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Research article

Ultrasound-guided percutaneous cholecystostomy as bridging or definitive treatment in patients with acute cholecystitis grade II or III

Çağrı Kesim [a,*], Özgür Özen [b]

[a] Başkent University, Konya Hospital, Department of Radiology, Interventional Radiology Section, Turkey
[b] Başkent University, Ankara Hospital, Department of Radiology, Interventional Radiology Section, Turkey

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ABSTRACT

Background: We aimed to investigate the extent to which ultrasound (US)-guided percutaneous cholecystostomy (PC) is used as a bridging or definitive therapy for grade II and III acute cholecystitis and whether this treatment causes significant changes in C-reactive protein (CRP) and direct bilirubin (DB) levels in the first 72 h and the first three weeks.
Methods: We included 145 consecutive patients who underwent PC over 17 years. No patient had cirrhosis. PC was performed in the interventional radiology department under US guidance.
Results: US-guided PC was the definitive treatment for more than half of the patients (51.7%) and decreased DB levels significantly more than CRP levels.
Conclusion: No statistically significant correlation between those whose CRP and DB levels normalized within three weeks and those who did not and required a second invasive procedure. Nevertheless, the bridging treatment group was significantly older than the definitive treatment group.

1. Introduction

Acute cholecystitis is characterized by hydropic dilatation gallbladder and inflammation of its wall. The most common cause is gallstones. This is followed by chronic critical illness and prolonged stay in the intensive care unit [1]. Abdominal ultrasonography is crucial for the diagnosis of acute cholecystitis. The main findings are an enlarged gallbladder, condensed debris in the lumen, thickening of the gallbladder wall, or fluid around the gallbladder [2]. Although the disease usually presents clinically with Charcot's triad (fever, jaundice, right upper quadrant pain) or Reynold's pentad (Charcot's triad plus shock and lethargy), these are insufficient in most patients. Measurement of C-reactive protein (CRP) is not common in many countries. However, CRP is very valuable for the diagnosis because acute cholecystitis is usually associated with increased CRP levels of 3 mg/dl or more. Diagnosis of acute cholecystitis by an increase in CRP level (3 mg/dl or more) with classical ultrasound findings suggestive of acute cholecystitis has a sensitivity of 97%, a specificity of 76%, and a positive predictive value of 95% (level 1b) [3]. On the other hand, direct bilirubin (DB) levels tend to increase in acute cholecystitis due to obstructive causes and are associated with increased direct bilirubin levels [4].

Although acute cholecystitis is usually treated surgically, the patient may be monitored and treated with pharmacotherapy depending on the cause. In more complicated clinical situations, such as perforated gallbladder or sepsis, it may not be possible to

* Corresponding author.
E-mail address: cagrikesim@hotmail.com (Ç. Kesim).

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Table 1
Description of grades II and III acute cholecystitis according to the Tokyo Guidelines.

Mild acute cholecystitis (grade II)	Severe acute cholecystitis (grade III)
Leukocytosis >18,000/mm^3	Cardiovascular dysfunction
Palpable gallbladder	Neurological dysfunction
Pain >72 h	Respiratory dysfunction
Marked local	Renal dysfunction
- inflammation	Liver dysfunction
- Gangrenous cholecystitis	Hematological dysfunction
- Perivesicular abscess	Disturbance of consciousness
- Hepatic abscess	PaO2/FiO2 ratio <300
- Biliary peritonitis	Oliguria
	PT-INR >1.5
	Platelet count <100,000/mm^3
	Hypotension requiring dopamine or dobutamine

Table 2
Distribution of patients by age, sex, and CRP/DB status according to the need for secondary surgery at the end of the third week after PC.

