

# Percutaneous Transcholecystic Metallic Stent Placement for Malignant Obstruction of the Common Bile Duct: Preliminary Clinical Evaluation

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**PURPOSE:** To evaluate the technical success and clinical effectiveness of percutaneous transcholecystic placement of self-expanding metallic stents for the treatment of malignant obstructions of the common bile duct.

**MATERIALS AND METHODS:** Fifteen patients with malignant obstruction at the lower level of the common bile duct not amenable to surgery were retrospectively reviewed in this study. In all patients, conventional biliary drainage via transhepatic peripheral duct access or endoscopic retrograde biliary drainage (ERBD) were technically difficult or deemed so at imaging evaluation. The causes of obstruction were cholangiocarcinoma ( $n = 7$ ), pancreatic carcinoma ( $n = 6$ ), and metastatic lymphadenopathy from gastric carcinoma in the hepatoduodenal ligament ( $n = 2$ ). Following percutaneous cholecystostomy, a 5-F catheter was inserted into the common bile duct, duodenum, or the anastomosed jejunum through the cystic duct and the malignant obstruction and metallic stents were placed. The technical success was defined as the removal of the drainage tube after the stent placement for the obstruction. The mean follow-up period was 25.4 months.

**RESULTS:** Sixteen stents were placed in 15 patients. Technical success was achieved in all patients (100%) without major complications. Minor complications included controllable pain or self-limited hemobilia in six of the 15 patients (40%). Lower bilirubin levels compared with those before the procedure were achieved in 14 of the 15 patients (93%).

**CONCLUSIONS:** Percutaneous transcholecystic placement of metallic stents is a feasible and effective method to manage malignant obstruction at the lower level of the common bile duct not amenable to surgery when conventional biliary drainage via transhepatic peripheral duct access or ERBD were technically difficult or deemed so at imaging evaluation.

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**Abbreviations:** ERBD = endoscopic retrograde biliary drainage, PTBD = percutaneous transhepatic biliary drainage

PERCUTANEOUS transhepatic biliary drainage (PTBD) and endoscopic retrograde biliary drainage (ERBD) have

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evolved from the diagnostic tools of percutaneous transhepatic cholangiography and endoscopic retrograde cholangiography. Subsequently, primary therapeutic interventions have been developed for biliary disorders involving stent insertion for obstructive jaundice, endoscopic papillary balloon dilation, or endoscopic sphincterotomy for acute cholangitis (1-6). In patients with acute cholangitis, cholecystitis, or obstructive jaundice, PTBD is the second-line interventional biliary treatment when the first-line treatment, ERBD, either has failed or was impossible because the patient underwent gastrectomy (especially Billroth II or Roux-en-Y methods), or if

the patient had a periampullary duodenal diverticulum (7).

When the intrahepatic bile duct is not dilated or delineated at ultrasonography (US), PTBD or conventional biliary drainage via transhepatic peripheral duct access under fluoroscopic guidance is technically difficult. Then, percutaneous cholecystostomy is occasionally performed as the third-line treatment to ease the biliary symptoms of acute cholangitis or cholecystitis (8). In patients with malignant biliary obstruction, however, percutaneous cholecystostomy is only a temporary procedure and the patients cannot be

freed from drainage tube insertion. Herein, we report our preliminary clinical evaluation of percutaneous transcholecystic stent placement in 15 patients with malignant obstruction of the common bile duct.

## MATERIALS AND METHODS

### Study Patients

From December 2002 to November 2008, 15 patients with unresectable malignant obstruction of the common bile duct at the lower level of the orifice of the cystic duct, for whom conventional endoscopic or percutaneous drainage was technically difficult or deemed likely so at imaging evaluation, were treated with percutaneous transcholecystic placement of expandable, uncovered metallic stents. The study included 10 men and five women with a mean age ( $\pm$ standard deviation) of 79.7 years  $\pm$  7.3 (range, 67–91 years). The study was approved by our institutional review board and followed the Declaration of Helsinki principles (9). Written informed consent was obtained from all patients after the purpose and protocol of the study had been fully explained.

