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The usefulness of percutaneous bile duct metal stent insertion for malignant biliary obstruction: a retrospective study

Hideki Izumi[1*], Hisamichi Yoshii[1], Rika Fujino[1], Shigeya Takeo[1], Masaya Mukai[1], Junichi Kaneko[1] and Hiroyasu Makuuchi[1]

Abstract

Background Percutaneous transhepatic bile duct stent insertion is a useful alternative to the endoscopic approach for malignant biliary strictures. This study retrospectively reviewed the cases of percutaneous metallic stent insertion at our institution to evaluate its safety and usefulness.

Methods The study included cases of percutaneous bile duct stent insertion performed between April 2016 and August 2024. All patients included those with malignant biliary obstruction and those in whom an endoscopic approach was first attempted but could not reach or cannulate the papilla of Vater. Two procedures were used: a two-stage procedure, in which a drain was inserted to create an external or internal fistula, followed by stent insertion, and a one-stage procedure, in which the stent was inserted at the same time as the approach to the bile duct. The causes of biliary strictures and complications were examined.

Results The study included 14 cases: seven patients had pancreatic head cancer, including biliary tract cancer ($n=4$) and postoperative gastric cancer ($n=3$); three patients who underwent a one-stage insertion. The number of inserted stents tended to increase in patients with postoperative cholangiocarcinoma recurrence. No complication occurred in any patient. One patient had severe cholangitis, eight had moderate cholangitis, and four had mild cholangitis; two patients who underwent one-stage procedures had moderate cholangitis and one had mild cholangitis. In cases of two-stage expandable metal stent (EMS) insertion, the average time from initial drainage to EMS insertion was 10.5 days (4–25).

Conclusions The stent can be safely inserted in a one-stage procedure without compromising the patient's quality of life. Therefore, one-stage insertion of EMS for malignant biliary stricture may be performed aggressively unless the patient has severe cholangitis.

Keywords Percutaneous bile duct metal stent, Malignant biliary obstruction, One-phase insert

*Correspondence:
Hideki Izumi
h_izumy@tokai.ac.jp
[1]Department of Gastrointestinal Surgery, Tokai University Hachioji Hospital, 1838 Ishikawa, Hachioji, Tokyo 192-0032, Japan

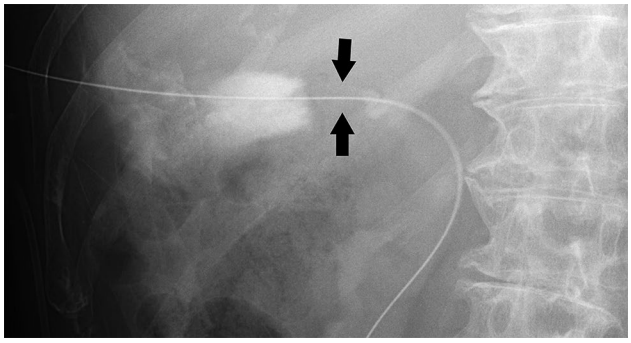

Fig. 1 A RADIFOCUS guide wire M 0.035 is inserted from the percutaneous transhepatic gallbladder drainage into the duodenum through the gallbladder duct (black arrow). The tip of the guidewire is placed in the duodenum (white arrow)

Background

Endoscopic or percutaneous stenting of malignant biliary strictures is a standard technique for relieving jaundice [1]. Endoscopic bile duct stent insertion is the first-line treatment for most patients with malignant biliary strictures; however, it is rarely possible in patients who have already undergone biliary reconstruction [2, 3]. In 2001, a technique for endoscopic ultrasound-guided biliary drainage was reported [4]. Although this technique is gaining popularity, it is difficult, and not all centers can perform it. Therefore, a percutaneous transhepatic approach may be an effective alternative [3, 5].

This study evaluated the use of percutaneous metal stents for malignant biliary strictures that cannot be drained using an endoscopic approach.