SECONDARY OPERATION	NO		YES		TOTAL
Gender	Female	Male	Female	Male	
Age	68.15 ± 10.94	64.97 ± 13.44	76.1 ± 8.45	71.38 ± 16.07	69.6 ± 13.8
Normalized CRP Normalized DB	7 (14.3%)	17 (34.7%)	11 (22.4%)	14 (28.6%)	**49 (33.8%)**
Normalized CRP High DB	3 (18.75%)	4 (25%)	1 (6.25%)	8 (50%)	**16 (11%)**
High CRP High DB	6 (14%)	17 (39.5%)	7 (16.3%)	13 (30.2%)	**43 (29.7%)**
High CRP Normalized DB	10 (27%)	11 (29.7%)	4 (10.8%)	12 (32.5)	**37 (25.5%)**
TOTAL	**26 (17.9%)**	**49 (33.8%)**	**23 (15.9%)**	**47 (32.4%)**	**145 (100%)**

LEGENDS FOR FIGURES.

operate on the elderly or patient populations with high ASA-PS (American Society of Anesthesiologists - physical condition classification) scores. Tokyo Guidelines also present a severity grading scale from grade I (mild) to grade III (severe). These guidelines single out patients with grade II (moderate) and grade III (severe) acute cholecystitis for percutaneous intervention (Table 1) [2].

Recently, the indications for PC have been expanded to include cholangitis, biliary obstruction, and as a potential route for stone extraction and dissolution [5]. Percutaneous transhepatic gallbladder drainage with the placement of a drainage catheter is recommended for all surgically unfit patients with cholecystitis [6]. In cases of acalculous cholecystitis or malignant obstruction, the patient's follow-up and drug treatment can be lengthy. In such cases, a hydropic gallbladder can cause severe pain in the right upper quadrant that may spread to the entire abdomen. In cases where surgery is impossible or in clinical situations where drug treatment must be prolonged, emptying the gallbladder can significantly relieve the patient's severe abdominal pain [7].

PC is a procedure to empty the gallbladder under ultrasound guidance used for over 40 years in a select group of patients [8]. With this method, it is possible to rapidly empty the bile sludge and pus and achieve rapid clinical improvement in patients. Although PC is the sole therapeutic method, it can also be used as a bridging treatment before cholecystectomy or other biliary surgeries, as the Whipple procedure in some cases.

The level of C-reactive protein as part of the Tokyo criteria for classifying the severity of acute cholecystitis [9] and direct bilirubin levels as the most rapidly changing parameter of common bile duct obstruction [4] were examined in detail in this study to evaluate the efficacy of US-guided PC treatment. Therefore, we conducted this study to understand better the fate of patients who received a PC and to clarify the optimal treatment strategy, including performing a secondary operation and/or the likelihood that the tube can be removed.

In this study, we aimed to report PC's immediate and short-term effects as definitive or bridging therapy, patients' CRP and DB levels, and the rate of secondary invasive procedures required after this treatment. We also investigated whether there was a statistically significant association between the change in CRP and DB levels after PC and the need for a second surgical intervention, and we wanted to determine whether the rate and extent of a decrease in CRP and DB levels affected whether the patient required a second surgical intervention.

2. Material and methods

Data collection, processing, monitoring, and analysis were prepared using the criteria of STROBE since this study is retrospective observational research. This study was approved by Başkent University Institutional Review Board with research number [KA22-387]. The study complies with all regulations and confirmation that informed consent was obtained from all patients before the PC

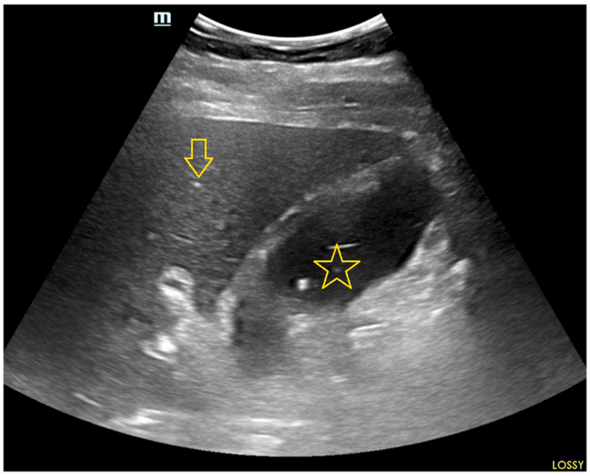

Fig. 1. US-guided PC procedure. Hydropic and inflamed gallbladder with thickened wall with a little stone in the lumen, the transhepatic route (arrow), and the tip of the guiding needle (star) in the lumen of the gallbladder.