In all patients, biliary drainage was needed for acute cholangitis, cholecystitis, or obstructive jaundice due to either malignant pancreaticobiliary tumors or metastatic lymphadenopathies in the hepatoduodenal ligaments. In 10 patients, the procedure was urgently needed for significant infection and in five patients it was performed electively. PTBD or ERBD was deemed to be technically difficult to perform because of the lack of dilatation of the intrahepatic bile duct and the history of gastrectomy or the procedures had resulted in failure, although they had been attempted before deciding on the gallbladder technique. The underlying diseases included cholangiocarcinoma in seven patients, pancreatic carcinoma in six, and metastatic lymphadenopathies from gastric carcinoma in the hepatoduodenal ligaments in two. Diagnoses were made on the basis of histologic or cytologic findings in 12 patients and on the basis of radiologic findings in three patients.

Pretreatment imaging studies in-

cluded abdominal US and dynamic computed tomography (CT). These examinations were routinely performed for all patients before the procedure. We used a real-time scanner with a 3.5-MHz transducer (EUB-7500; Hitachi, Tokyo, Japan) for abdominal US and a multi-detector row CT scanner (LightSpeed16; GE Medical Systems, Milwaukee, Wisconsin) for dynamic CT. Early-phase CT scans were obtained 35 seconds after the initiation of a bolus injection of 100 mL of iopamidol (Iopamiron 370; Bayer Health Care, Osaka, Japan), and late-phase CT scans were obtained 70 seconds after the initiation of contrast medium injection. We observed the anatomic findings of the cystic duct or the common bile duct and the confluence of them. Then we measured the diameter of the intrahepatic bile duct (especially the intrahepatic bile duct in segment 3, the left lateral, anterior and inferior segment in the liver, from the first branch of the left bile duct to the second branch) and common bile duct in detail on multiplanar reconstruction images by using raw data sets of both early- and late-phase CT on a workstation monitor (Advantage Workstation 4.2, GE Medical Systems). In addition, we staged malignant tumors of the bile duct, pancreas, or hepatoduodenal ligament—especially lymph node metastases—and simultaneously evaluated the operability, including invasions to the portal vein, superior mesenteric artery, celiac artery, common hepatic artery, and right hepatic artery as well as ascites, disseminated nodule, or distant metastasis. If the cystic duct or the common hepatic duct was occluded by tumor invasion and tortuosity of the cystic duct or a stone was identified in the cystic duct at CT, we excluded the patient from this study.

If the maximum diameter of the intrahepatic bile duct in segment 3, the left lateral, anterior and inferior segment in the liver, from the first branch of the left bile duct to the second branch, was at least 2 mm, the duct was considered to be dilated. The intrahepatic duct was dilated at CT in six patients. For three of these patients the intrahepatic duct was invisible or unclear on US scans owing to ascites, free air, or the

presence of colon gas anterior to the atrophic liver. In the remaining three patients, cholecystostomy was given a priority over PTBD due to acute cholecystitis. No patients presented with cholecystitis alone, and all three patients with acute cholecystitis complained of right hypochondrial pain complicated by malignant diseases diagnosed at CT—although obstructive jaundice was not too clinically severe during the time of the first procedure (Table 1).

### Techniques

US-guided percutaneous cholecystostomy was first performed through the right flank with a 7-F pigtail catheter (CLINY; Create Medic, Yokohama, Japan) after puncture with an 18–22-gauge needle (Figure, a). The reasons for the puncture of the gallbladder were the lack of dilatation or visualization of the intrahepatic bile duct on US scans for a safe puncture; the failure of conventional biliary drainage via transhepatic peripheral duct access; the impossibility or failure of ERBD due to past gastrectomy, periampullary duodenal diverticulum, or severe stenosis of the papilla of Vater; and the need for the highest priority of percutaneous cholecystostomy because of acute cholecystitis.

Pentazocine (15 mg Sosegon; Astellas, Tokyo, Japan) was intravenously injected 10 minutes before therapy as premedication for sedation under local anesthesia with 1% lidocaine (Xylocaine; AstraZenca Japan, Osaka, Japan). We then attempted common bile duct drainage, the second procedure, through the cholecystic route by using a 0.035-inch-diameter, 80-cm-long guide wire (Terumo, Tokyo, Japan) and a 5-F seeking catheter (KMP catheter; Cook Incorporated, Bloomington, Indiana) under fluoroscopic control after injection of contrast medium into the gallbladder within the visualization of the cystic duct and common bile duct. The second procedure was performed at the same time as the first puncture in four patients when the cystic duct and common bile duct were clearly revealed. In 11 patients, the second procedure was performed a few days after the puncture because there were severe clinical symptoms (eg,

