

One-Stage Percutaneous Self-Expandable Metal Stent Placement for Malignant Biliary Obstruction: A Five-Case Series

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Objective: Endoscopic retrograde cholangiopancreatography (ERCP) with self-expandable metal stent (SEMS) placement is the standard treatment for malignant biliary obstruction; however, it may not be feasible in cases of duodenal invasion, altered anatomy, or failed cannulation. Although percutaneous transhepatic biliary drainage is a reliable alternative, it is associated with external catheter-related complications and impaired quality of life. Recently, a one-stage percutaneous SEMS placement procedure has been proposed to overcome these limitations.

Methods: We retrospectively reviewed five patients (four women and one man; median age, 68 years) with malignant biliary obstruction who underwent one-stage percutaneous SEMS placement between April 2016 and March 2025 at the Tokai University Hospital. The procedures were performed under ultrasonographic guidance using a 19-gauge EVS™ needle, followed by guidewire exchange, tract dilation with an 8-Fr dilator, and deployment of an Epic™ biliary SEMS. Technical and clinical success and procedure-related complications were evaluated.

Results: Herein, the underlying diseases included pancreatic head carcinoma (n = 1), postoperative cholangiocarcinoma with lymph node recurrence (n = 2), postoperative gallbladder carcinoma with lymph node recurrence (n = 1), and postoperative gastric carcinoma with peritoneal dissemination (n = 1). ERCP failure was due to the following reasons: duodenal stenosis, choledochojunostomy, subtotal stomach-preserving pancreaticoduodenectomy (SSPPD) with cannulation failure, laparoscopic SSPPD not attempted due to inflammation, and Roux-en-Y reconstruction. Three and two patients presented with moderate and mild cholangitis, respectively, as per the Tokyo Guidelines 2018. Technical success was achieved in all patients. No procedure-related complications occurred.

Conclusion: One-stage percutaneous SEMS placement is a safe and effective option for treating malignant biliary obstruction in patients unsuitable for ERCP or endoscopic ultrasound-guided biliary drainage. With careful case selection, this approach enables rapid biliary decompression without external drainage and may improve the patient's quality of life.

Key words: Malignant biliary obstruction, Self-expandable metal stent, Percutaneous drainage, One-stage procedure, Endoscopic retrograde cholangiopancreatography failure

INTRODUCTION

Malignant biliary obstruction—most commonly caused by pancreatic head cancer, cholangiocarcinoma, gallbladder cancer, or ampullary carcinoma—often presents at an advanced stage when curative resection is no longer feasible [1]. Obstruction leads to jaundice, fatigue, and pruritus and may progress to life-threatening cholangitis or sepsis [2]. Furthermore, cholestasis-induced hepatic dysfunction frequently prevents the initiation or continuation of chemotherapy and worsens the prognosis [3]. Thus, timely and reliable biliary drainage is essential not only for symptom relief but also systemic treatment. Endoscopic retrograde cholangiopancreatography (ERCP) is the first-line, minimally invasive, and highly effective option for most patients [4]. However, ERCP may be technically unfeasible in cases of duodenal invasion, ampullary obstruction, or surgically altered anatomy. In such cases, percutaneous transhepatic biliary drainage (PTBD) may serve as an

alternative; however, long-term reliance on an external catheter may impair patient quality of life (QOL) and lead to infection and catheter occlusion [2, 5].

Self-expandable metallic stents (SEMS), which provide superior long-term patency compared with plastic stents, are currently considered the standard palliation for malignant biliary obstruction [3, 6]. Traditionally, percutaneous drainage follows a two-stage approach: initial external drainage via PTBD, followed by stent placement [7]. Although this method is effective for infection control, it requires multiple procedures, prolongs hospitalization, increases costs, and imposes physical and psychological burdens due to external drainage. To address these limitations, one-stage percutaneous SEMS placement with direct stenting at the time of initial puncture, without prior external drainage, has gained attention. This strategy reduces the number of procedures, shortens hospital stays, lowers costs, and avoids catheter-related QOL issues. We have previously reported the safety and efficacy of this pro-

cedure in a retrospective study [8], providing evidence that challenges the conventional notion that two-stage placement is mandatory.