Methods

Patients

This study included 14 cases of percutaneous bile duct metal stent insertion performed at Tokai University Hachioji Hospital from April 2016 to August 2024. All 14 patients included those with malignant biliary obstruction and those in whom endoscopic approach was first attempted but could not reach or cannulate the papilla of Vater. This study conformed to the ethical principles of the Declaration of Helsinki and was approved by the Institutional Review Board of Tokai University in December 2022 (Approval Number 22R-197). Informed consent was obtained from all the participants or their guardians. Written informed consent was obtained from all patients before data release.

Technique

The procedures were performed under sedation and local anesthesia. The bile duct was punctured with a 19G EVS (HAKKO, Japan) under echo guidance. The stenotic site was crossed using a RADIFOCUS guide wire M 0.035 (Terumo, Japan) (Fig. 1). Once the stenotic site was crossed with a RADIFOCUS guide wire, the outer tube of the 19G EVS was inserted deep enough to go over the stenotic site. This enabled to insert Amplatz Super Stiff 0.035 wire (Boston Scientific, USA). After replacing the guidewire with an Amplatz Super Stiff 0.035 wire, an 8-Fr dilator was inserted. An Epic biliary stent (Boston Scientific, USA) was inserted, and the guidewire was removed.

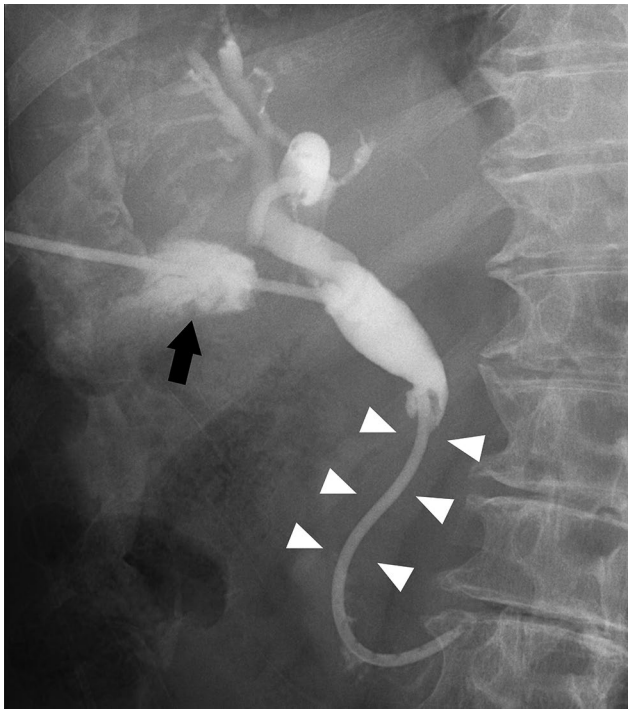

Fig. 2 An 8.5-Fr bile drainage catheter with a side hole makes an internal/external fistula. The white triangle is the location of the stenosis. The black arrow indicates the gallbladder

In the two-stage procedure, an 8.5-Fr bile drainage catheter (Cook, USA) was placed after dilatation to 9 Fr (Fig. 2). A hole was created in the drain and the drain was placed so that the tip could be placed in the duodenum, which also allows for an internal fistula. The two-stage procedure completed this step in 1 day. An Amplatz Super Stiff 0.035 wire (Boston Scientific, USA) was inserted, an Epic biliary stent (Boston Scientific, USA) was inserted (Fig. 3), the guidewire was removed, and the procedure was completed (Fig. 4). In the two-stage procedure, all catheters were removed after stent insertion.

The complications were assessed up to the time of patient discharge.

For percutaneous expandable metal stent (EMS) insertion, a two-stage procedure was chosen for cases of severe cholangitis. For others cases, selection was done on the spot by the clinician.