**Table 1**  
Summary of Cases

Patient No./Sex/Age (y)	Diseases	Intrahepatic Bile Duct	Time (d)	Total Bilirubin Level (mg/dL)	Total Bilirubin Level (mg/dL)*	After Treatment	Other Factors†	Past History	ERBD‡	PDD
1/M/72	PC, ACC	Dilated	7	3.6	1.2	...	...	...	Failed	Yes
2/M/82	CC, ACC	Not dilated	21	1.5	0.8	...	...	...	NA	
3/F/90	PC	Unclear	8	7.8	3.9	Ascites, liver atrophy	...	...	Failed	No
4/M/84	CC, AC	Not dilated	5	9.2	2.6	...	...	...	NA	
5/F/81	PC	Dilated	13	4.5	2.9	Liver atrophy	...	...	Failed	No
6/M/67	GC, ML	Not dilated	16	10.7	1.6	...	...	DG	NA	
7/M/82	CC, AC	Not dilated	6	1.3	1.5	...	...	DG	NA	
8/M/72	PC, ACC	Dilated	14	3.6	2.5	...	...	...	Failed	Yes
9/M/70	PC	Unclear	11	7.8	2.7	Ascites	...	...	Failed	No
10/M/86	PC	Not dilated	4	3.7	2.2	Liver atrophy	...	...	Failed	Yes
11/M/82	CC, ACC	Not dilated	9	6.7	0.6	...	...	...	Failed	No
12/F/81	CC	Invisible	7	7.3	0.9	Duodenal perforation	...	...	Failed	No
13/M/91	CC	Not dilated	14	1.5	1.1	PTBD dislocation	...	...	NA	
14/F/83	CC, AC	Not dilated	12	1.7	1.3	...	...	DG	NA	
15/M/73	GC, ML, AC	Not dilated	7	5.8	0.7	...	...	DG	NA	

AC = acute cholangitis, ACC = acute cholecystitis, CC = cholangiocarcinoma, DG = distal gastrectomy (Billroth II or Roux-en-Y), GC = gastric carcinoma, ML = metastatic lymphadenopathy in the hepatoduodenal ligament, PC = pancreatic carcinoma, PDD = periampullary duodenal diverticulum.

\* The normal range for serum total bilirubin is 0.2–1.0 mg/dL (3.42–17.1 μmol/L). After treatment = 30 days after metallic stent placement.

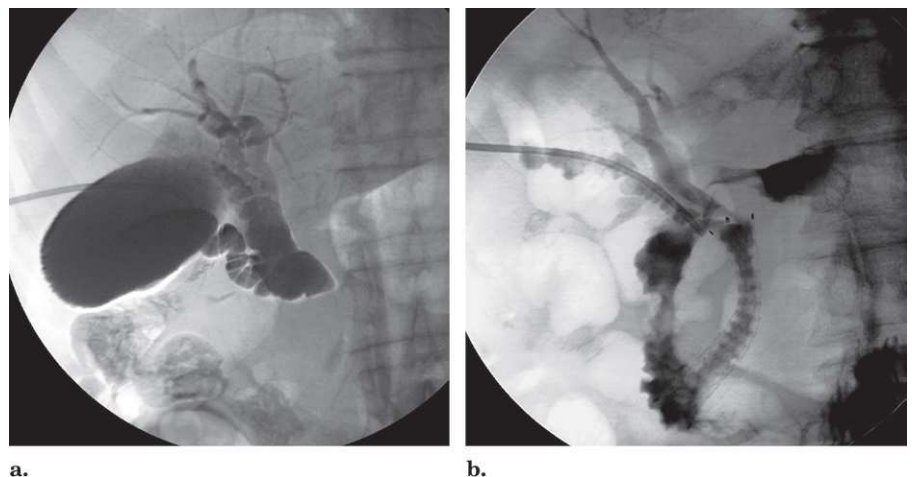
† Other factors = other reasons for puncture of the gallbladder.

‡ NA = not attempted.

The wire grasp was needed in patients 4 and 9. It was performed by a forceps through the upper gastrointestinal endoscope assisted catheter insertion into the common bile duct or duodenum. PTBD dislocation means that a PTBD tube was dislocated and the additional drainage tube needed to be inserted.

uncontrollable pain or severe inflammation, including acute cholecystitis).