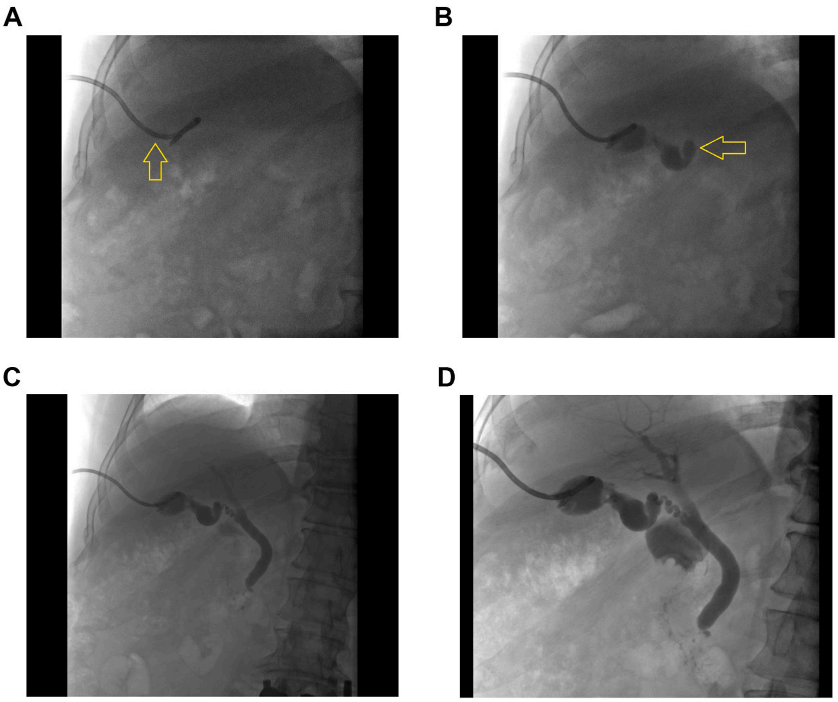

Fig. 2. Fluoroscopic image of a cholecystogram after technically successful percutaneous cholecystostomy. A newly placed 8F all-purpose drainage catheter (APD) is seen within the right upper quadrant (arrow) (a). Contrast medium is confirmed to flow through the gall bladder lumen until the cystic channel junction (arrow) (b), through the cystic channel to extrahepatic bile ducts and common bile duct (c), and into intrahepatic bile tree and the 2nd part of the duodenum (d) without obstruction.

operation.

Between July 2004 and July 2021, 145 consecutive patients who presented to the emergency department, general surgery, or gastroenterology outpatient clinic for acute cholecystitis and required PC because of comorbidities, ongoing infections, or advanced age or had no chance of endoscopic retrograde cholangiography or cholecystectomy enrolled in our study. We did not prefer to do PC when the patient had cirrhosis and similar parenchymal diseases. Therefore, none of the patients had cirrhosis and had sonomorphologically usual liver features. The distribution of our patients in terms of age, sex, and need for a second surgery after PC is summarized in Table-2.

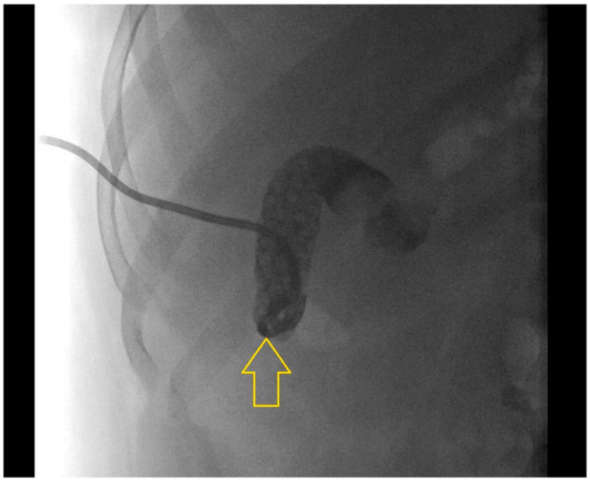

Fig. 3. The distal end of the transhepatically inserted 8F all-purpose drainage (APD) pigtail catheter is in the fundus portion of the gallbladder (arrow). The contrast agent administered through the catheter stained the lumen to the neck of the gallbladder in the tenth minute of the procedure and visualized numerous stones in the lumen, but even in the twentieth minute of the procedure, there was no contrast transition into the cystic duct and common bile duct. This patient required cholecystectomy after ERCP with the healing of the sepsis clinic.