In this study, we sought to build upon this foundation by further characterizing the safety and efficacy of one-stage percutaneous SEMS placement to establish it as a viable standard option in clinical practice. Additionally, we determined how this simplified strategy might reduce patient burden and potentially influence future approaches toward the management of malignant biliary obstruction.

MATERIALS AND METHODS

Patients

This retrospective study included patients with malignant biliary obstruction for whom ERCP was deemed unfeasible because of tumor invasion of the ampulla, duodenal stricture, or surgically altered

anatomy after pancreaticoduodenectomy. Between April 2016 and March 2025, consecutive patients who underwent one-stage percutaneous SEMS placement at our institution were included in the analysis. We have previously reported three cases included in the present study [8], in which both one-stage and two-stage percutaneous SEMS placements were analyzed. This study differs in that it focuses exclusively on one-stage procedures and includes additional cases, enabling a more detailed assessment of this technique. Patients' clinical background, indications for percutaneous intervention, and periprocedural courses were reviewed from medical records. Acute cholangitis was diagnosed according to the Tokyo Guidelines 2018 (TG18) [9].

Procedure

All procedures were performed under sedation and local anesthesia. Under ultrasonographic guid-

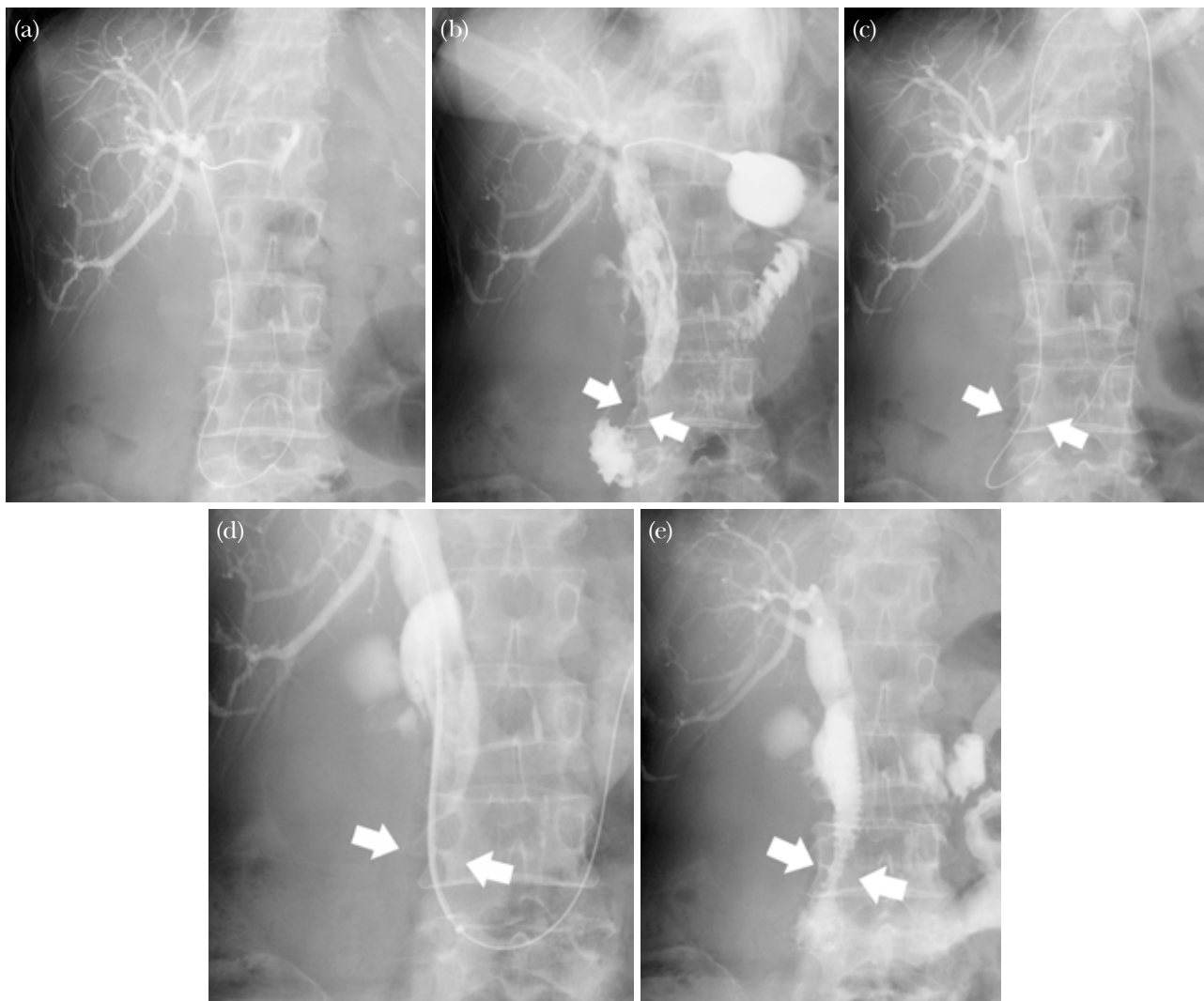


Fig. 1 One-stage percutaneous SEMS placement under ultrasound and fluoroscopic guidance.
 (a) Ultrasonographic image showing puncture of the intrahepatic bile duct with a 19-gauge EVS™ needle (HAKKO, Japan).
 (b) The stenotic site indicated by a white arrow.
 (c) Fluoroscopic image demonstrating advancement of a 0.035-inch RADIFOCUS® guidewire (Terumo, Japan) across the stricture (white arrow), and subsequent exchange for an Amplatz™ Super Stiff 0.035-inch wire (Boston Scientific, USA).
 (d) Fluoroscopic image showing tract dilation with an 8-Fr dilator and deployment of an Epic™ biliary stent (Boston Scientific, USA) across the stricture (white arrow).
 (e) Final fluoroscopic image confirming correct stent placement without external drainage. The stricture site is indicated by a white arrow.
 SEMS, self-expandable metal stent.

