biliary pancreatitis, (c) who suffered in-hospital death, and (d) those lost to follow-up.

Data collection included demographic characteristics of the patients, including comorbidities and ASA score, laboratory, and radiological findings, PC catheter placement and time of removal, complications related to PC, hospital stay, follow-up period after PC removal, and readmission to the hospital.

Consideration of AC diagnosis was based on positive symptoms of Murphy's sign, palpable gall bladder, fever, elevated C-reactive protein (CRP), and leukocytosis, and all of the patients were graded according to the Tokyo guidelines. The radiological diagnosis included US and computerized tomography. A final AC diagnosis was based on the combination of the findings from the patient history, physical examination, and laboratory and radiological results, and subsequently, patients were evaluated in 3 categories, according to the severity of the cholecystitis.

If the ASA score was high, the patient was considered to be a high-risk surgical patient due to comorbidities, and if sufficient improvement with medical treatment was not observed, PC was recommended. After an informed consent form was signed, a PC procedure was performed under local anesthesia with US guidance, and a transhepatic Seldinger technique was used to insert a 10-F pigtail catheter. The first sample taken after the PC catheter was inserted was sent for microbiological examination for all patients. Following the procedure, a third-generation cephalosporin (ceftriaxone) was administered intravenously, and the antibiotic regimen was changed if necessary, according to the culture results.

Results

In all, 127 (13.3%) of 952 patients treated medically in our clinic for AC had a cholecystectomy before discharge as a result of clinical findings that deteriorated under medical therapy. PC was performed in 29 cases, despite some being considered at high- risk for anesthesia application due to comorbidities. Two of these patients were excluded from the study because physical examination findings deteriorated despite the PC and emergency cholecystectomy.

There were 11 male (40.7%) and 16 female (59.3%) patients in the study, with a mean age of 73±12.4 years (range: 49-97 years). Patients were graded according to the Tokyo criteria: Grade I (n=6, 22%), Grade II (n=15, 55.6%), and Grade III (n=6, 22%) (Table 1). While the radiological findings revealed AC in all of the patients, other, more complicated entities, such as gangrenous cholecystitis (n=5), acalculous cholecystitis (n=4), and perforated cholecystitis (n=2), were also specifically identified in some patients. All of the patients had at least 2 comorbid diseases; the most commonly detected were hypertension, diabetes mellitus, and cerebral-renal-cardiac-respiratory diseases (Table 2).

Pre-anesthetic assessment of the patients found that 17 of the 27 patients included (63%) were ASA IV, while the remaining 10 patients (37%) were ASA III. PC was performed after an average of 2.2±1.4 days (range: 1-3 days) after the diagnosis of AC. Before the PC, the medications of patients taking anticoagulant drugs were adjusted to maintain an international normalized ratio ≤1.5. The PC was performed transhepatically with US guidance and no complications were detected during the procedure in any patient. Microbial growth was detected in the bile cultures of 17 (63%) patients: *Escherichia coli* (n=12), anaerobic bacteria (n=4), and *Candida albicans* (n=1).

The septic condition of the patients improved within 48 hours after the PC was performed, and the mean hospital stay was 9.6±2.1 days (range: 7-14 days). The patients whose clinical, laboratory, and radiological findings showed improvement were discharged with a percutaneous catheter and orally administered second-generation cephalosporin. The patients were seen weekly in the outpatient clinic until the PC catheter was removed. The mean length of time until the PC catheter was removed was 30.2±4.5 days (range: 22-38 days). The mean length of the follow-up period was 19.6±8.6 months (range: 10-38 months) (Table 1).

Six patients (22%) were readmitted to the hospital due to recurrent complaints, with a mean length of time after the catheter removal of 9.8±2.7 months (range: 6-13 months). According to the Tokyo guidelines, these patients were diagnosed with grade II recurrent AC. Two of the 6 patients were discharged after clinical improvement with appropriate medical treatment, including a third-generation cephalosporin (ceftriaxone), while the remaining 4 underwent a cholecystectomy within the first 48 hours after readmission. A laparoscopic approach was successful in 2 patients, whereas for the others, an open conversion was performed due to a failure to maintain a critical view of safety. No major complication was observed, other than wound infection in 1 patient who underwent open cholecystectomy for recurrent cholecystitis. The 21 patients (77.7%) who underwent PC without experiencing recurrent cholecystitis were followed up for a mean of 21.9±8.4 months (range: 10-38 months). During this period, the patients did not complain of cholecystitis symptoms, and there was no evidence of AC recurrence at the outpatient clinic (Table 3).