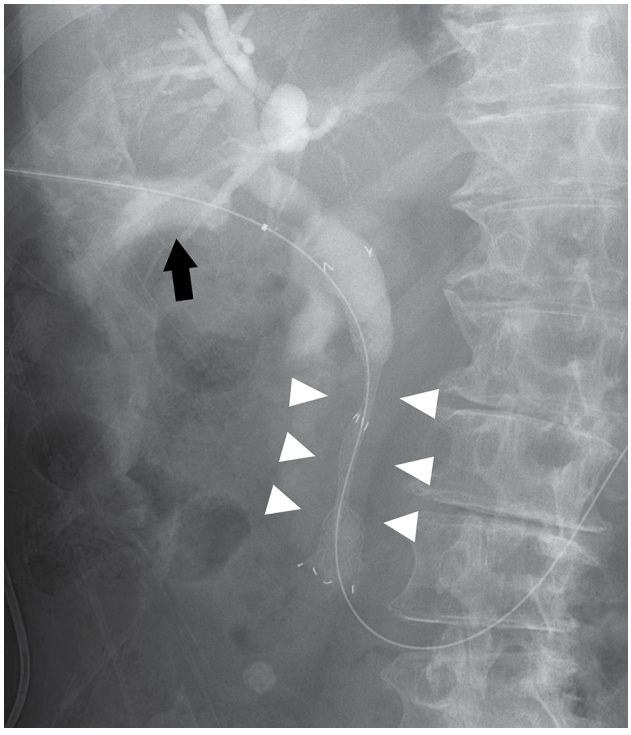

Fig. 3 An Amplatz Super Stiff 0.035 wire and percutaneous stent are inserted. The white triangle is the location of the stenosis. The black arrow is the gallbladder

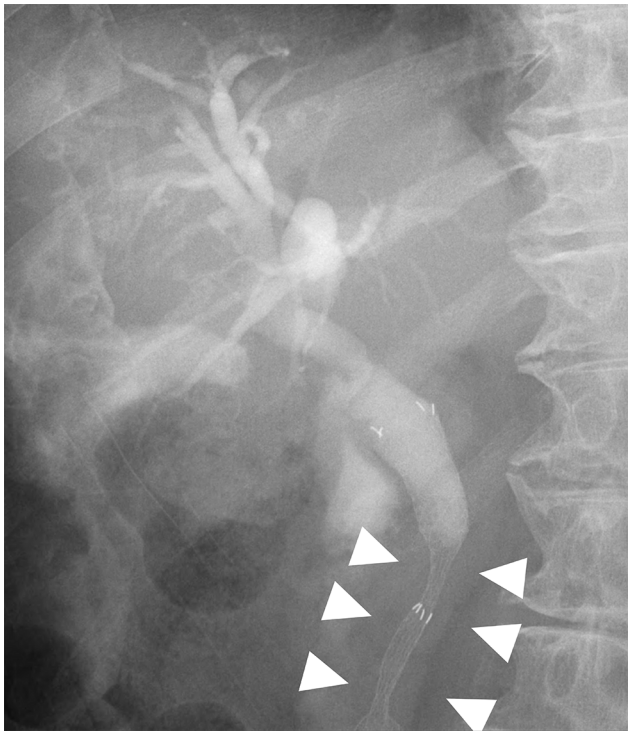

Fig. 4 The stent is successfully inserted with access through the gallbladder. The procedure is terminated by removal of the guidewire. The white triangle is the location of the stenosis

Results

All patients (six male and eight female) were Japanese, with a mean age of 66.5 (39–79) years (Table 1). Seven patients had pancreatic head cancer, four had postoperative bile duct cancer, and three had postoperative gastric cancer. Either one ($n=9$ cases), two ($n=3$), or three ($n=3$) stents were inserted. Three patients underwent a one-phase insertion. One patient was approached through percutaneous transhepatic gallbladder drainage (PTGBD). There were no complications, including perihepatic bile leakage or pancreatitis.

Pancreatic head cancer

Seven patients had unresectable pancreatic head cancer. Five of the seven patients had duodenal stenosis, and the papilla of Vater was unreachable. In one patient, the papilla of Vater was reachable, but cannulation was impossible. One patient had a postoperative gastric ulcer and Billroth-2 reconstruction; the papilla of Vater was unreachable. Only one patient had an additional insertion because of stent obstruction: one stent was inserted in a one-stage procedure; the others required two procedures. One case involved stent insertion from a PTGBD via the cystic duct (Fig. 1).

Postoperative cholangiocarcinoma

All cholangiocarcinoma cases were postoperative, with bile duct resection and choledochal anastomosis. The causes of obstructive jaundice included lymph node recurrence ($n=3$) and local recurrence ($n=1$). The papilla of Vater was reachable in one case, but the insertion angle was incorrect, and cannulation was impossible. In the other three cases, the papilla of Vater was unreachable. Although it was possible to guide the guidewire to the intestinal tract via a percutaneous approach, percutaneous EMS insertion was possible without modification. Therefore, an endoscopic approach using the Rendezvous technique was not performed. A stent was inserted in a one-stage procedure in one case.

