Ann Med Res 2021;28(1):113-9

Annals of Medical Research

DOI: 10.5455/annalsmedres.2020.08.819

Original Article

Is percutaneous cholecystostomy bridge to cholecystectomy or definite therapy in high-risk patients with severe acute calculous cholecystitis?

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Abstract

Aim: The medical records of 68 patients diagnosed with severe ACC and treated with PC at Başkent University Faculty of Medicine, General Surgery Clinic between January 2011 and January 2018 were retrospectively analyzed.

Results: Among patients who underwent PC for severe ACC at our clinic, 39 (57.4%) were male. Their mean age was 71.7 (28-94) years. All patients had pain; 13 (19.1%) patients had nausea-vomiting; 8 (11.8%) had had fever. The mean time from symptom onset to hospital admission was 6.2 (1-30) days; the mean time from admission to PC placement was 2.1 (1-9) days. Twelve (17.6%) patients had minor complications due to cholecystostomy catheter. Twenty seven (39.7%) patients underwent cholecystectomy with a mean of 83.1 (20-705) days after cholecystostomy placement. Seventeen of these patients underwent laparoscopic surgery and 3 of them converted to open surgery. In 5 of 41 patients who did not undergo cholecystectomy, AC recurrence developed (12.2%) and PC was inserted again. Five (7.4%) patients died.

Conclusion: Percutaneous cholecystostomy catheter is an effective treatment to control inflammation until cholecystectomy among high-risk patients diagnosed with severe cholecystitis and may be a definitive therapy for patients unable to undergo surgery.

Keywords: Acute cholecystitis; percutaneous drainage; cholecystostomy

INTRODUCTION

Acute calculous cholecystitis (ACC) is the most common complication of cholelithiasis and reportedly occurs in 20% of patients with bile stones (1,2). ACC is one of the commonest causes of presentations to surgery clinics owing to the high prevalence of cholelithiasis (1,3). The Tokyo guidelines of the Japanese Society of Hepato-Biliary-Pancreatic Surgery, which was issued after an international consensus meeting in 2007 (TG07), recommended early cholecystectomy among patients presenting with ACC (4). In 2013, the revised Tokyo guidelines (TG13) adjusted the treatment according to cholecystitis severity (5–7). They were classified cholecystitis with organ dysfunction as "grade 3" cholecystitis (severe); cholecystitis with signs of local inflammation as "grade 2" cholecystitis (moderate); and cholecystitis lacking the above criteria as "grade 1 "cholecystitis (mild). TG13 recommended gallbladder drainage as a tool for treating grade 3 ACC and grade 2 ACC that unresponsive to medical therapy due to increased mortality risk of early surgery.

The treatment objective for septic patients or patients with comorbidities should be a rapid control of septic condition. In such patients, decompression of an inflamed gallbladder eliminates the need for urgent operation and reduces mortality and morbidity (8). It has been reported that a cholecystostomy catheter percutaneously placed under ultrasonographic guidance was easy-to-apply and effective for the treatment of acute severe cholecystitis (9,10) Percutaneous cholecystostomy (PC) was shown to be a good definitive therapy approach alternative to surgery

Received: 10.08.2020 **Accepted:** 16.10.2020 **Available online:** 26.01.2021
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in acalculous cholecystitis (11,12). It is believed that PC can be used both for serving as a bridge to an elective surgery in patients with moderately severe acute calculous cholecystitis and a definitive treatment procedure as an alternative to surgery in critical patients. However, some authors have stressed the absence of evidence about the efficacy of PC (13,14) while some studies have shown increased mortality after PC compared to cholecystectomy among patients with severe cholecystitis (15,16).

Herein, we aimed to assess the early and late efficacy and outcomes of PC used to treat patients with comorbidities who were diagnosed with severe and moderately severe acute calculous cholecystitis.

MATERIALS and METHODS

This retrospective study was performed at Başkent University Faculty of Medicine, General Surgery Clinic between January 2011 and January 2018. It was approved by Başkent University Institutional Review Board and Ethics Committee and supported by Başkent University Research Fund (Project no: KA 18/282).