Table 1. Demographic characteristics of the patients and pre-interventional data

Variables	Value	No. of patients, (%) (n=27)
Age, years (mean±SD)	73±12.4	
Gender		
Male		11 (40)
Female		16 (59)
WBC (>10*10^3 cells/mL)		27 (100)
CRP (>5 mg/dL)		27 (100)
Fever (>38°C)		17 (63)
Tachycardia (>100 bpm)		11 (40.7)
Progressive abdominal pain		24 (89)
ASA score		
I-II		-
III		10 (37)
IV		17 (63)
Grade of cholecystitis*		
I		6 (22)
II		15 (68)
III		6 (22)
Indications for PC		
Poor surgical candidate/high-risk patients		19
Resistance to medical treatment		5
Severely ill patients in intensive care		3
Duration between admission and PC (days, mean±SD)	2.2±1.4	
Hospital stay, days, (mean±SD)	9.6±2.1	
Timing of PC catheter removal (days, mean±SD)	30.2±4.5	
Follow-up time, months (mean±SD)	19.6±8.6	

ASA: American Society of Anesthesiologists; CRP: C-reactive protein; PC: percutaneous cholecystostomy; WBC: White blood cell count; *Patients were grouped using the Tokyo guidelines.

Table 2. Co-morbidities precluding cholecystectomy (n=27)

Comorbidity	No. of patients (%)
Cardiovascular diseases	6 (22)
Respiratory disease*	6 (22)
Diabetes mellitus**	5 (18)
Multisystem diseases	10 (37)

*Advanced chronic obstructive respiratory disease; **Severely uncontrolled patients.

Table 3. Long-term management after PC during follow-up period

Treatment modality	No. of patients (%)
PC as definitive management	21(78)
Readmission and management	6 (22)
Medical	2 (7.4)
Surgery- Laparoscopic	2 (7.4)
Surgery- Conversion to open cholecystectomy	2 (7.4)

PC: Percutaneous cholecystostomy.

Discussion

Despite all efforts, surgical treatment can lead to severe morbidity and mortality, especially for high-risk, geriatric patients with AC.[3] Yet since PC emerged as an alternative choice for treatment of AC, it has become a safe and cost-effective intervention for patients with comorbidities.[12] PC may be life-saving, particularly for high-risk surgical patients requiring an emergency procedure. PC provides not only successful bile drainage, at a rate of 98%, but also extra time for patients to recover and become medically stable before elective surgery.[13, 14] However, to be effective, treatment must address the individual's comorbidities. Although the exact role of PC in the clinical management of high-risk surgical patients has not yet been well-established,[15] the recent 2018 Tokyo guidelines confirmed that percutaneous transhepatic gallbladder drainage should be considered the first alternative to surgical intervention in surgically high-risk patients with AC.[16] The general trend for the treatment of AC in our clinic is to perform an elective cholecystectomy 6 weeks after relieving acute inflammation. However, LC is performed when the medical condition of the patient worsens despite medical treatment. PC is a clinically acceptable approach in patients with severe comorbidities. In this study, 27 of 29 patients (93.1%) were treated successfully with PC. Yet, despite the PC, cholecystectomy was required for 2 patients whose condition worsened, and 1 of them died in the intensive care unit on postoperative day 3.

The decision to pursue a PC is made by the clinician according to the facilities of the hospital and the risk-benefit of the technique for the patient.[17] The preoperative assessment revealed an increased risk of perioperative and postoperative complications in addition to the risks related to the surgery itself for the patients in this study; therefore, emergency surgical intervention for AC-induced sepsis was not suitable. In our study, the average PC catheter insertion time was 2.2 days (range: 1-3 days). The timing of the intervention was based on the patients' medical and physical status. PC is an effective procedure with a high success rate, low morbidity and mortality, and provides the possibility for interval cholecystectomy.[18] Studies have shown that more than 80% of patients with AC experience rapid improvement in clinical manifestations within 3 days of PC.[18] Likewise, in our series, the septic condition of the patients improved within 48 hours after the insertion of a PC catheter. None of the patients required emergency surgical intervention for any complication related to catheter placement.

