Percutaneous cholecystostomy for biliary decompression in patients with cholangitis and pancreatitis

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Abstract
Objective: This study was performed to assess the effectiveness and safety of percutaneous cholecystostomy (PC) for biliary decompression.

Methods: We retrospectively analyzed our institution’s PC database from March 2015 to August 2017 and selected patients with biliary obstruction. The primary outcomes were the technical and clinical success rates. As secondary outcomes, adverse events and pain after PC were compared with those of patients who underwent PC for acute cholecystitis during the same period.

Results: Twenty patients underwent PC for biliary obstruction (cholangitis, 19; pancreatitis, 1). The technical and clinical success rates were 100%. The median serum total bilirubin level decreased considerably from 4.5 to 1.4 mg/dL after PC. An adverse event (catheter migration) occurred in 1 patient, and 17 patients developed pain after PC. During the same period, 104 patients underwent PC for cholecystitis. Adverse events occurred in 7 patients, and 62 developed pain. There was no significant difference in the adverse event rate between the cholangitis/pancreatitis and cholecystitis groups (5.0% vs. 6.7%, respectively), but pain occurred considerably more frequently in the cholangitis/pancreatitis group (94.4% vs. 63.9%, respectively).

Conclusions: PC is an effective and safe method for biliary decompression in selected patients. However, attention should be paid to postoperative pain.

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Keywords
Cholecystostomy, cholestasis, cholangitis, pancreatitis, biliary decompression, biliary obstruction

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Introduction

Biliary decompression is usually needed for management of cholestasis associated with cholangitis or pancreatitis, and endoscopic retrograde cholangiopancreatography (ERCP) has been the standard method of biliary drainage. However, selective biliary cannulation, which is essential for ERCP, reportedly fails in up to 5% of patients, even when conducted by experienced endoscopists.1 Furthermore, it may be risky in patients with critical conditions such as hypoxia or septic shock.

Percutaneous transhepatic biliary drainage (PTBD) is usually conducted as an alternative option when ERCP is impossible or has failed. Although PTBD is a relatively simple and effective method in patients with marked intrahepatic duct dilation, it may fail in patients with minimal intrahepatic duct dilation.2 For some of these patients, endoscopic ultrasound-guided biliary drainage (EUS-BD) can be performed.3 However, this method is technically difficult and not available in many centers.

Percutaneous cholecystostomy (PC) is a simple method for gallbladder drainage that is considered a safe alternative to early cholecystectomy in surgically high-risk patients with acute cholecystitis.4 Although PC has been widely applied to manage cholecystitis, the first ultrasound-guided PC was performed in a patient with obstructive jaundice secondary to malignancy in 1979.5 Since then, this technique has been described as an effective method for decompression of common bile duct (CBD) obstruction in small case series.6–8 The present study was conducted to assess the effectiveness and safety of PC for biliary obstruction when ERCP and PTBD are impossible or have failed.

Patients and methods

Patients

We retrospectively analyzed our institution’s PC database, to which patient data were consecutively added and in which the data were prospectively maintained. From this database, we identified patients who underwent PC for relief of biliary obstruction due to cholangitis or pancreatitis from March 2015 to August 2017. These patients underwent PC as an alternative therapy when ERCP and PTBD were impossible because of an unstable patient condition, biliary cannulation failure, or difficult anatomy or when the intervention radiologists judged that PTBD was difficult due to insufficient intrahepatic duct dilation. PC was not attempted if cystic duct takeoff was suspected to be involved with either the biliary stricture or CBD stone on computed tomography or magnetic resonance cholangiopancreatography because cystic duct patency is mandatory in this setting. Patients with sepsis of unknown origin or concurrent acute cholecystitis were excluded from the analysis. The study protocol was approved by the institutional review board of our institution. All patients provided written informed consent.

Techniques

Radiologists performed PC by a transhepatic route under ultrasonographic and fluoroscopic guidance. The gallbladder
was localized with ultrasonography and then punctured with a needle. Bile was aspirated through the needle, after which a wire was coiled into the gallbladder. Fluoroscopy was used to confirm the position of the wire within the gallbladder and to monitor the subsequent placement of an 8.0- or 8.5-Fr pigtail catheter.