We included a total of 68 patients with grade 3 and grade 2 ACC based on Tokyo guidelines (Table 1), and an American Anesthesiology Association (ASA) score III (a patient with severe systemic disease) or IV (a patient with severe systemic disease that is a consistent threat to life), who were placed a PC catheter.

Table 1. Criteria for acute cholecystitis severity based on Tokyo guidelines (Tokyo Guidelines 2013)

Grade II (moderately severe) acute cholecystitis ("Grade II" acute cholecystitis is related to any of the following conditions)

- Elevated white blood cell (WBC) count (> 18.000/mm^3)
- Palpable tender mass in the right upper abdominal quadrant
- Duration of complaints >72 hours
- Marked local inflammation (biliary peritonitis, pericholecystic abscess, hepatic abscess, gangrenous cholecystitis, emphysematous cholecystitis)

Grade III (Severe) acute cholecystitis ("Grade III" acute cholecystitis is related to the dysfunction of any of the organs/systems below)

- Cardiovascular dysfunction (hypotension requiring treatment with dopamine or dobutamine)
- Neurological dysfunction (decreased level of consciousness)
- Respiratory dysfunction (PaO_2 / FiO_2 ratio <300)
- Renal dysfunction (oliguria, creatinine> 2.0 mg/dl)
- Hepatic dysfunction (PTINR> 1.5)
- Hematological dysfunction (platelet count <100.000/mm^3)

ACC was diagnosed on the basis of radiological studies (sonographic findings; gallbladder wall thickening of 5 mm or greater, gallbladder wall anechoicity, gallbladder distension, as determined by an external anteroposterior width of 4 cm or greater, and cholelithiasis) in addition to local (Murphy's sign, upper right quadrant tenderness or palpable mass) and systemic (fever, elevated C-reactive protein (CRP), leukocytosis) signs of inflammation. Patients with choledocholithiasis, pancreatitis and acalculous cholecystitis treated with percutaneous cholecystostomy were excluded. All patients were admitted to hospital, their oral intake was stopped, and fluid resuscitation was begun. All patients were treated with third-generation cephalosporins. The decision to place a PC catheter was made by the General Surgery department and based on patients' ASA score, presence of signs of systemic inflammation, and symptom duration. Patients with grade 3 ACC were placed a PC catheter immediately upon making the diagnosis. Patients with grade 2 ACC were placed a PC catheter when clinical or radiological signs did not regress under medical therapy.

PC catheter was placed by specialised interventional radiologists under local anesthetics and ultrasonography guidance at the interventional radiology unit or intensive care unit. The fundus of the gallbladder was visualised by ultrasonography and accessed via a transhepatic route with an 18-gauge needle. Bile samples for aerobic and anaerobic cultures were taken from all patients. A guide wire (Amplatz Super Stiff Guidewire, Boston Scientific Corp, Natick, MA, USA) was placed, and dilatation was performed, which was followed by the placement of a 8-10 French lockable pigtail catheter into the gallbladder through the transhepatic route that had just been formed. After the catheter was placed, it was stabilized to abdominal skin using sutures at the puncture site. Twenty-four to forty-eight hours after PC catheter placement, the position of the catheter in the gallbladder was assessed using a water-soluble contrast material under fluoroscopy. Fresh frozen plasma (FFP) is used for reversal of elevated INR levels to patients who were taking Warfarin. Patients whose INR level were lower than 1.5 were catheterized. PC catheter was placed to patients who were taking

other anticoagulants 24 hours later after stopping their treatment. Clinical improvement was evidenced by pain alleviation, reduced tenderness on physical examination, and a drop in leucocyte count and CRP level. The patients visited outpatient surgery clinic twice a week after discharge. A transcatheter cholecystography was taken 3 weeks after catheter placement. The catheters were left open in patients with cystic canal obstruction. In patients with a patent cystic canal in cholecystography, PC catheter was closed, and either followed until the time of the operation or waited for the maturation of the fistula tract for 3 weeks and the catheter was removed in suitable patients. In non-operated patients, PC catheter placement was repeated at disease recurrence.