Postoperative gastric cancer

Two patients underwent total gastrectomy followed by Roux-en-Y reconstruction. One patient underwent Billroth-2 reconstruction. The papilla of Vater was unreachable in all cases. As with postoperative cholangiocarcinoma, guidewire insertion into the intestinal tract was possible. However, the endoscopic approach using the Rendez-vous technique was not chosen because a percutaneous stent could be inserted directly. One patient underwent a one-stage procedure.

One patient had severe cholangitis, eight had moderate cholangitis, and four had mild cholangitis; two patients who underwent one-stage procedures had moderate cholangitis and one had mild cholangitis.

Table 1 Characteristics of the patients

Sex	Age	Diagnosis	Reasons for failure of the endoscopic approach	Severity classification by TG18	Number of stents	Number of stage	Days of two-stage
M	79	Pancreatic head carcinoma	Duodenal stenosis	Moderate	1	2	3
F	66	Pancreatic head carcinoma	Duodenal stenosis	Moderate	1	1	
M	64	Pancreatic head carcinoma	Duodenal stenosis	Moderate	2	2	6
F	76	Pancreatic head carcinoma	Duodenal stenosis	Moderate	1	2	5
F	77	Pancreatic head carcinoma	Duodenal stenosis, gastrojejunostomy	Moderate	1	2	10
F	71	Pancreatic head carcinoma	Not cannulated	Mild	1	2	11
M	62	Pancreatic head carcinoma	Postoperative gastric ulcer, Billroth-2 reconstruction	Moderate	1	2	10
F	71	Postoperative cholangiocarcinoma, lymph node recurrence	Choledochotomy, choledocho-jejunostomy	Mild	3	2	6
F	63	Postoperative cholangiocarcinoma, lymph node recurrence	Choledochotomy, choledocho-jejunostomy	Moderate	1	1	
M	57	Postoperative cholangiocarcinoma, lymph node recurrence	Choledochotomy, choledocho-jejunostomy	Moderate	2	2	24
M	71	Postoperative cholangiocarcinoma, local recurrence	Choledochotomy, choledocho-jejunostomy	Moderate	3	2	12
M	67	Postoperative gastric carcinoma, lymph node recurrence	Total gastrectomy, Roux-en-Y reconstruction	Mild	2	2	4
F	39	Postoperative gastric carcinoma, lymph node recurrence	Distal gastrectomy, Billroth-2 reconstruction	Severe	1	2	25
F	68	Postoperative gastric carcinoma, peritoneal dissemination	Total gastrectomy, Roux-en-Y reconstruction	Mild	1	1	

In cases of two-stage EMS insertion, the average time from initial drainage to EMS insertion was 10.5 days (4–25).

There were no cases of stent occlusion during the course of the procedure that required reinsertion.

Discussion

The EMS was introduced in the late 1980s to overcome the drawbacks of thin and easily clogged plastic stents [6–8]. The EMS is held in the outer sheath of a 3.5–4 mm diameter delivery system, which expands to 8–10 mm in the bile duct after being released from the delivery system. An EMS held in the outer sheath has shown longer patency and lower occlusion rates compared with those of conventional plastic stents [9–13]. Endoscopic or percutaneous stenting of malignant biliary strictures has become a standard procedure to relieve jaundice [1]. The endoscopic ultrasound-guided biliary drainage technique was first reported in 2001 [4] and has become more widespread. The success and incidence rates of biliary drainage under endoscopic ultrasound were 91.8% and 19.7% in high-volume centers, respectively [14], compared with 64.7% and 29% in low-volume centers [15], suggesting that this technique is difficult and not available in all centers. Therefore, a percutaneous transhepatic approach may be an effective alternative [3, 5]. In particular, percutaneous transhepatic biliary drainage is best for hilar cholangiocarcinoma with complex stenosis [16–18], suggesting that percutaneous stents may be useful for hilar cholangiocarcinoma. Drainage of >50% of the liver volume is necessary to be effective [19, 20]; however, cholangiocarcinoma often requires multiple stent insertions. This study included two cases of postoperative recurrence of cholangiocarcinoma in which three stents were inserted. Side-by-side techniques are necessary in such cases.