Once access to the common bile duct proximal to the malignant obstruction was obtained, we attempted to insert the seeking catheter into the duodenum or the anastomosed jejunum distal to the obstruction with the same technique by using the guide wire as above in the traversal of the cystic duct. At this point, we exchanged the catheter over the 0.035-inch super-stiff guide wire (Amplatz; Cook, Bloomington, Indiana) for a new 7-F pigtail catheter with a side hole, which was placed in the common bile duct, duodenum, or anastomosed jejunum to assess the obstruction. Then, placement of a bare expandable metallic stent, as the third procedure, was performed without balloon dilation of the stenosis. A 7-F straight catheter (CLINY, Yokohama, Japan) without side holes was left in place proximal to the end of the metallic stent as a safety measure during the initial



**Figure.** Images in an 82-year-old man with common bile duct cancer, acute cholecystitis, and obstructive jaundice. ERBD had failed because of the severe stenosis of the papilla of Vater, but the intrahepatic bile duct was not dilated at US. **(a)** US-guided percutaneous transhepatic gallbladder drainage was first performed through the right flank with a 7-F pigtail catheter because of the cholecystitis. **(b)** A percutaneous transcholecystic metallic stent was placed, without balloon dilation, for the malignant obstruction of the common bile duct.

stent placement (Figure, b). Even if the stenosis was not fully dilated immediately, within a week we rou-

tinely examined under fluoroscopy with injection of contrast medium from the catheter and estimated the

extent of the stent dilatation and the patency of the biliary tract. Stent placement was performed in four patients immediately on the same day when inoperability was determined at the second procedure. In 11 patients, stent placement was performed on another day after acquiring informed consent regarding the indications for permanent stent placement. This was after the decision for operability was delayed because of detailed examinations with follow-up contrast-enhanced CT, magnetic resonance (MR) imaging, or positron emission tomography/CT or the patient's request for a second opinion about the possibility of surgery or if the total bilirubin level decreased before the second procedure.

In all patients, a 6-F Luminexx stent (Bard Peripheral Vascular, Inc.; C.R. Bard, Tempe, Arizona) was used without the sheath. Sixteen stents were inserted into 15 patients. The fully expanded diameter of the inserted stents was 10 mm, and the fully opened lengths were 6 or 4 cm. We determined the stent length after the measurement of that of the obstruction by using the stiff guide wire through the 7-F pigtail catheter under fluoroscopy. We removed the 7-F catheter after the clamp test when the serum total bilirubin level was lower than that at stent placement or when clinical symptoms (eg, cholangitis, fever, pain, or inflammation) recovered within a week after the confirmation of full stent expansion and there was good passage of contrast medium from the intrahepatic bile duct to the duodenum or jejunum at cholangiography. After a successful clamp test, we considered that there was no biliary leakage and removed the drainage catheter.

When the seeking catheter buckled in the gallbladder, cannulation into the common bile duct through the cystic duct was technically difficult and the same guide wire described earlier that was inserted into the duodenum or anastomosed jejunum was grasped by using forceps with endoscopy (Olympus, Tokyo, Japan). This was performed by an experienced endoscopist. The catheter was inserted over the wire into the common bile duct or duodenum by applying a "rendez-vous proce-

dure" as previously reported (10). Then, the guide wire could be easily passed through all occlusions. After the endoscopic guide wire grasp, placement of the metallic stent, as the intended procedure, could be performed by inserting the stiff guide wire into the seeking catheter. The rendez-vous procedure was performed in two patients.

We retrospectively examined the technical success rate of percutaneous transcholecystic metallic stent placement, complication rates, reason for a puncture in the gallbladder, serum total bilirubin level, rate of assistance using an endoscopic guide wire grasp (the rendez-vous procedure), time between drain placement and stent placement, and term of stent patency.

#### Study Endpoints and Definitions

Technical success was defined as percutaneous transcholecystic stent placements that provided continuous bile drainage. Stent expansions were considered to be satisfactory if the diameter was 7–10 mm in the common bile duct as measured with multi-detector row CT. The mean period between percutaneous cholecystostomy as a first procedure and stent placement was estimated.

The procedure was determined to be clinically successful if the serum total bilirubin level decreased 30 days after stent placement compared with levels before the first procedure or the level was 3 mg/dL (51.3  $\mu$ mol/L) or less or if the clinical symptoms such as cholangitis had improved. The term of stent patency was defined as the period between insertion and stent occlusion or the patient's death. Thus, we defined stent patency as a primary patency that meant the term from the day of stent placement to the day of cholangiography. Complications arising from the procedure were divided into major and minor categories according to the reporting standards of the Society of Interventional Radiology (11).