Statistical analysis was performed with SPSS soft-ware, version 17.0 (SPSS, Chicago, IL, USA). Distribution of the quantitative data was tested with Kolmogorov-Smirnov test. The descriptive statistics included mean ± standard deviation or median (minimum-maximum) for continuous quantitative variables and number and percentage (%) for categoric variables. The two groups were compared using the independent samples t test for normally distributed continuous variables and the Mann–Whitney U test for non-normally distributed continuous variables. Categoric variables were compared with Fisher's exact test when the expected frequency was below 5 or with Chi-Square test with continuity correction when the expected frequency was between 5 and 25. A p value of less than 0.05 was considered statistically significant.

RESULTS

Of the patients included in the study, 39 were male (57.4%) and 29 were female (42.6%). The mean age was between 71.7 ± 14.6 (28-94) years. All patients had abdominal pain at admission. There were 132 comorbid diseases in 68 patients, the most common being hypertension (54.4%). In ultrasonographic examination; Transverse size of the gall bladder average was 43.1 ± 12.5 (15-75) (mm) and wall thickness of the gall bladder average was 4.9 ± 1.7 (3-13) (mm). Twenty-four patients (35.3%) had previous abdominal surgery. Eighteen patients (26.5%) were using anticoagulant or antiaggregant drugs (10 patients warfarin, 8 patient other anticoagulants). In the evaluation of ASA score, 41 (60.3%) of the patients were ASA III and 27 (39.7%) were ASA IV.

Forty-three (63.2%) patients were placed a PC catheter due to persistent symptoms under medical treatment. Twenty-five (36.8%) patients were placed a PC catheter at the time of admission. The mean time from symptom onset to admission was 6.2±6.5 (1-30) days, and time from admission to PC placement was 2.1±1.6 (1-9) days. Clinical improvement after PC was evaluated by resolution of initial symptoms and resolution of leukocytosis and CRP level within 3 days. When the leukocyte and CRP values of the patients were compared before and 3 days after PC insertion, it was observed that the level of acute phase reactants decreased significantly after the procedure ($p < 0.001$, $p < 0.001$, respectively). The mean duration of hospital stay was 8.7±9.9 (2-60) days. The mean duration of follow-up was 10.2±6.3 (2-24) months. The PC complication rate was 17.6% (n=12). Based on the cholecystography findings, PC catheter was removed in 36 (52.9%) patients and cholecystectomy was performed in 27 (39.7%) patients. Among 27 patients, cholecystectomy was performed by laparoscopy in 20 patients, with a conversion rate of 15% (3/20). Seven patients underwent open cholecystectomy because of their previous abdominal surgery (Table 2).

There were no complications related to catheter insertion. Twelve (17.6%) patients presented procedure-related complications including the following: 8 patients presented with a bile leak following catheter removal, 3 patients presented with bleeding, 1 patient presented with catheter dislodgement. PC catheter was re-inserted to patients after PC removal. 2 patients were followed who were using anticoagulant/antiaggregant medications and had bleeding after PC placement. Blood transfusion was done and bleeding were stopped with medical treatment. Bleeding was taken under control with inserted a larger catheter in 3rd patient presented bleeding. A new PC was placed in a patient with PC dislodgement. No statistical difference were found when sex, age, complaint time, comorbidities of 12 patients with PC complication and 56 other patients were compared (respectively p=0.536, p=0.288, p=0.475, p=0.282). PC was placed again due to recurrence of cholecystitis in 5 of 41 (12.2%) patients who could not be operated.

Five patients (7.4%) who could not be operated due to comorbidities were died. Four patients died due to multiorgan failure and one patient died due to malignancy. None of the patients had their PC catheter removed. Mean follow-up time was found as 14.2±6.8 (8-23) days. Mortality was not significantly correlated to age, sex, and duration of complaints, comorbid diseases, WBC and CRP levels before and after PC placement, PC complications and PC withdrawal (Table 3).