ance, the bile duct was punctured using a 19-gauge EVS™ (HAKKO, Japan) needle, and a 0.035-inch RADIFOCUS™ guidewire (Terumo, Tokyo, Japan) was advanced across the stenotic site (Fig. 1a). Following the bile duct puncture, contrast medium was injected to delineate the stenotic site (Fig. 1b). Once successful passage was confirmed, the outer sheath of the 19-gauge EVS™ needle was advanced beyond the stricture. The guidewire was then exchanged with an Amplatzer™ Super Stiff 0.035-inch wire (Boston Scientific, USA) to provide sufficient support (Fig. 1c). An 8-Fr dilator was used for tract dilation, followed by the deployment of an Epic™ biliary stent (Boston Scientific, USA) (Fig. 1d). After ensuring correct deployment, the guidewire was withdrawn. External drainage catheters were not routinely placed (Fig. 1e).

Clinical and Technical Outcomes

Technical success was defined as the accurate placement of the SEMS across the intended stricture. Clinical success was defined as a reduction in serum total bilirubin by $\geq 50\%$ or to < 2.0 mg/dL within 7 days of the procedure. The procedure time was measured as the interval from puncture to the completion of stent deployment. Post-procedural complications, including bleeding, bile leakage, cholecystitis, hepatic abscess, and bile peritonitis, were documented. Additionally, the length of the hospital stay was assessed.

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Tokai University in December 2022 (approval number: 22R-197). Informed consent for participation was obtained from all patients or their legal guardians. Written informed consent for publication and data release was obtained from all participants prior to their inclusion in the study.

RESULTS

Patient Characteristics

The clinical characteristics of the patients are summarized in Table 1. Five patients (four females and one male) were included in this study, with a median age of 68 years (range, 63–76 years; mean, 68.2 years).

The underlying diseases included pancreatic head carcinoma (n = 1, 20%), postoperative cholangiocarcinoma with lymph node recurrence (n = 2, 40%), postoperative gallbladder carcinoma with lymph node recurrence (n = 1, 20%), and postoperative gastric carcinoma with peritoneal dissemination (n = 1, 20%).

The reasons for ERCP failure were as follows: duodenal stenosis (n = 1, 20%), choledochojejunostomy after choledochotomy (n = 1, 20%), cannulation failure after subtotal stomach-preserving pancreaticoduodenectomy (SSPPD) (n = 1, 20%), not attempted because of inflammation after laparoscopic SSPPD (n = 1, 20%), and Roux-en-Y reconstruction after total gastrectomy (n = 1, 20%).