For all patients, follow-up (clinical examination, laboratory data, and CT examinations) was performed after the 1st, 2nd, 3rd, and 4th months after stent placement and then every 6 months thereafter until the time of

death or the end of the study. When stent occlusion occurred, an attempt at correction was made by inserting an additional stent. If occlusion was not evident during a patient's life, the patency period was considered to be equal to the survival period. The end of the study, if not by death, was determined by stent patency by May 2009.

#### Statistical Analysis

A Kaplan-Meier curve was used to calculate stent patency. Statistical comparison among primary diseases was performed with the Student *t* test. A *P* value of .05 or less was considered statistically significant.

#### RESULTS

The technical success rate for the placement of percutaneous transcholecystic and cystic ductal metallic stents was 100% (15 of 15 patients). Sixteen metallic stents were placed into 15 patients. In 14 patients, immediate stent expansion was satisfactory and balloon dilation was not needed after stent placement. In one patient (patient 4), an additional stent had to be inserted because of restenosis of the common bile duct with sludge 1 week after placement of the first metallic stent. This immediately resulted in a good passage of contrast media.

In eight patients, an endoscopic approach was attempted but resulted in failure because of periampullar duodenal diverticulum (*n* = 4) and rigidity of the papilla of Vater (*n* = 4). ERBD was not attempted in seven patients. Four patients had previously undergone gastrectomy, and four patients were considered in urgent need of transcholecystic drainage due to acute cholecystitis. We attempted to perform conventional biliary drainage via transhepatic peripheral duct access under fluoroscopic guidance in two patients and under US guidance in two patients, but the attempts resulted in failure. In 11 patients, the conventional percutaneous procedures were technically difficult or deemed so at imaging evaluations. In eight patients there was lack of biliary dilatation visible at US and in two patients the intrahepatic bile duct was

unclear because of ascites, intestinal gas, or liver atrophy. In one patient the intrahepatic bile duct was invisible at US because of free air due to duodenal perforation.

The mean follow-up period was 25.4 months after percutaneous cholecystostomy as a first procedure. The mean period between percutaneous cholecystostomy and stent placement was 10.4 days (range, 5–21 days). There was no bile leakage in the clamp test. In one patient (patient 12) with obstructive jaundice due to common bile duct carcinoma, the duodenum was perforated while ERBD was performed. Because of the presence of an acute abdomen with sudden pain onset, tenderness, and muscular rigidity, an emergency operation was required. The intrahepatic duct was invisible at US because of the free air around the liver, but the dilated gallbladder was clearly visible. Thus, we initially performed cholecystostomy and, after decompression of the duodenum with transcystic ductal drainage, a self-expanding metallic stent was successfully placed into the common bile duct through the cystic duct. The patient is still alive 32 months after the initial treatment without any recurrence of obstructive jaundice.

Four patients complained of pain within the period from stent placement to the removal of the drainage tube. The pain was controlled with an intravenous analgesic drug, pentazocine. There was no requirement for additional hospital admission. There were no major complications (eg, active bleeding or biliary perforation). In two of the 15 patients (13%), hemobilia occurred after transcystic ductal drainage before stent placement but was self-limited.

The serum total bilirubin level before the first procedure was less than 2.0 mg/dL (34.2  $\mu$ mol/L) in four patients and greater than or equal to 2.0 mg/dL (34.2  $\mu$ mol/L) in 11. A lower bilirubin level compared to that before the procedure was achieved in 14 of the 15 patients (93%). In one patient (patient 7), the serum total bilirubin level after stent placement (1.5 mg/dL [25.6  $\mu$ mol/L]) was slightly higher than that before the procedure (1.3 mg/dL [22.2  $\mu$ mol/L]); however, symptoms caused by cholangitis (eg, abdominal pain and

**Table 2**  
Mean Length of Stent Patency

Patient Group	No. of Patients	Mean Length of Stent Patency (d)
Overall	15	297
Cholangiocarcinoma	7	365
Pancreatic carcinoma	6	256
Metastatic lymphadenopathies	2	333
<i>P</i> > .05		
Differences are not statistically significant.		

inflammatory findings in the blood examination) improved after metallic stent placement. The procedure with an endoscopic guide wire grasp was needed in two of the 15 patients (13%, patients 4 and 9).