DISCUSSION

The main treatment objective for septic patients or patients with comorbidities should be a control of the septic condition. In such patients, decompression of an inflamed gallbladder eliminates the need for urgent operation and reduces mortality and morbidity (8). However, before PC treatment, the patient should be sure of the diagnosis and the indication should not be suspected. After excluding atypical pathology conditions, PC treatment should be applied after making sure of acute cholecystitis picture (17,18). PC is also regarded as a definitive therapy for patients deemed at high surgical risk (19). As there are no randomised studies, however, timing of PC catheter placement is unclear, and the treatment protocol could not be standardised. Therefore, the preferred treatment approach varies by a surgeon's experience and choice.

In our study, 25 (36.8%) patients were placed a PC catheter at the time of admission while 43 (63.2%) patients

Table 2. Applied treatment and gastric surgery history due to anatomic localisation of bezoar type		
Age (years)	**71.7±14.6 (28-94)**	
Sex (male/female)	39 (57.4%)/29 (42.6%)	
Admission complaint		
Pain	68 (100.0%)	
Nausea/vomiting	13 (19.1%)	
Fever	8 (11.8%)	
Time from symptom onset (days)	6.2±6.5 (1-30)	
Comorbidity	132	
Hypertension	37 (54.4%)	
Diabetes mellitus	18 (26.5%)	
Coronary artery disease	16 (23.5%)	
Chronic obstructive pulmonary disease	15 (22%)	
Chronic renal failure	8 (11.8%)	
Malignancy	5 (7.3%)	
Other	33 (48.5%)	
WBC level before PC	13607.3±4543.6	t=7.366; p<0.001
WBC level after PC	8633.8±3217.6	
CRP level before PC	197.7±93	Z=-6.38; p<0.001
CRP level after PC	97.9±62.2	
PC complication	(n=12) (17.6%)	
PC catheter removal	8 (67%)	
Bleeding	3 (25%)	
PC dislodgement	1 (8%)	
Timing of cholecystography (days)	23.7±21.2 (1-105)	
PC removed	36 (52.9%)	
Operated	27 (39.7%)	
Laparoscopic	17 (63%)	
Conversion to open surgery	3 (11.1%)	
Open	7 (25.9%)	
Time to operation (days)	83.1±126.7 (20-705)	
Operated with PC catheter in place	15 (55.6%)	

Table 3. Demographic properties of the deceased and surviving patients			
Mortality	**Yes (n=5)**	**No (n=63)**	**p-value**
Age (years)	73.2±9.5	71.5±15	Z=-0.165; p=0.869
Sex (male/female)	2 (40%)/3 (60%)	37 (58.7%)/26 (41.3%)	χ^2 =0.664; p=0.644
Time from symptom onset (days)	11.8±12.3	5.8±5.8	Z=-1.102; p=0.271
Comorbidity	11	120	χ^2 =27.282; p=0.608
Hypertension	2	35	
Diabetes mellitus	1	17	
Coronary artery disease	2	14	
Chronic obstructive pulmonary disease	1	14	
Chronic renal failure	1	7	
Malignancy	1	4	
Other	3	30	
PC complication	0	12 (17.6%)	χ^2 =1.156; p=0.577
PC catheter removal		8 (67%)	
Bleeding		3 (25%)	
PC dislodgement	0	1 (8%)	
PC removed		36 (57.1%)	χ^2 =6.071, p=0.019