In the literature, some 35% to 60% of bile cultures in these cases have been reported as positive.[19, 20] The most frequently isolated microorganisms are Enterobactericeae, Streptococcacae, Candida, and anaerobes.[21] The incidence of resistant microorganisms is higher in these patients due to comorbidities and older age. Therefore, the bile culture is important and the treatment should be planned according to the results.[22]

The treatment approach after the PC catheter removal, usually meaning definitive surgery, remains a challenge for surgeons. Some authors recommend performing an interval cholecystectomy after PC to prevent repeated episodes of AC;[23] however, a growing trend suggesting that PC may not only serve as a bridge to LC may also be a long-term treatment option in patients with high-risk AC, has emerged.[24] Moreover, Chang et al.[24] have pointed out that PC may be a primary treatment option for AC in patients with severe comorbidities and avoid the need for interval cholecystectomy. In the present study, this idea was the core of the research. Although it was not the case for all of the PC-patients, almost four-fifths responded well to interventional treatment and did not require further surgical procedure. In fact, although PC is frequently considered a bridge to an interval cholecystectomy in high-risk surgical patients, fewer than half of patients undergo an interval cholecystectomy after PC intervention.[25] For these high-risk surgical patients, despite time to stabilize the underlying diseases and properly prepare for the procedure, significant perioperative morbidities can occur during an interval cholecystectomy procedure.[26] In our study, recurrence occurred in 6 patients (22%); however, only 4 underwent surgical treatment within the first 48 hours after readmission. A laparoscopic approach was successful in 2 cases, whereas open conversion was necessary in the others due to a failure to maintain a critical view of safety. No perioperative complication was observed. When the laboratory results taken before the PC insertion were examined, the mean white blood count value of these patients was 15686/mm^3 (range: 10300-22800 /mm^3), and the CRP level was 97 mg/dL (range: 10-180 mg/dL). There was no significant statistical difference between these patients and those without recurrence. No other evidence indicating recurrence was found in the other parameters that were measured.

Although it has been reported in the literature that a PC catheter can be clamped and a cholangiography can be performed to ensure that there is no bile leakage or cystic duct obstruction before withdrawal, it is not routine procedure.[27] In our study, clamping or cholangiography was not required in any of our patients before the PC catheter was withdrawn. US was performed before and after the catheter was removed, and no catheter-related complications were observed during follow-up.

No precise optimal time for the withdrawal of the PC catheter has been reported in the literature. Sanjay et al.[28] noted that the drain should remain for at least 6 weeks and then be withdrawn after performing a cholangiography. It has also been reported in some publications that the removal should be determined based on the PC technique: at least 2 weeks for a transhepatic approach and at least 3 weeks for a transperitoneal approach.[29] In our study, the PC procedure was performed with a transhepatic technique and the catheter was withdrawn at a mean of 30.2±4.5 days after the procedure for all of the participants. No bile leakage was observed after removal.

Another controversial issue involves the approach to patients with recurrent cholecystitis following PC catheter withdrawal. In the literature, the frequency of recurrent cholecystitis after PC catheter withdrawal is 4% to 22%.[24, 28, 29] Treatment options for recurrent cholecystitis include medical therapy, repeat PC, and emergency cholecystectomy.[24, 28, 30] Sanjay et al.[28] reported that 22% of patients were readmitted with recurrent cholecystitis during follow-up, and about half had a repeat PC. In our study, no patients underwent repeat PC. McGillicuddy et al.[30] recommended an interval cholecystectomy only for recurrent AC patients. In our study, 4 of 6 patients with recurrent cholecystitis were treated with surgical intervention (cholecystectomy) due to a status that was suited to the setting of elective surgery, while the remaining 2 responded to medical treatment. It is recommended that elective cholecystectomy be performed if the patients' status conforms to the conditions for elective surgery.[16] Patients who developed recurrent cholecystitis in this study were treated medically. It was observed that the clinical status of these patients was comparatively better than the previous AC condition. After PC treatment, 4 patients underwent cholecystectomy as a result of a deteriorated clinical status under medical therapy. Laparoscopic surgery was planned, but due to adhesions and significant inflammation in 2 of the patients, an open conversion was necessary. The other 2 patients were successfully discharged after medical treatment. No complaints were reported in the follow-up of these patients.

The main limitations of our study include the retrospective design and the small number of patients. In conclusion, although LC is accepted as the gold standard in the treatment of AC, emergent cholecystectomy is still a challenging process due to the high rate of morbidity and mortality, particularly in high-risk surgical patients. For these patients, in the event of ongoing inflammation despite appropriate medical therapy, PC, an alternative, minimally invasive approach, may provide both definitive treatment and a bridge protocol to elective surgery. Cholecystectomy is not necessarily needed after PC in high-risk patients. Malignancy must also be kept in mind in these patients. Further studies with a larger sample size and long-term follow-up are warranted to support our findings.

Disclosures

Ethics Committee Approval: The study was approved by the Local Ethics Committee.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

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