**Assessment**

The primary outcomes were technical and clinical success rates of PC. The secondary outcomes were adverse events and pain after PC. Technical success was defined as tube placement within the gallbladder and drainage of bile. Clinical success was defined as resolution of fever and reduction of symptoms within 72 hours of insertion of the tube. Occurrence of adverse events such as catheter migration, bile leakage, or bleeding within 4 weeks was also investigated. Pain after PC was deemed present when analgesics were administered within 24 hours of PC. Intravenous meperidine was the main pain reliever administered. For comparison, adverse events and pain after PC were compared with those of patients who underwent PC for acute cholecystitis during the same period. Patients with decreased consciousness were excluded from the pain analysis.

**Statistical analysis**

According to the Kolmogorov–Smirnov test, the total bilirubin level did not demonstrate normality before or after PC; therefore, it was compared using the Wilcoxon signed rank test. Comparisons of categorical variables between the cholangitis/pancreatitis and cholecystitis groups were conducted using the chi-square test or Fisher’s exact test, and P values of <0.05 were considered statistically significant. All statistical analyses were performed using MedCalc 16.1 (MedCalc Software, Mariakerke, Belgium).

**Results**

**Patient characteristics**

A total of 134 patients underwent PC from March 2015 to August 2017. Of these patients, five underwent PC for sepsis of unknown origin and another five showed acute cholangitis accompanied by cholecystitis; therefore these patients were excluded from the analysis. Among the resultant 124 patients, 19 underwent PC for acute cholangitis and 1 had pancreatitis complicated with distal CBD obstruction. The remaining 104 patients had acute cholecystitis (Figure 1).

Table 1 shows the characteristics of the patients with cholangitis/pancreatitis. Their mean age was 77.0 ± 10.6 years, and men were more prevalent than women (65.0%). Most cases of acute cholangitis were moderate to severe according to the updated Tokyo guideline.9 A CBD stone was the most common cause of cholangitis (89.5%), while pancreatic cancer and peribiliary metastasis were the causes of cholangitis in the other patients. The one case of pancreatitis was alcohol-induced.

Table 2 shows the clinical situations of these patients. PC was performed in eight patients with shock and three patients with hypoxia. ERCP was attempted in five patients, but selective biliary cannulation failed; therefore, PC was conducted as rescue therapy. Additionally, four patients underwent PC because of a difficult anatomy for ERCP, while two patients had previously undergone total gastrectomy and one patient was diagnosed with unresectable pancreatic cancer with duodenal obstruction. ERCP was not performed in these three patients. Billroth II gastrectomy had been previously performed in the
remaining patient, and ERCP was attempted. However, access to the ampulla of Vater was impossible because the afferent loop was long.

**Primary outcomes**

Technical and clinical success was achieved in all patients (Table 1). The median total bilirubin level significantly decreased from 4.5 to 1.4 mg/dL after PC ($P < 0.01$).

**Secondary outcomes**

An adverse event occurred in an 87-year-old man with a CBD stone. ERCP was performed for this patient, but selective biliary cannulation failed. Although he clinically improved after PC, the drain inadvertently came out after 3 days. However, he reported no abdominal pain and did not develop a fever. The second ERCP was performed the next day, at which time the CBD stone was successfully removed. He was then discharged without further adverse events.

Adverse events occurred in seven patients in the cholecystitis group. Three patients developed shock, two developed bile leakage, and two developed catheter migration. The shock was managed with hydration and inotropic agents. The bile leakage was conservatively treated with...
Table 2. Patients’ clinical parameters and subsequent treatment