were placed a PC catheter due to unresponsiveness to medical treatment. The mean duration of hospital stay was 8.7±9.9 (2-60) days, whose main determinant was comorbidities. All patients had their ACC symptoms regressed after PC catheter placement. We preferred transhepatic route over the transperitoneal route regarding the PC catheter placement in the absence of severe liver disease and coagulopathy. The transhepatic route provides better catheter stability and earlier tract maturation and correlated with a lower risk of bile leak (20,21). The Seldinger technique was used in combination with the transhepatic approach, since this enables the use of smaller-gauge needles, thus limiting the risk of hepatic injury. PC related complications usually occur immediately or within days (22). These early complications include hemorrhage, bile peritonitis, pneumothorax, perforation of the intestinal loop and catheter dislodgment. Late complications have been reported as catheter dislodgment and recurrent cholecystitis (23). The rate of catheter-related complications was 17.6% (n=12). The commonest complication was PC dislocation (75%, n=9). Charrier et al. reported a catheter-related complication rate of 29% and PC catheter dislocation is the commonest complication (12.2%) (3). Winbladh et al. in a systematic review, reported a catheter dislocation rate of 8.5% (n=98/1144) (15). A minor complication rate similar to previously reported rates as well as the resolution of ACC symptoms upon PC placement in our study indicates that PC may be effectively and safely used for patients with comorbidities deemed at high risk for complications.

We found a mortality rate of 7.4% (n=5), but no case of mortality occurred secondary to catheter placement or to ACC and there is no difference between deceased and surviving patients WBC and CRP levels before and after PC placement. Previous studies have reported mortality rates ranging between 6% and 17% (16,19,24). However, Joseph et al. (20) reported a 10-year mortality rate of 36%. That difference may be explained with patients' median age, comorbidities, and study duration.

Another subject of debate is whether PC catheter must be removed. In the present study, cystic canal obstruction was assessed using transcatheter cholecystography. The decision to remove PC catheter was made on the basis of symptom resolution, patency of the cystic canal, and the time to tract maturation (Figure 1). In our study the PC catheters of 32 patients (47.1%) were not removed due to cystic canal obstruction (Figure 1); among these patients, 15 patients were undergone cholecystectomy, 5 of them were died. Twelve patients were followed with a PC catheter in place until the end of the study, and the corresponding figure reported by Bundy et al. was 13.9% (21); the difference between the two rates may be explained by patients being unable to be operated due to their comorbidities or refusing the operation.

Previous studies have reported a recurrence rate as high as 35-50% within one year among patients not operated following PC catheter removal (25–27); the most significant risk factor for ACC recurrence was named as cystic canal obstruction (28). In our study, 24 (35.3%) patients had their catheter removed but were not operated, and 5 of these patients underwent repeat PC catheter placement due to high surgical risk. A transcatheter cholecystography of these patients, performed before the removal of the first PC catheter, revealed no cystic canal obstruction.

Figure 1. Fluoroscopic images of the cholecystography procedure

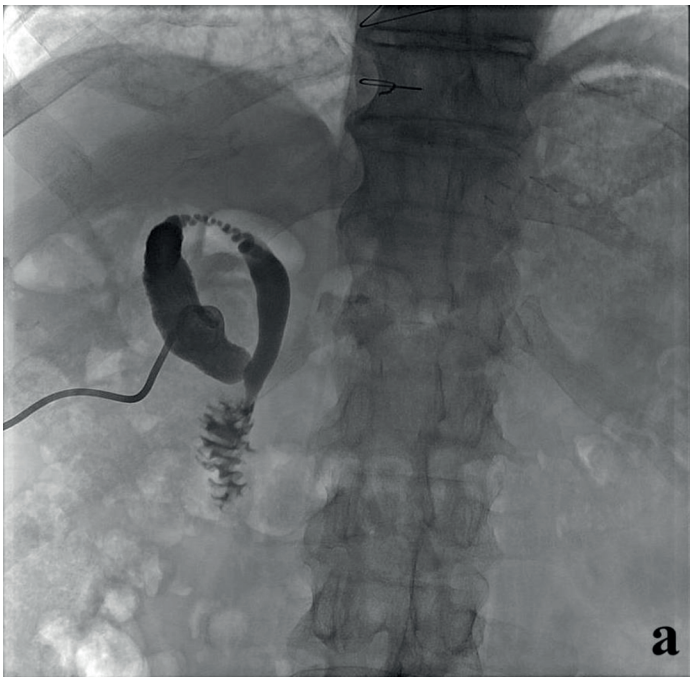

Figure 1a. The fluoroscopic image taken at cholecystography shows a normal passage of the water-soluble contrast agent into the duodenum