According to the TG18, the severity of acute cholangitis was classified as moderate in three patients (60%) and mild in two patients (40%); no severe cases were included herein.

Table 1 Characteristics of the patients

sex	age (years)	diagnosis	Reasons for failure of the endoscopic approach	Severity classification by TG18	Stricture site	Puncture route	Number of stents	complication	Length of hospital stay	Prognosis	Stent patency period	Additional salvage procedures
F	66	pancreatic head carcinoma	duodenal stenosis	Moderate	distal bile duct	B2–B3 confluence	1	no	9	12 m/death	7 m (occluded)	PTBD
F	63	Postoperative cholangiocarcinoma, lymph node recurrence	post Choledochotomy, choledochojejunostomy	Moderate	perianastomotic region of the choledochojejunostomy	B6–B7 confluence	1	no	20	5 m/death	5 m (patent)	None
M	76	Postoperative cholangiocarcinoma, lymph node recurrence	post SSPPD, Cannot cannulate	Mild	perianastomotic region of the choledochojejunostomy	B6–B7 confluence	1	no	8	8 m/death	8 m (patent)	None
F	68	Postoperative gall bladder carcinoma, lymph node recurrence	post Lap-SPPD, Not challenged due to inflammation.	Moderate	perianastomotic region of the choledochojejunostomy	B6–B7 confluence	1	no	3	13 m/alive	13 m (patent)	None
F	68	Postoperative gastric carcinoma, peritoneal dissemination	post Total gastrectomy, Roux-en-Y reconstruction	Mild	distal to middle bile duct	B6–B7 confluence	1	no	5	15 m/alive	15 m (patent)	None

Procedural Outcomes

All procedures were completed successfully, yielding a technical success rate of 100% (5/5). The number of stents placed per patient was consistently one (median, 1; range, 1–1).

Post-procedural Course and Safety

During the perioperative period (from immediately post-procedure to hospital discharge), no procedure-related complications (0/5, 0%), such as puncture site bleeding, bile leakage, cholecystitis, hepatic abscesses, or bile peritonitis, were observed. Long-term outcomes, including stent patency and overall survival, are summarized in Table 1.

DISCUSSION

This study highlights the clinical significance of a one-stage percutaneous SEMS placement strategy in patients with malignant biliary obstruction in whom ERCP is unsuccessful or technically unfeasible. Traditionally, percutaneous biliary drainage relies on a two-stage approach: an external catheter is initially inserted and subsequently replaced with a stent after several days or weeks [2, 10]. However, this strategy inevitably entails external drainage-related issues, such as impaired QOL, catheter-related infections, and frequent occlusion [5, 11, 12]. In patients with advanced malignancy or poor performance status, these factors can impose a significant burden, as they may spend a substantial portion of their remaining life dependent on external catheters. Even when ERCP is not feasible, percutaneous one-stage SEMS placement can achieve rapid biliary decompression while avoiding external drainage, thereby reducing patient discomfort and complications. In this study, one-stage SEMS placement was associated with high clinical success and acceptable safety, reinforcing the feasibility and practicality of this approach. Shim *et al.* demonstrated that percutaneous SEMS placement achieved clinical success rates exceeding 90%, with limited major complications [13]. Similarly, Inal *et al.* reported that a one-stage strategy was associated with shorter hospital stays and lower readmission rates than the traditional two-stage approach [5]. These findings suggest that one-stage percutaneous SEMS placement is a viable therapeutic option. This approach is particularly valuable in patients with duodenal invasion, ampullary obstruction, or surgically altered anatomy, for whom ERCP is technically impossible. Although endoscopic ultrasound-guided biliary drainage (EUS-BD) has emerged as an alternative, its availability remains limited in many centers. In contrast, this approach can be readily performed in most centers. Accordingly, the findings of the present study have considerable implications in clinical practice, especially in settings where EUS-BD is not accessible.