2.1. Percutaneous transhepatic cholecystostomy technique

Under the guidance of the US, the PC procedure is performed by an interventional radiology specialist with 5 or 20 years of experience. Although local anesthesia is usually used for this procedure, sedation may sometimes be preferred in the agitated patient group. After the patient was supine, the right upper quadrant of the abdomen was adequately sterilized. Then local anesthesia with 20 ccs prilocaine was applied to the liver capsule, subcutaneous fat, and skin under the guidance of the US A 10-cm 19-gage guiding needle (Geotek Medical and Health Services., Ankara, Türkiye) was advanced transhepatically into the lumen of the hydropic gallbladder via an intercostal approach, also under ultrasound guidance (Fig. 1), and 20 ccs of bile were aspirated. Then, a 75-cm rigid Amplatz Super Stiff guidewire (Boston Scientific, Heredia, Costa Rica) was advanced through the guiding needle, and its distal soft end was placed in the fundus of the gallbladder. Tract dilation was performed with an 8F dilator (Balton, Warszawa, Poland) over the guidewire. An 8F 25-cm Flexima™ APDL locking pigtail catheter (Boston Scientific, Alajuela, Costa Rica) was then placed, with its distal end in the cholecyst lumen and its proximal end connected externally to the drainage bag.

2.2. Post-procedure care and follow-up

Patient vitals are monitored for at least 4–6 h (most patients are already under intensive care). Adequate intravenous hydration is ensured with the continuation of the recommended antibiotic regimen. The catheter is gently flushed with 5–15 ml of sterile saline every 12 h to prevent clogging by debris and bile salts. After PC, ideally, patients are clinically and radiologically assessed 3 days, 1 week, 4 weeks, and 6 weeks after the procedure [10]. Therefore, routine CRP and DB checks were performed in all patients within 72 h after drainage catheter insertion. The drainage catheter was left in place for at least three weeks, and at the end of this period, a CRP and DB control examination with cholecystography/choledochography was performed. In this examination, a contrast agent containing iodine (Opaxol™ 300 mgl/ml, MDS Health Products, Gebze, Türkiye) is connected to the drainage catheter and before the contrast medium injection, an image was taken without contrast medium (Fig. 2a). After the contrast medium injection, images were acquired at different time intervals and projections. We see the contrast medium in the proximal orifice of cystic duct (Fig. 2b). It was verified that the contrast agent administered in these images reached the lumen of choledoch (Fig. 2c) and the duodenum without interference (Fig. 2d). If there was no stone in the gallbladder neck, cystic duct, or common bile duct, the drainage catheter was removed, and treatment was terminated. This group was considered the definitive treatment group. However, in the presence of stones in the extrahepatic bile ducts or when the contrast medium was halted in the cystic duct or common duct (Fig. 3), the drainage catheter was left in place, and a second operation was planned according to the patient's condition, which is formed bridging treatment group of the current study.

2.3. Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 26.0. (IBM Corp Armonk, NY). All patients were divided into two groups: those who needed a second operation and those who did not. All patients' CRP and DB levels were recorded at baseline, 72 h, and three months later, and patients were divided into those whose CRP and DB levels fell within the indicated period and those who did not. Then, patients whose CRP and DB levels declined after three weeks were distinguished from those in whom they did not. The relationships between those who required surgery after PC and those who did not were examined. In addition, demographic characteristics such as the sex and age of patients and whether they needed a second surgery were examined statistically. Parametric data are specified in the format mean ± standard deviation. While the independent-samples *t*-test was used for parametric data, multiple chi-square analyzes were performed for nonparametric data.