Various complications of percutaneous bile duct stenting have been reported, including acute cholangitis, pancreatitis, bleeding, and restenosis [21]. Pancreatitis is a relatively common complication (0.9–24.2%) [22–26]. Compared with plastic stents, EMSs are more prone to pancreatitis because of their larger diameter and greater dilatation force [27, 28]. In particular, when the stent is tipped into the duodenum through the papilla of Vater, its pressure drainage affects the flow of pancreatic juice in the main pancreatic duct, causing pancreatitis [29]; therefore, caution should be exercised. The pancreatitis incidence after stenting is lower for patients with an already dilated main pancreatic duct [22, 30]. Therefore, pancreatitis does not need to be considered in pancreatic cancer. However, EMS insertion for non-pancreatic duct dilatation should be performed with caution because of the high risk of pancreatitis. We have been using bare metal stents for insertion when the main pancreatic duct might be obstructed. We believe the main pancreatic duct is less likely to be obstructed by bare metal stents

than by covered stents. In our study, no pancreatitis occurred among the 10 patients who underwent bare EMS insertion through the papilla of Vater.

A meta-analysis reported no difference in the incidence of pancreatitis between bare and covered metal stents [31]. Other reports also found no difference in pancreatitis or other complications between bare metal and covered metal stents [32, 33], suggesting that the pancreatitis incidence due to stent type should not be a concern.

For bile duct stent insertion, obtaining adequate contrast and determining the stenosis length are important. If severe cholangitis develops, drainage should be performed first. Performing another stent insertion is safer once the cholangitis subsides [34]. In cases of cholangitis due to gallstones, the outcomes and complications of one-stage stone removal in patients with mild or moderate disease are comparable to those of two-stage stone removal [35]. Therefore, if a patient does not have severe cholangitis according to the Tokyo Guidelines 2018 (TG18), one-stage stent insertion is feasible on the day of drainage. For mild cholangitis according to TG18, a one-stage insertion maybe feasible. We performed one-stage insertions in three cases without any complications. If possible, one-stage insertion should be performed to free the patient from the need of drainage tubing.

This study has some limitations. First, the study was retrospective. Making a simple comparison was difficult because percutaneous insertion was attempted only in cases where endoscopic insertion was impossible. Second, only a few studies from a single institution were available. No significant complications were observed in this study, possibly because of the small number of cases. The number of cases needs to be increased to re-evaluate the usefulness of percutaneous metal stent insertion to increase the generalizability of our findings.

Conclusion

Percutaneous metal stent insertion is a useful alternative for malignant bile duct stenosis that is difficult to approach endoscopically. The stent can be safely inserted in a one-stage procedure without compromising the patient's quality of life. Therefore, one-stage insertion of EMS for malignant biliary stricture may be performed aggressively unless the patient has severe cholangitis.

Abbreviations

EMS	Expandable metal stent
PTGBD	Percutaneous transhepatic gallbladder drainage

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Author contributions

Hideki Izumi performed drainage, stent insertion, clinical follow-up, and data curation, and wrote the original draft. Hisamichi Yoshii performed drainage, stent insertion, and clinical follow-up. Rika Fujino performed drainage, stent insertion, and clinical follow-up. Shigeya Takeo performed drainage, stent insertion, and clinical follow-up. Masaya Mukai supervised the study. Junichi Kaneko supervised the study. Hiroyasu Makuuchi supervised the study. All authors read and approved the final manuscript.

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None.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The protocol for this research project was approved by a suitably constituted Ethics Committee of the institution and conformed to the provisions of the Declaration of Helsinki (Committee of Tokai University in December 2022, Approval No 22R-197). Informed consent was obtained from all the participants or their guardians. A copy of the written consent form is available for review by the journal's Associate Editor.

Consent for publication

Written informed consent was obtained from all patients before data release.

Competing interests

The authors declare no competing interests.

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