In the present study, one-stage percutaneous SEMS placement demonstrated a high rate of technical and clinical success; however, procedure-related complications should be carefully considered. Major adverse events include bleeding, bile leakage, and infectious complications [2, 11]. As these complications can occasionally be life-threatening, meticulous periprocedural management is essential. Puncture site bleeding may occur when the access tract intersects the hepatic parenchyma and vascular structures, particularly in

cases requiring multiple puncture attempts or a longer intraparenchymal course [14, 15]. To minimize this risk, careful sonographic guidance to avoid vascular structures and limit tract dilation to the minimum necessary diameter is essential. Bile leakage is another common complication associated with percutaneous SEMS placement. Leakage through the puncture tract can lead to intra-abdominal abscess formation and bile peritonitis. In this study, tract dilation was limited to an 8-Fr dilator, and no bile leakage was observed; however, given the small sample size of five patients, further studies are warranted to adequately assess the safety of this approach. From a safety standpoint, temporary placement of a PTBD catheter for several days may be considered.

Additionally, cholecystitis is a recognized adverse event, particularly when covered stents are used to occlude the cystic ducts. Preprocedural imaging to confirm cystic duct patency and the selective use of uncovered stents in at-risk patients are recommended to reduce this complication [5].

ERCP with SEMS placement remains the standard first-line therapy when feasible [3, 16]. However, ERCP may be technically unfeasible in certain situations, such as ampullary tumor invasion, duodenal stricture, or surgically altered anatomy after pancreaticoduodenectomy. For such patients, EUS-BD has recently emerged as an alternative, with promising technical and clinical success rates [17, 18]. In particular, EUS-BD may be especially useful in patients with duodenal invasion [19]. Nevertheless, EUS-BD requires advanced expertise and specialized devices, and its availability is limited to select centers.

In contrast, the need for external drainage catheters can impair QOL and carry risks of infection and occlusion [2, 11], which are particularly burdensome for patients with advanced malignancy and reduced life expectancy. In this context, a one-stage percutaneous SEMS placement is a clinically meaningful option. Specifically, in patients in whom ERCP is not feasible, and EUS-BD is not available or appropriate, this approach can achieve rapid biliary decompression while avoiding external drainage. Since the technique builds upon well-established PTBD methods, it can be implemented in many institutions and may facilitate earlier initiation of chemotherapy, reduce hospital stay, and improve QOL; therefore, one-stage percutaneous SEMS placement may be considered a useful option in selected patients.

This study has several limitations. First, it was conducted retrospectively at a single center, and the sample size was relatively small. These factors may introduce selection bias and limit the generalizability of our findings. Second, although the study focused on the technical feasibility and short-term outcomes of one-stage percutaneous SEMS placement, long-term stent patency and overall survival were not comprehensively evaluated. Third, systematic comparisons with alternative approaches such as EUS-BD or surgical bypass were not performed; thus, the relative advantages and disadvantages of each method remain to be elucidated. Finally, procedural techniques, device selection, and periprocedural management may vary across institutions and operators, which could influence the complication rates and clinical outcomes. Further studies

are warranted to validate these findings and to better define the indications for this procedure.

CONCLUSION

One-stage percutaneous SEMS placement appears to be a technically feasible and clinically effective approach for managing malignant biliary obstruction in patients in whom ERCP or EUS-BD is not feasible or available. This approach may enable rapid biliary decompression without the need for external drainage and facilitate early initiation of systemic therapy, potentially improving quality of life. Although careful patient selection is essential, this strategy may be considered a useful therapeutic option in the multidisciplinary management of malignant biliary obstruction.

LIST OF ABBREVIATIONS

SEMS, self-expandable metal stent; PTGBD, percutaneous transhepatic gallbladder drainage

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, December 2022, Approval No. 22R-197). Informed consent was obtained from all 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.

Availability of data and materials

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

Competing interests

The authors declare no competing interests.

CONFLICT OF INTEREST

None.

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None.

AUTHOR CONTRIBUTIONS

Hideki Izumi: Performed the interventional procedures, Clinical follow-up, Data curation, Writing – original draft.

Junichi Kaneko: Writing – review & editing, Critical revision of the manuscript for important intellectual content.

Toshihito Ogasawara: Performed the interventional procedures and clinical follow-up.

Masaya Mukai: Writing – review & editing, Critical revision of the manuscript for important intellectual content.

Hiroyasu Makuuchi: Writing – review & editing, Critical revision of the manuscript for important intel-

lectual content.

All authors read and approved the final manuscript.