3. Results

Of 145 patients, 49 (33.8%) were female and 96 (66.2%) were male, and the distribution of these patients among all parameters within the study is detailed in Table - 2. The mean age of females was 72.37 ± 10.39 years, and that of males was 68.24 ± 15.11 years. When analyzed with the T-test for independent samples, no significant difference was found between the ages of the two groups ($p > .05$). In all patients who underwent PC, more than a 25% decrease in CRP and DB levels was observed in the first 72 h with the significant symptomatic relief. Besides, regression of obstructive jaundice was observed accompanying sepsis clinic in most patients.

Of our 145 patients treated with PC, 75 (51.7%) were discharged without additional surgical intervention. CRP levels returned to the normal range in 31 (41.3%) of these 75 patients. In 44 (58.7%) patients whose CRP levels remained high, the reason was another disease outside the hepatobiliary system. DB values normalized in 45 (60%) patients. In the remaining 30 (40%) patients, parenchymal liver diseases such as cirrhosis and hepatitis were present, and DB levels did not return to the normal range.

Of our 70 patients who required secondary surgery after PC, 68 needed laparoscopic cholecystectomy within three months, one had cholecystoenterostomy, and the last had Whipple surgery. CRP normalized in 34 (48.6%) of our 70 patients in the first three weeks after PC; DB levels returned to normal in 41 (58.6%).

The mean age of the 70 patients who required surgery after PC was 73.01 ± 1.62 years; for the 75 patients who did not, it was 66.01 ± 1.52 years. The independent samples T-test showed a significant difference between these two groups, and the group that needed surgery was significantly older ($p < .05$).

The mean age of our 49 patients in whom both CRP and DB levels returned to normal after PC was 67.94 ± 15.53 years, and 24 of these patients (49%; 17 men, 7 women) did not require surgery in the three months follow-up. Of the remaining 25 (51%; 14 men, 11 women), patients underwent laparoscopic cholecystectomy under elective conditions because of cholelithiasis.

The mean age of the 43 patients whose CRP and DB levels did not normalize after PC was 73.09 ± 9.69 years, and 23 of these patients (53.49%; 17 men, six women) did not require surgery in the three months follow-up. Of the remaining 20 patients (46.51%; 13 men, 7 women), 18 underwent laparoscopic cholecystectomy, 1 underwent cholecystoenterostomy, and 1 underwent Whipple surgery.

Six different comparisons were performed by chi-square analyses within four parameters such as sex (male/female), CRP (normalized/non_normalized), DB (normalized/non_normalized), and need for a second surgery (yes/no). Groups were formed as follows (sex*2nd surgery, sex*CRP, sex*DB, 2nd surgery*CRP, 2nd surgery*DB, CRP*DB). According to the results of multiple chi-square analysis, no difference was found in the five groups. A statistically significant ($p < .05$) difference was found only in the CRP*DB group, and the normalization rate of DB values within three weeks after the PC procedure (86 patients, 59.3%) was significantly higher than the normalization rate of CRP values (65 patients, 44.8%).

4. Discussion

US-guided PC has been used as a bridging treatment technique to treat numerous gallbladder conditions, including biliary tract emergencies such as cholecystitis or cholangitis, malignant or benign biliary obstruction, gallbladder perforation, and percutaneous gallstone removal. Although it has rarely been the first choice in the past, PC is often preferred in patients who are too ill to tolerate surgical procedures. In the meantime, since its introduction in 1980, new technical innovations have redefined the role of PC in the treatment of gallbladder disease [8].

While predicting the eventual need for secondary operation is challenging, some papers suggest that patients with elevated DB have a significantly higher chance of surgery [11]. They postulate that increased inflammation may result in cystic duct obstruction that is less likely to resolve with drainage and antibiotics. On the contrary, in our study, the rate of those whose DB levels normalized at the end of the third week after PC was 86 (59.3%) of 145 patients. Of these 86 patients, 47.7% required surgery, and 52.3% did not in the following three months. Chi-square analysis revealed no significant difference between these two groups ($p > .05$). We interpreted this as adequate biliary drainage with PC and therefore saw no association between the decrease in DB level and the second surgery.