| No. | Sex/age (years) | Etiology            | Comorbidities          | Clinical situation | Subsequent treatment |
|-----|-----------------|---------------------|------------------------|--------------------|---------------------|
| 1   | F/81            | CBD stone           | HTN, dementia          | Shock              | ERCP                |
| 2   | M/82            | CBD stone           |                        | Billroth II gastrectomy | CBD exploration |
| 3   | F/87            | CBD stone           |                        | Shock              | ERCP                |
| 4   | M/67            | CBD stone           | Liver cirrhosis        | Shock, status epilepticus | ERCP |
| 5   | F/92            | CBD stone           | HTN                    | Biliary cannulation failure | 2nd ERCP |
| 6   | M/70            | CBD stone           | DM, HTN, CKD           | Shock              | ERCP                |
| 7   | M/81            | CBD stone           | HTN, Parkinson’s disease | Shock              | ERCP                |
| 8   | M/79            | CBD stone           | DM                     | Total gastrectomy  | CBD exploration |
| 9   | F/73            | CBD stone           | Mitral valve           | Shock              | ERCP                |
| 10  | M/87            | CBD stone           | Angina, RA             | Biliary cannulation failure | 2nd ERCP |
| 11  | M/76            | Pancreatic cancer   | HTN                    | Duodenal obstruction | none |
| 12  | M/68            | CBD stone           | DM, HTN                | Shock              | ERCP                |
| 13  | M/75            | CBD stone           | DM, HTN, pneumonia     | Hypoxia            | ERCP                |
| 14  | M/41            | Pancreatitis        | DM                     | Biliary cannulation failure | 2nd ERCP |
| 15  | M/81            | CBD stone           | HTN                    | Hypoxia            | ERCP                |
| 16  | F/79            | CBD stone           | DM, HTN, angina, CKD   | Hypoxia            | ERCP                |
| 17  | F/80            | CBD stone           | HTN                    | Shock              | ERCP                |
| 18  | F/76            | CBD stone           | DM                     | Total gastrectomy  | CBD exploration |
| 19  | M/77            | CBD stone           | HTN, angina            | Biliary cannulation failure | 2nd ERCP |
| 20  | M/85            | Peribiliary         | Urothelial cancer, DM  | Biliary cannulation failure | 2nd ERCP |

F, female; M, male; CBD, common bile duct; HTN, hypertension; ERCP, endoscopic retrograde cholangiopancreatography; DM, diabetes mellitus; CKD, chronic kidney disease; RA, rheumatoid arthritis.

Table 3. Adverse events

| Adverse event                  | Cholangitis/pancreatitis (N = 20) | Cholecystitis (N = 104) | P value |
|--------------------------------|-----------------------------------|------------------------|---------|
| Catheter migration             | 1 (5.0)                           | 7 (6.7)                | >0.99   |
| Shock                          | 0 (0.0)                           | 3 (2.9)                |         |
| Bile leakage                   | 0 (0.0)                           | 2 (1.9)                |         |

Data are presented as n (%).

antibiotics. For catheter migration, reinsertion was conducted if possible. The adverse event rate was not significantly different between the cholangitis/pancreatitis and cholecystitis groups (5.0% vs. 6.7%, respectively) (Table 3). In the subgroup analysis, the occurrence of shock and bile leakage was not significantly different between the two groups (cholangitis/pancreatitis: 0.0%, cholecystitis: 4.8%).

The characteristics of the pain after PC were various. Patients complained of gradual or sudden-onset pain. Some patients complained of dull pain, and sharp pain was present in others. In the cholangitis/pancreatitis group, two patients showed a decreased level of consciousness and were therefore excluded from the analysis. Pain was present in 17 patients after PC (94.4%).
In the cholecystitis group, seven patients showed a decreased level of consciousness and were excluded. Among the remaining 97 patients, 62 developed pain after PC (63.9%), which was significantly less frequent than in the cholecystitis/pancreatitis group ($P = 0.01$) (Figure 2). Pain occurred with similar frequency in men and women (67.7% vs. 70.0%, respectively) and in young and old patients (based on the median age; 75.4% vs. 62.1%, respectively).

**Subsequent treatments**

Subsequent treatments were conducted for 19 of 20 patients; ERCP was performed for 16 patients (CBD stones, 14; peribiliary metastasis, 1; pancreatitis, 1), and three patients with CBD stones underwent surgery (CBD exploration). No subsequent treatments were performed for the one patient with unresectable pancreatic cancer (Table 2).

**Discussion**

PC has been performed for treatment of acute cholecystitis since 1980, and it is known to be an effective and safe alternative treatment method for patients with high surgical risk. The gallbladder communicates with the CBD through the cystic duct. If the cystic duct is patent and its takeoff is not involved in the bile duct obstruction, PC can provide drainage of the CBD. PC was found to be effective for treatment of patients with obstructive jaundice with no complications in a previous study. Shitrit and Braverman reported that PC is an appropriate bridging procedure to ERCP for selective high-risk patients. In another study, PC and subsequent surgery were effective and safe for choledocholithiasis management when ERCP failed. All of these studies were case series with limited numbers of patients, the mean serum bilirubin level was not compared before and after PC, and the rate of adverse events was not compared with a control group.

The present study showed that PC is effective as a bridging procedure for biliary decompression, regardless of its etiology (stone, malignancy, or pancreatitis) or the patient’s clinical situation (shock, hypoxia, difficult anatomy, or failed selective biliary cannulation). The serum bilirubin level decreased and the patients clinically improved after PC. Subsequent treatments such as ERCP or surgery were performed successfully without any disturbance from the previous PC.