The overall mean stent patency and mean patient survival were 297 and 341 days (range, 7–982 and 76–982 days), respectively (Table 2). The mean stent patency and patient survival period of patients with cholangiocarcinoma (365 and 407 days, respectively) were not significantly different from those of patients with pancreatic carcinoma (256 and 256 days, respectively) or metastatic lymphadenopathies of gastric carcinoma in the hepatoduodenal ligaments (333 and 333 days, respectively) (*P* > .05).

## DISCUSSION

PTBD and ERBD for acute cholangitis or malignant biliary obstruction are well-established methods (1–3). However, in the quality improvement guidelines for PTBD, the technical success rate of PTBD for acute cholangitis is assumed to be 95% when the intrahepatic bile duct is dilated but only 70% when it is not dilated (12). In those cases in which the intrahepatic bile ducts are not dilated, PTBD under fluoroscopic guidance after percutaneous cholecystostomy is reported as another technique; however, it can cause some complications (eg, hemobilia) more frequently than PTBD under US guidance (13).

The diameter of the cystic duct in the healthy adult is 2 or 3 mm (14). Phillips et al (15) reported that laparoscopic transcystic duct common bile duct exploration was a safe and

effective way of extracting common bile duct stones (15), and Dennis et al (16) reported the usefulness of cholecystoscopy via the cystic duct. Itoi et al (17) reported the usefulness of endoscopic transpapillary gallbladder drainage in patients with acute cholecystitis.

The cystic duct is variable in length, course, and site of termination (eg, a low position of confluence to the common bile duct with a long cystic duct, an abnormal high position of confluence [trifurcation], a subcommon hepatic duct, and confluence to the right hepatic duct) (18–20). Our technique may be more difficult with such variations, and further experience is needed.

Rajnakova et al (21) reported that a periampullary duodenal diverticulum could be identified in 11.5% patients and that ERBD in these cases was difficult. Transcholecystic drainage was useful in these cases and, in our study, four patients had their periampullary diverticuli successfully treated with expandable metallic stents. In such cases, however, we believe that careful guide wire manipulation is needed as the guide wire is advanced into the duodenum.

In recent years, the shaft diameter for the delivery of a metallic stent has become smaller than 7–8 F (22–24). The metallic stent used in our institution, the Luminexx stent, has a shaft diameter of 6 F. In all patients, the metallic stents were passed into the cystic ducts. The smaller size of stent delivery catheters may have helped us achieve success in this study.

In this study, the mean period between the first procedure and stent placement was 10.4 days. Yoshida et al (25) reported the efficacy of one-

step insertion of an expandable metal stent through the PTBD route for obstructive jaundice caused by unresectable malignancies. However, we consider that, with a percutaneous transcholecystic approach, the two-step stent placement is safe and feasible because of the anatomic spiral structure of the cystic duct and the avoidance of biliary injury—especially in patients with acute cholecystitis.

Lee et al (26) reported that the median period of stent patency was 360 days and the patency rate in patients with bile duct carcinoma showed no statistically significant difference from that in patients with other malignant biliary obstruction. In our study, the mean stent patency in patients with cholangiocarcinoma was also not significantly different from those with other malignant biliary obstruction.

One limitation of this procedure is the lack of a proximal stent margin, which results in early stent occlusion when cancer is near or across the orifice of the cystic duct to the common bile duct or the malignant biliary obstruction exists at the level of the common hepatic duct or the intrahepatic duct. Thus, we should examine the tumor location in detail with multi-detector row CT or MR cholangiopancreatography before the procedure. In addition, further examination regarding the usefulness of expandable metal stent placement for such difficult cases is needed. Another limitation is the lack of a statistical difference in the efficacy between percutaneous cholecystostomy and stent placement through the cystic duct. However, no scientific basis has been reported regarding the usefulness of percutaneous cholecystostomy in patients with malignant biliary obstruction.

In a large-scale investigation, Fatima et al (27) reported that pancreaticobiliary and duodenal perforations after periampullary endoscopic procedures occurred in 0.6% of patients and that, among these, the overall mortality was 7%. Hence, it was suggested that the transcholecystic approach may be also feasible, such as in an emergency situation as we experienced in one case. However, it may be a rare case, so further experience is needed.

In conclusion, we believe that placement of percutaneous transcholecystic metallic stents offers good palliation in patients with malignant obstruction of the common bile duct that is not amenable to surgery, conventional biliary drainage via transhepatic peripheral duct access, or ENBD and is an excellent alternative for the treatment of inoperable malignant obstruction of the common bile duct at the lower level of the orifice of the cystic duct.

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