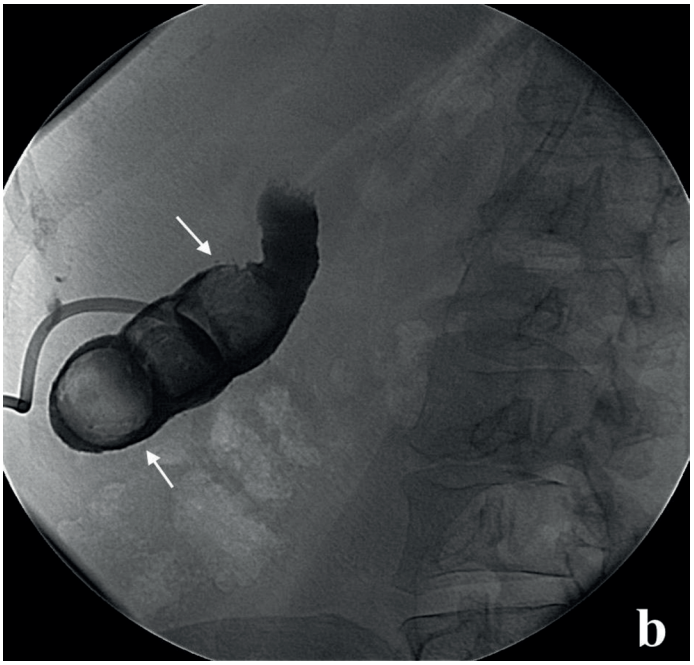

Figure 1b. the fluoroscopic image shows filling defects in the gallbladder lumen (white arrow) and complete obstruction of the cystic canal

The rate of elective cholecystectomy has been reported to be 30-57% among patients who were placed a PC catheter, had comorbidities and were diagnosed with moderately severe to severe cholecystitis (10,26,29). Similarly, the rate of elective cholecystectomy was 39.7% (n=27). Seventeen (63%) patients underwent laparoscopic cholecystectomy, and 3 (11.1%) patients were converted to open procedure from the laparoscopic technique. Fifteen (55.6%) of the operated patients were operated in the presence of a PC catheter. Mirzahi et al. (30) compared the outcomes with delayed cholecystectomy between patients with and without PC catheter placement. They reported that the presence of PC was an independent risk factor for both conversion to open surgery and the development of any bile duct-related complication. None of our operated patients developed any bile duct-related complication. No significant correlation was observed between the presence of PC catheter and conversion to open surgery (p=0.506).

Our study's limitations include its retrospective design, enrolling a limited number of patients from a single centre, the absence of a control group, and the variability of the timing and indications of cholecystectomy by surgeons experience after PC catheter removal. Prospective studies with larger sample size are needed to determine and standardise the role of PC catheter placement for treatment of patients with comorbidities and grade II-III cholecystitis.

CONCLUSION

The definitive treatment of ACC is early cholecystectomy. The use of PC catheter in patients diagnosed with moderate or severe ACC according to Tokyo criteria and concomitant comorbidities appears to be therapeutic treatment until elective surgery. PC can be considered as a life saving procedure in inoperable patients. We did not encounter mortality or technical failure due to PC administration in our study. However, we think that, weak candidacy for surgery of patients because of their comorbidities, risk of disease recurrence after PC catheter removal, and risk of the inability to remove PC catheter should be remembered..

Competing interests: The authors declare that they have no competing interest.

Financial Disclosure: There are no financial supports.

Ethical approval: It was approved by Başkent University Institutional Review Board and Ethics Committee and supported by Başkent University Research Fund (Project no: KA 18/282)

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