While premedication before ERCP or surgery may lead to complications such as hypoventilation and arrest in critically ill patients, PC can be performed under local anesthesia and does not require medications such as sedatives or general anesthetics. Therefore, PC is useful as a bridging therapy for critically ill patients.

When selective biliary cannulation fails, repeat ERCP can be successfully accomplished within a few days. However, patients might develop symptoms, and there is risk of clinical deterioration during the interval between the first and second ERCP. PC can be performed on
the day of failed ERCP and is known to reduce symptoms and the risk of clinical deterioration.

Catheter migration occurred in one patient (5.0%), and this was not associated with any symptoms or further complications. This adverse event rate is comparable to that of previous studies, in which such events occurred in 0% to 50% of patients who underwent PC for bile duct drainage. vanSonnenberg et al. reported that among 11 cases, 1 catheter migration occurred 4 days after PC. Although attempts to replace the catheter via the tract were unsuccessful, the patient experienced no symptoms or other complications. In another study, three of six patients developed adverse events. One patient developed hemoperitonoeum, and hemostasis was conducted by conservative therapy. The other two patients developed bile leakage; the leakage spontaneously resolved in one patient, and the other developed a biloma that required ultrasonography-guided aspiration.

Adverse events, such as catheter migration, bile leakage, hemorrhage, bowel perforation, and pneumothorax, have been reported after PC in patients with cholecystitis. The adverse event rate ranged from 0% to 25% in a systematic review, which is similar to our findings. In addition, our study showed that the adverse event rate after PC for cholangitis or pancreatitis was comparable to that after PC for cholecystitis (5.0% vs. 6.7%, respectively). Such comparisons were not made in previous studies.

Pain after insertion of a PC catheter may originate from the primary disease or the catheter itself. No studies have assessed pain after PC. In the present study, pain occurred more frequently in the cholangitis/pancreatitis group than in the cholecystitis group. Neither age nor sex was associated with pain. We consider three possible explanations for this. First, decompression of the CBD may be delayed in patients with cholangitis or pancreatitis because the cystic duct is usually narrow and tortuous. In contrast, PC confers immediate decompression of the inflamed gallbladder in patients with acute cholecystitis. Therefore, improvement of pain may be delayed in patients with cholangitis or pancreatitis relative to cholecystitis. Second, the obstruction site may change when a CBD stone is present because the stone is mobile. If a CBD stone migrates toward the cystic duct takeoff and plugs it, PC may be ineffective and improvement of pain may be delayed. Third, minor bile leakage may be present. Bile leakage may develop after PC, and some studies have shown that bile leakage is more frequent in the transperitoneal than transhepatic approach, but this remains controversial. Although we conducted PC using a transhepatic approach, minor bile leakage has the potential to occur when the gallbladder wall inflammation is minimal. Bile leakage is caused by the gap between the tube and the tract of the gallbladder wall. Edema and wall thickening of the inflamed gallbladder could seal the gap and cause less bile leakage. Although bile leakage seemed to be more frequent in the cholecystitis group as shown in Table 3, the sample size was small in the cholangitis/pancreatitis group. Therefore, its occurrence might be underestimated in this group. Further study is needed to confirm this assumption.

In a recent study, the efficacy and safety of EUS-guided gallbladder drainage was assessed for malignant biliary obstruction after unsuccessful ERCP as well as unsuccessful or impractical EUS-BD. In that study, the gallbladder was irrigated with saline to prevent peritonitis caused by bile leaking out of the needle immediately after gallbladder puncture, and bile leakage did not occur after EUS-guided gallbladder drainage. Although we conducted PC rather than EUS-guided drainage, saline irrigation may be helpful for prevention of
bile leakage in PC, and the pain after PC could be reduced if its cause is minor bile leakage. However, further study is needed to confirm this assumption.

The present study has some limitations. First, adverse events might have been underestimated because of the retrospective nature of the study. Second, pain after PC was not evaluated directly. Therefore, there is the potential for overestimation or underestimation of pain. Finally, the number of patients was small, and all patients were from a single institution. Therefore, our findings might not be generalizable. Further studies are needed to validate our findings.

In conclusion, PC is effective and safe for decompression of the CBD in selected patients when ERCP, PTBD, and EUS-BD are impossible or have failed. However, attention should be paid to management of pain after PC.

Declaration of conflicting interest
The authors declare that there is no conflict of interest.

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