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REFERENCES

- 1) Moss AC, Morris E, Leyden J, *et al.* Malignant distal biliary obstruction: a systematic review and meta-analysis of endoscopic and surgical bypass results. *Cancer Treat Rev* 2007; 33: 213–21.
- 2) Covey AM, Brown KT. Percutaneous transhepatic biliary drainage. *Tech Vasc Interv Radiol* 2008; 11: 14–20.
- 3) Almadi MA, Barkun A, Martel M. Plastic vs. Self-Expandable Metal Stents for Palliation in Malignant Biliary Obstruction: A Series of Meta-Analyses. *Am J Gastroenterol* 2017; 112: 260–73.
- 4) Moole H, Jaeger A, Cashman M, *et al.* Are self-expandable metal stents superior to plastic stents in palliating malignant distal biliary strictures? A meta-analysis and systematic review. *Med J Armed Forces India* 2017; 73: 42–8.
- 5) Inal M, Aksungur E, Akgül E, *et al.* Percutaneous placement of metallic stents in malignant biliary obstruction: one-stage or two-stage procedure? Pre-dilate or not? *Cardiovasc Intervent Radiol* 2003; 26: 40–5.
- 6) Sawas T, Al Halabi S, Parsi MA, *et al.* Self-expandable metal stents versus plastic stents for malignant biliary obstruction: a meta-analysis. *Gastrointest Endosc* 2015; 82: 256–67. e7.
- 7) Yarmohammadi H, Covey AM. Percutaneous biliary interventions and complications in malignant bile duct obstruction. *Chin Clin Oncol* 2016; 5: 68.
- 8) Izumi H, Yoshii H, Fujino R, *et al.* The usefulness of percutaneous bile duct metal stent insertion for malignant biliary obstruction: a retrospective study. *BMC Gastroenterol* 2025; 25: 211.
- 9) Kiriya S, Kozaka K, Takada T, *et al.* Tokyo Guidelines 2018: diagnostic criteria and severity grading of acute cholangitis (with videos). *J Hepatobiliary Pancreat Sci* 2018; 25: 17–30.
- 10) van Delden OM, Laméris JS. Percutaneous drainage and stenting for palliation of malignant bile duct obstruction. *Eur Radiol* 2008; 18: 448–56.
- 11) Saad WE, Wallace MJ, Wojak JC, *et al.* Quality improvement guidelines for percutaneous transhepatic cholangiography, biliary drainage, and percutaneous cholecystostomy. *J Vasc Interv Radiol* 2010; 21: 789–95.
- 12) Knyrim K, Wagner HJ, Pausch J, *et al.* A prospective, randomized, controlled trial of metal stents for malignant obstruction of the common bile duct. *Endoscopy* 1993; 25: 207–12.
- 13) Shim DJ, Gwon DI, Han K, *et al.* Percutaneous Metallic Stent Placement for Palliative Management of Malignant Biliary Hilar Obstruction. *Korean J Radiol* 2018; 19: 597–605.
- 14) Hsu YC, Lee HY, Chang CM, *et al.* Clinical outcomes of percutaneous transhepatic biliary drainage at different Couinaud's hepatic entry segments for treating obstructive jaundice. *Front Surg* 2023; 10: 1039106.
- 15) Pedersoli F, Schröder A, Zimmermann M, *et al.* Percutaneous transhepatic biliary drainage (PTBD) in patients with dilated vs. nondilated bile ducts: technical considerations and complications. *Eur Radiol* 2021; 31: 3035–41.
- 16) Dumonceau JM, Tringali A, Papanikolaou IS, *et al.* Endoscopic biliary stenting: indications, choice of stents, and results: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline - Updated October 2017. *Endoscopy* 2018; 50: 910–30.
- 17) Wang K, Zhu J, Xing L, *et al.* Assessment of efficacy and safety of EUS-guided biliary drainage: a systematic review. *Gastrointest Endosc* 2016; 83: 1218–27.
- 18) Minaga K, Kitano M. Recent advances in endoscopic ultrasound-guided biliary drainage. *Dig Endosc* 2018; 30: 38–47.
- 19) van der Merwe SW, van Wanrooij RLJ, Bronswijk M, Everett S, Lakhtakia S, Rimbas M, *et al.* Therapeutic endoscopic ultrasound: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. *Gastrointest Endosc* 2022; 95: 185–205.