In our series, PC was the definitive treatment for 51.7% of the patients, slightly higher than similar studies in the literature [12–15]. In treating acute cholecystitis, such as PC, laparoscopic cholecystectomy is an emergency procedure, but it carries a much higher risk of complications and prolongs hospital stay [13]. These investigators used PC as a short-term bridge to cholecystectomy during the same hospitalization. Instead, we reserve PC for patients who are a prohibitive surgical risk. For this reason, we often preferred PC in patients with acute cholecystitis grade II and III.

DB is a strong predictive factor for choledocholithiasis, which excludes patients with fatty liver [4]. Therefore, we chose to determine the levels of DB instead of ALT, AST, GGT, or ALP, which are constantly affected by fatty liver and other parenchymal liver diseases. The rate of return of DB levels to the normal range (0–0,5 mg/dl) was significantly higher than that of normalization of CRP (0–5 mg/L). This finding indicates that PC can lower blood bilirubin levels significantly, even in obstructive causes such as malignant obstructions or choledocholithiasis.

Historically, PC is a valuable technique for critically ill patients as a salvage or definitive therapy when endoscopic retrograde cholangiopancreatography and cholecystectomy have failed [16–18]. Today, PC is a proven treatment method as a first choice for elderly and critically ill patients that eliminates the pain in a few hours caused by a hydropic gallbladder. It does this by significantly reducing the wall tension despite the ongoing inflammation around the gallbladder (Fig. 4). Furthermore, with this study, we have

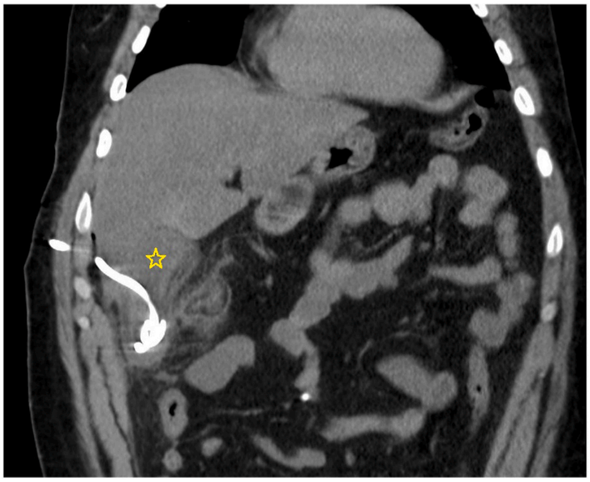

Fig. 4. In this computed tomography image of the patient whose pain was relieved significantly 1 h after insertion of the 8F 25 cm all-purpose drainage (APD) pigtail catheter. The catheter has traversed segment VI and reached the lumen of the gallbladder. The extensive hydrops of the gallbladder has decreased significantly (star), but severe inflammation persists in the soft tissue planes around the gallbladder wall (white streaks in the adipose tissue).

presented that PC can be a definitive treatment in all patients with grade II and III acute cholecystitis, and not just for the patients who are not suitable for surgery. PC improved laboratory values by swiftly lowering CRP and DB levels in patients with grade II and III acute cholecystitis. Although CRP and DB levels decreased by more than %25 in the first 72 h after PC in all 145 patients, the rate of normalization of DB levels was significantly higher than the rate of normalization of CRP levels at the end of three weeks after catheter insertion.

5. Conclusion

Our study concludes that older patients are more likely to require further surgical intervention. This situation is usually related to multiple gallstones and malignant or benign biliary strictures, which are more common in elderly patients. However, we found no association between CRP or DB levels and sex for the need for a second invasive procedure. The significant decrease in DB values despite biliary stenosis or obstruction can be explained by PC providing very effective drainage.

The main limitation of our study is that it is a retrospective observational study, but the most important part is the homogeneous patient series. We performed PC in all patients with a hydropic gallbladder and the evidence of acute cholecystitis grade II or III without parenchymal liver disease.

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Author contribution statement

Çağrı Kesim: Conceived and designed the experiments; Performed the experiments; Wrote the paper.
Özgür Özen: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Data availability statement

The data that has been used is confidential.

Additional information

Supplementary content related to this article has been published online at [URL].

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No one other than the authors contributed to this article.

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